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Skills and Knowledge Needs Assessment For Pharmaceutical Industry

Report, Volume I

Skills and Knowledge Needs Assessment

Authored By: AM Partners Consulting Company

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EXECUTIVE SUMMARY

Introduction: Base and Motivation for the Assessment

Within the USAID/CAPS Project in Armenia, in the context of the Workforce Development component, significant efforts are engaged in enhancing workforce and skills development for ultimate purpose of matching qualified labor with potential needs of employers of the pharmaceutical industry in Armenia. CAPS Project has identified the need to undertake the "*Skills and Knowledge Needs Assessment*" among pharmaceutical firms and academic institutions for:

i) Identifying gaps between existing skills and knowledge and those that are required;
ii) Identifying skills, knowledge, and competences, as well as training needs of the pharmaceutical workforce;
iii) Identifying shortcomings of the educational system and actual demand for the long-run prospective,

The *Skills and Knowledge Needs Assessment* consisted of the following specific tasks:

1. Classify the main positions (jobs) of pharmaceutical enterprises in Armenia;
2. Conduct *Skills and Knowledge Needs Assessment,* including the qualitative assessment of the managers of pharmaceutical enterprises and representatives of educational institutions, as well as polling (self-regulated survey) of employees of pharmaceutical enterprises in Armenia;
3. Analysis of the data collected via the assessment and polling and completion of reports.

Main findings

The "*Skills and Knowledge Needs Assessment*" has resulted in specific findings that are thoroughly described below and in the other two reporting volumes. The main findings of the assessment with regard to the review of the international best practice, as well as the qualitative survey of representatives of pharmaceutical industry and educational institutions are summarized below:.

1. Fifteen key employment positions have been identified via the review of international best practice. Although respondents from local enterprises accept (recognize) the importance of employing specialists for those positions, no local enterprise meets this requirement. Such Job roles such as Qualified Person, Pharmacovigilence Specialist, R&D Specialist, etc., are usually performed by other employees in addition to their normal responsibilities, or those responsibilities are carried out by the manager/director of the enterprise.
2. In order to generally meet the structural requirements (according to GMP and international experience), local producers should have clearly defined organizational structures. Unfortunately, only a few local enterprises have such structure. Meantime, other local producers really need to structure their business for meeting the minimum requirements.
3. The situation is similar with Job Descriptions. The majority of respondents stated that they have developed their Job Descriptions and practice them, but very few of them could produce these documents. Some respondents even think that these documents are not so necessary, since the situation is changing very often, and those Job Descriptions should be revised regularly, and thus they lose their currency.
4. As of the November 2008 the pharmaceutical industry of Armenia accounts for more than fifteen enterprises including facilities producing various herbs, additives and other by products. The survey covered 9 leaders. Only 5 of the enterprises produce and supply a relatively wide assortment of pharmaceuticals. Some enterprises are not only producing pharmaceuticals locally, but also are engaged in imports, distribution and retail trade of pharmaceuticals.
5. The surveyed enterprises employ about 570 people. Almost 60% of those employees are concentrated in two comparatively big enterprises – Yerevan CPFirm and Liqvor. Currently, only a

few employment positions are vacant in the surveyed enterprises, and management state that they will be filled in near future.

6. Local producers do not usually employ qualified specialists from the onset and prefer to attract employees with the minimum knowledge and skills (except of key positions). These employees are trained on-the-job at the enterprise in order to gain the necessary skills. This situation is twofold: on the one hand producers get what they specifically need after that training; on the other hand, the remuneration demands of those employees notably increase after improving their experience and qualifications. In many cases producers cannot afford to pay significantly increased compensation to their employees and lose them. This circle is quite destructive; comparatively strong producers suggest higher remuneration and headhunt qualified specialists, whilst smaller competitors have to adopt alternative strategies.
7. All companies stated that they needed to improve the qualifications of their employees. Some managers would like to improve the qualifications of all employees; others prefer to train only some specific specialists. The availability of needs is explained by the following main reasons:
   - Specialists' knowledge is outdated and employees are not familiar with modern technologies. There are no training programs in Armenia for improving the skills of pharmaceutical industry employees;
   - Where the producers do possess modern equipment, operators are not completely aware of the capability of that equipment and need to improve their training to operate the equipment more effectively;
   - There is a general lack of qualified specialists in Armenia. Producers usually attract general specialists and conduct on-the-job training for them;
   - Professional education and training at educational institutions is not adequate enough to allow the graduates to meet requirements of producers.

8. Managers of pharmaceutical enterprises think that training is the main tool for improving the employees' qualification. It should be noted that this idea is not shared by the majority of employees. The latter group either cannot understand the real importance of intensive training, or don't want to spend time for that purpose.
9. Managers declared that their personnel need to receive training in GMP, GLP, and other professional subjects. This is legitimate, since currently almost all producers are planning to apply GMP requirements, and some of them have already initiated specific activities. Besides that, in near future some legislative and regulatory changes are also imminent, which aim to bring pharmaceutical production closer to GMP standards. Pharmaceutical enterprises understand all this very well, and try to react promptly and effectively. According to top managers of the pharmaceutical enterprises, training needs to be conducted urgently.
10. Cooperation between the pharmaceutical producers and educational institutions is not very close. Their relations are mainly limited to providing room for passing some practical classes for students of medical and chemical educational institutions. No joint working groups, no research projects, no ventures, no planned labor-educating policy, no influence on educational disciplines and curricula, etc. In fact, the current situation is something like "relations" but not "cooperation".
11. Producers expect closer cooperation from educational institutions. Educational providers must try to meet the requirements of the industry as much as possible. Producers' specific expectations from the educational institutions are the following:
    - Training of qualified GMP and related specialists. Skillful GMP specialists become a necessity.
    - Students of medical educational institutions are not meeting requirements of producers of pharmaceuticals. The theoretical knowledge is obsolete, they strongly lack practical classes.
    - Revision of educational disciplines and curricula to meet industry requirements.
    - Research and synthesis of new pharmaceuticals. Some producers are not able to develop new pharmaceuticals, since that requires the availability of special infrastructure, analytical laboratory equipment, and R&D specialists. Normally, educational institutions possess these assets, and are able to develop new pharmaceuticals.

- Application and implementation labor projects. This involves the selection of the best students still studying, train them by special programs and curricula, prepare qualified specialists and ensure their employment. In fact this means investments in education.

12. Managers of local enterprises stated that about 170 potential new jobs will need to be filled in coming 12 months. Thus the pharmaceutical industry in Armenia plans to increase employment figures by 30%. At the same time, some producers have more preconditions for the success than others. Thus, almost 65% of the planned increase in the number of employees is forecasted by only two enterprises.
13. Local producers usually attract general specialists from employment agencies. They may not even be graduates of medicinal educational institutions. Employees attracted from general educational institutions are comparatively cheap, but lack skills and knowledge due to short working experience or even an absence of such experience. However, producers really like the idea of attracting specialists exactly from the educational institution, and this may become the first step towards the real cooperation between the educational institutions and producers.
14. Total number of potential specialists of the pharmaceutical sector that are currently studying in various educational institutions of Armenia comprises 1,563 people/students. This figure contains all students of tertiary, higher and post-graduate education. Secondary education may be enough for undertaking the responsibilities of operators or engage positions of the middle management, while for higher positions more educated and skillful specialists are to be attracted.
15. On average the demand for the pharmaceutical education is almost matched by supply. This coefficient is quite different for various educational institutions. Some institutions were not able to meet the demand. Other institutions that are more famous faced significant shortage of applicants. The main reason for this is the high cost of the education – only a very small number of educational places free of charge.
16. The overwhelming majority of students of pharmacy faculties don't even think about working at pharmaceutical enterprises. They prefer to find employment at pharmacies, where their work is perceived to be much easier, safer and well-paid. At pharmacies these specialists do not have good career opportunities, but the majority of specialists prefer today's better conditions in pharmacies.
17. The number of educational places in pharmacy faculties bears no relation to industry dynamics. Educational institutions operate separately, under the strict control of state regulation. Decision making on the number of educational places is by the License issued by the Ministry of the Education and Science of Armenia. The Ministry makes licensing decisions based on the capacity of the certain institution, i.e. availability of classrooms and infrastructure, laboratories and equipment, etc.
18. In a 5-year prospective about 2,500 students will graduate from pharmacy faculties of various educational institutions in Armenia. In a 5-year prospective the total demand of pharmaceutical producers will comprise at least 410 employees.
19. Managers of enterprises are dissatisfied with current educational system and suggest immediate changes to it. Some managers complained that educational programs and curricula have not been changed for up to 30 years. By contrast, educational institutions claim that current curricula and disciplines best match industry requirements.
20. According to the majority of the representatives of educational institutions, visits to pharmaceutical enterprises are the most practiced type of cooperation between educational institutions and producers. Practical classes and on-site training are the next prevailing option. Some enterprises organize these events on commercial bases, others provide that for free. In some cases producers select some best students, organize special classes for them and even pay them some remuneration. Implementation of joint projects and research is the rarest type of cooperation.
21. Pharmaceutical enterprises have no real influence on education processes. Producers are allowed to apply for an educational place for a student that will not participate in entry competition. In some cases, managers of enterprises are invited to participate to examination committees; sometimes producers are invited to discuss *minor modifications* in educational programs.

METHODOLOGICAL ASPECTS OF THE ASSESSMENT

STUDY LOGIC: TECHNICAL APPROACH TO RESEARCH

Identification of the pharmaceutical industry key positions

Although, one of the most important tasks of the assessment is the classification of existing jobs in Armenian pharmaceutical enterprises, the assessment was not limited to it, and reviewed main employment positions also in some advanced international companies, as well as various informative documents. The assessment has been conducted among 9 Armenian pharmaceutical producers: managers of those enterprises have been asked to provide the management structure of their enterprises. This was the only way to collect data on local enterprises, although some producers refused to provide such information on the basis of privacy issues.

Nevertheless, we tried to base our analysis on information available from other enterprises and authoritative documentation, such as GMP and other relevant papers. This approach allows us to review the task both from theoretical and practical viewpoints. This approach has resulted in the identification of 15 key positions, necessary for operating a pharmaceutical enterprise. These positions are based on survey questionnaires, and Job Description Templates have been developed for those positions. The 15 classified key positions are listed below:

Table 1 - List of classified positions

1. Qualified person,
2. Head of quality control
3. Head of production
4. Head of technology
5. Laboratory supervisor
6. Registration specialist
7. Production operator
8. Packaging operator
9. Quality control analyst, chemist
10. Laboratory technician
11. Microbiologist
12. Storage / Warehouse person
13. Marketing specialist
14. Complaint and pharmacovigilence specialist
15. R&D specialist / Scientist

Development of the Job Description Templates

Job Description Templates for key employment positions of pharmaceutical enterprises are the major deliverable of the current assignment. In order to develop useful, applicable and well-grounded templates two methodological tools have been applied: *review of international best practice* and *assessment of Armenian local practices*.

Best practice review

In order to conduct the review of the international best practice the following methodological base was adopted:

1. The following three directions were selected to be the review objects:
   - ⇨ Assessment and analysis of the experience of International Pharmaceutical Associations that were presented by EphMRA (European Pharmaceutical Market Research Association), PHMRA (Pharmaceutical Research and Manufacturing of America), IFPMA (International Federation of Pharmaceutical Manufacturers and Associations).

- ⇨ Assessment of the EU, WHO (World Health Organization) GMP documents.
- ⇨ Assessment and analysis of the successful experience of advanced international pharmaceutical enterprises. The parameters for selecting successful producers of pharmaceuticals were the turnover and the number of employees. The following companies have been assessed:

Table 2 - List of assessed companies

- ☞ Pfizer, USA
- ☞ Bayer, Germany
- ☞ GlaxoSmithKline, United Kingdom
- ☞ Novartis, Switzerland
- ☞ Sanofi-Aventis, France
- ☞ Hoffmann–La Roche, Switzerland
- ☞ AstraZeneca, UK/Sweden
- ☞ Merck & Co., USA;
- ☞ Abbott Laboratories, USA
- ☞ Wyeth, USA
- ☞ Bristol-Myers Squibb, USA
- ☞ Eli Lilly and Co., USA
- ☞ Schering-Plough, USA
- ☞ Elan Corporation, Ireland

2. The online internet search method was selected as the main tool for conducting the desk research and assessment of pharmaceutical companies. The WebPages of abovementioned Associations and companies were thoroughly reviewed; information was collected about the obligations and functions, as well as skills and knowledge requirements for those organizations' personnel. Concurrently, the necessary experience and required educational levels were also assessed.
3. The collected information has been summarized, analyzed and attributed to classified key positions of specialists of pharmaceutical enterprises.

Local practices

Although the assessment has thoroughly analyzed the advanced best practices of international successful companies (pharmaceutical producers), not all of these practices are applicable to Armenian realities. Some requirements of international producers are too tough for Armenian producers and may not be faced for many years, yet.

On the other hand, local peculiarities may cause specific requirements for employees, who are applying for specific positions at pharmaceutical enterprises in Armenia. Holding several positions simultaneously, working without narrow specialization, 6 day working week, are examples of specific requirements that are requested from employees at local pharmaceutical enterprises, but cannot be considered as widely adopted practices abroad.

Survey component

Sample frame

The survey component of the assessment consists of 3 main blocks: a qualitative survey of the managers of pharmaceutical enterprises, the same assessment for representatives of educational institutions, and self-regulated survey/polling of employees of those enterprises. The sample frame of the pharmaceutical enterprises contained 9 local producers illustrated at Appendix 1.

Specially trained surveyors visited abovementioned enterprises and conducted face to face interviews with their top management. The answers will be justified and crosschecked with the data collected from other sources. The survey of educational institutions also covered 9 academic entities, providing various types of education (see Appendix 2).

Methodological aspect of the self-regulated survey of employees of pharmaceutical enterprises is presented in Volume II of the current report.

Survey tools and topics

Separate survey tools have been developed for conducting each part of the survey. The questionnaire for interviewing the managers of pharmaceutical enterprises consisted of the following main sections:

a) Respondent's profile;
b) Number of employees and vacancies;
c) Job descriptions and delegation of responsibilities;
d) Importance of main responsibilities;
e) Skills and knowledge improvement needs and ways;
f) Trainings required and their format;
g) Relations with educational institutions;
h) Number of employees to be attracted in a 5-year prospective.

The questionnaire for interviewing the representatives of educational institutions consisted of the following main sections:

a) Profile of the educational institutions;
b) Dynamics of the number of students and applicants during the last 3 years;
c) Prospective of changes of the number of students;
d) Suggested disciplines and curricula;
e) Availability of capacities;
f) Cooperation with the pharmaceutical enterprises.

OUTPUTS AND DELIVERABLES

The assessment has resulted in the following outputs:

a) Qualitative assessment of the managers of local pharmaceutical enterprises;
b) Qualitative assessment of the representatives of educational institutions;
c) Polling of the employees of local pharmaceutical enterprises;
d) Assessment of the international best practice.

The following deliverables will be submitted to CAPS within the current assessment:

a) Report on qualitative assessment of managers of pharmaceutical enterprises and representatives of educational institutions on the theme of *Skills and knowledge needs*;
b) Report on the assessment of employees of pharmaceutical enterprises on the theme of *Skills and knowledge needs*;
c) Classification of 15 key employment positions at pharmaceutical enterprises, and
d) Job Description templates for 15 key employment positions at pharmaceutical enterprises.

BEST PRACTICE REVIEW

KEY POSITIONS' CLASSIFICATION OF THE PHARMACEUTICAL INDUSTRY

GMP Requirements

Premises

Premises must be located, designed, constructed, adapted, and maintained to suit the operations to be carried out. The layout and design of premises must aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt, and, in general, any adverse effect on the quality of products.

1. Production - In order to minimize the risk of a serious medical hazard due to cross-contamination, dedicated and self-contained facilities must be available for the production of particular pharmaceutical products.
   - Different operational areas - the production should take place in areas connected in a logical order corresponding to the sequence of the operations and to the requisite cleanliness levels;
   - Packaging area - Premises for the packaging of pharmaceutical products should be specifically designed and laid out so as to avoid mix-ups or cross-contamination.

2. Quality Control Laboratory(ies) – QCLs should be separated from production areas. Areas where biological, microbiological or radioisotope test methods are employed should be separated from each other.

3. Storage - Storage areas should be of sufficient capacity to allow orderly storage of the various categories of materials and products with proper separation and segregation:
   - Storage of starting and packaging materials,
   - Storage of products in quarantine,
   - Storage of finished products,
   - Storage of rejected, returned or recalled products

Key Personnel

Key personnel include the Head of Production, the Head of Quality Control and the Authorized/Qualified Person. The Heads of Production and Quality Control should be independent of each other. Duties and responsibilities of the key personnel are described in a range of international documents[1].

It is impossible to provide ideal solutions for the structure of the pharmaceutical enterprise, covering all possible varieties and nuances. Below we present an exemplary structure that illustrates minimum requirements and may serve as guidance.

[1] 1. EU Directive 2001/83/EC
2. EU DIRECTIVE 2003/94/EC "The principles and guidelines of GMP in respect of medicinal products and investigational medicinal products for human use"
3. EudraLex Volume 4: The Rules Governing Medicinal Products in the European Union, EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use
4. WHO, Quality Assurance of Pharmaceuticals (WHO Good Manufacturing Practice: main principles for pharmaceutical products) volume 2
5. PIC's Good Manufacturing Practice

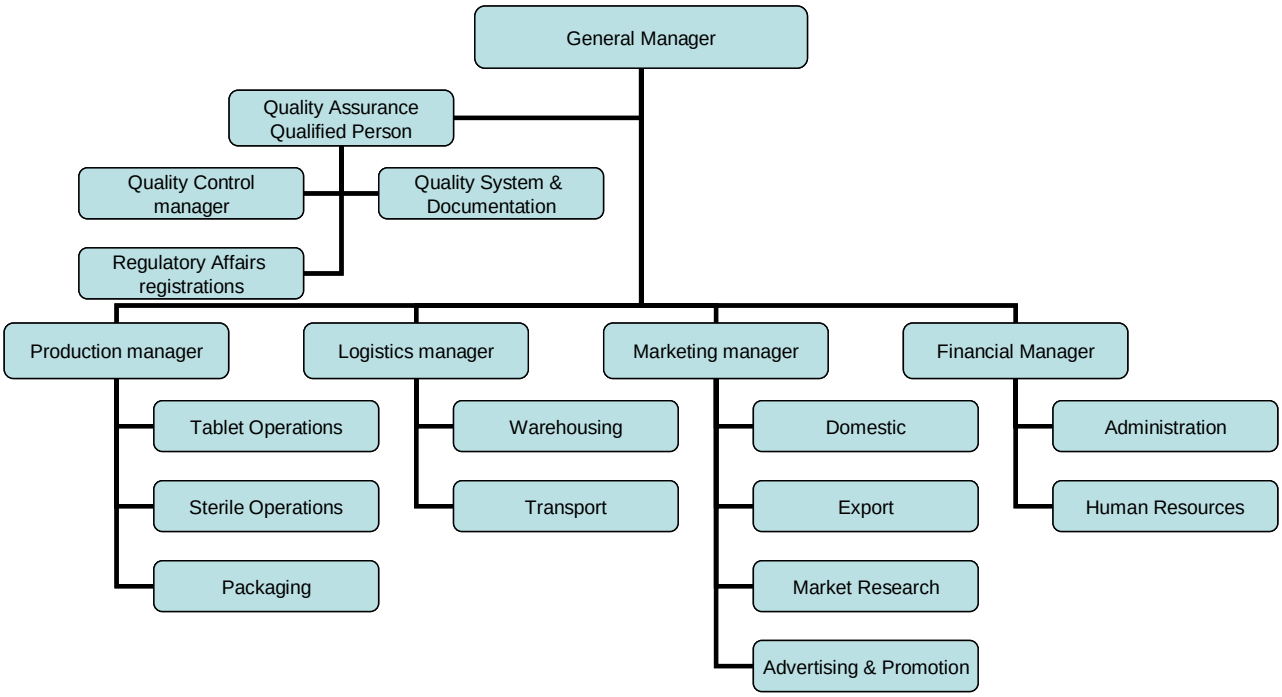

Chart 1 - Exemplary structure for the pharmaceutical enterprise (based on the best practice analysis)

Local Achievements

During the assessment we reviewed organizational structures of some local producers, and have to note that some leading enterprises have quite sophisticated and impressive structures, those enterprises need no modifications. In fact, these are companies with ISO Certification, and it is a requirement to have an organizational chart. This is legitimate, since those advanced enterprises have spent a lot of resources on the organizational aspect of their businesses. Meantime, some organizational structures and Job Descriptions may be applicable from an ISO point of view, but may not be GMP compliant.

At the same time, the assessment also identified some enterprises that have relatively weak structure, although this can be explained by restricted needs. Relevant operational units are created and specialists are attracted as the need arises. Except for some 4-5 leaders local pharmaceutical enterprises are quite weak and are still looking for best solutions for their business. Below we present the structure of one of the intermediary enterprises.

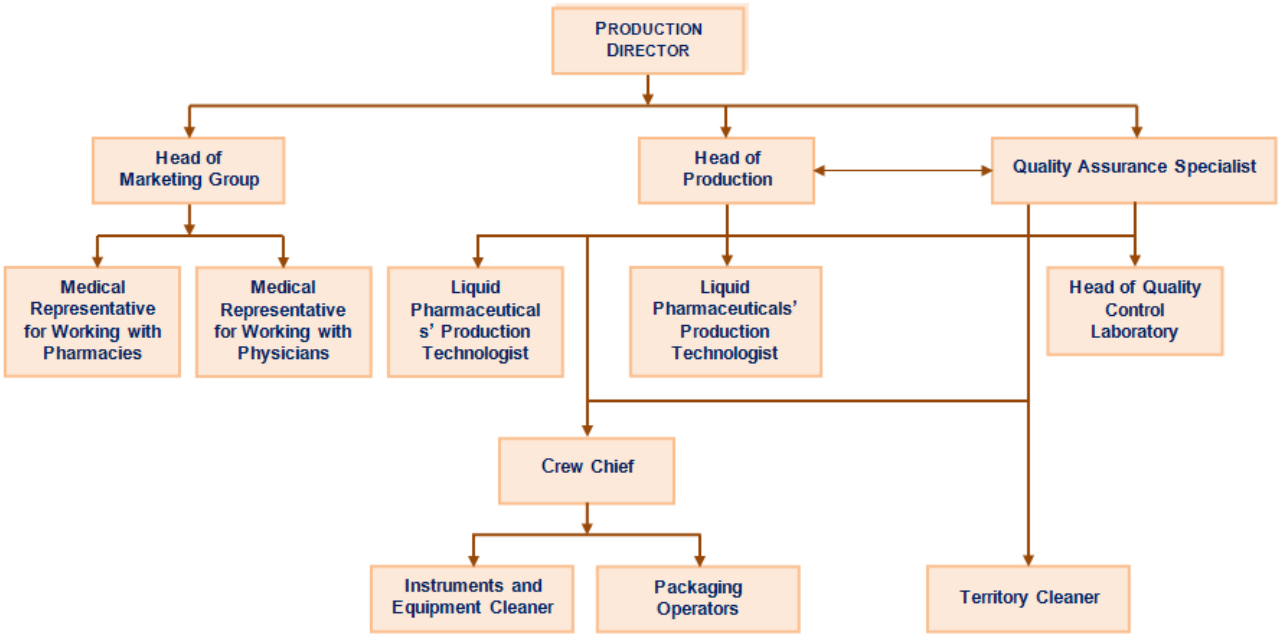

Chart 2 - Organizational chart for one of intermediary enterprises

The presented chart is not very sophisticated one, but it is a real achievement in comparison with other ones. There are some enterprises that even don't pay attention to this issue.

JOB DESCRIPTIONS

Availability

All enterprises that were involved in the assessment have been asked about the availability of the responsibilities delegation procedures and relevant tools, i.e. Job Descriptions. Again the same advanced enterprises declared that they are practicing the system of Job Descriptions; others are either in process of preparation or even don't want to apply them at all. Nevertheless, we asked the management of all enterprises to supply their Job Descriptions for conducting comparison with international best practice.

Unfortunately, only one enterprise[2] supplied us with their Job Descriptions. Others either refused to supply, explaining their position on the basis of privacy issues and commercial factors (for some enterprises those Job Descriptions have been developed by professionals and cost them substantial financial means), or have nothing to provide. As a result, it was simply impossible to compare local practices with internationally adopted ones, and we have to limit ourselves only to provision of expertise of advanced international producers of pharmaceuticals. Source of information that were used during the desk research are presented at the chapter *References*, at the end of document.

Composition and templates

The standard composition of Job Descriptions is the following:

a) Name of the position;
b) Short summary or description of the position;
c) Primary duties and responsibilities to be undertaken by the employee;
d) Relevant additional requirements – mainly regarding to education and experience;

[2] Vitamax - E

e) Skills and knowledge necessary for the implementation of professional responsibilities and duties.

Listed positions comprise the main body of Job Descriptions. In various enterprises this document is modified in different ways: they may also contain terms and conditions of the employment, maturity of suggested contract, required social (age, gender) status, etc.

For the exemplary enterprise we have identified 15 key positions and developed model Job Descriptions for them, i.e. templates. We don't claim that prepared templates are the last truth and the best way for organizing the work of specialists at certain positions, but we think that these templates will serve as a good guidance for local pharmaceutical producers on the way of developing their own Job Descriptions.

Templates of the Job Descriptions for 15 key positions are presented by the separate document attached to the current report (*Volume III: Job Description Templates*).

ASSESSMENT OF THE PHARMACEUTICAL CLUSTER PARTICIPANTS

SKILLS AND KNOWLEDGE GAP BY MANAGERS OF PHARMACEUTICAL ENTERPRISES

Need for additional employees

Rate of employment

As of the November 2008 the pharmaceutical industry of Armenia accounts more than fifteen enterprises including those facilities producing various herbs, additives and other by products. The survey covered 9 leaders. Only 5 enterprises produce and supply a relatively wide assortment of pharmaceuticals: others are specialized in the production of very few types of pharmaceuticals or have just started their activity. Some enterprises are not producing pharmaceuticals locally, but also are engaged in imports, distribution and retail trade of pharmaceuticals.

Nine surveyed pharmaceutical enterprises together employ about 570 people. Almost 60% of those employees are concentrated in two comparatively large enterprises – Yerevan Chemical Pharmaceutical Firm and Liqvor. One of the important deliverables of the current assessment is the identification of the "rate of employment" or the current number of vacancies at pharmaceutical enterprises. At the time of the assessment only 4 out of 9 surveyed enterprises stated that they had vacancies; others have no vacancies. In total, the demand of surveyed pharmaceutical enterprises for new specialists comprised 16 employees for existing vacancies and 12 more employees for new openings (only in Vitamax-E, in case of opening new production facilities).

Positions to be filled and urgency

The assessment of the pharmaceutical enterprises' vacancies has resulted in a very interesting finding – their employees are not necessarily narrow specialists of pharmaceutical science. In a practice, so called "non-specialists" comprise quite a notable proportion of the personnel. For some positions, such as operators, medical representatives, and marketing staff, pharmaceutical enterprises employ personnel for specialist positions with quite general knowledge and skills. Narrow specialization is not always obligatory.

Managers of pharmaceutical enterprises have mentioned the following positions that were not filled at the time of the survey:

Table 3 - List of vacancies at assessed enterprises

1.	Marketing specialist	☞ 2 employees
2.	Designer	☞ 1 employee
3.	Medical representative	☞ 1 employee
4.	Technologist	☞ 3 employees
5.	Head of quality control unit	☞ 1 employee
6.	Laboratory analyst	☞ 1 employee
7.	??? (Confidential info)	☞ 7 employees[3]
8.	Lyophilization[4] specialist	☞ 10-12 employees (new openings)

As to urgency of attracting new specialists, both for the vacant positions and new openings, the situation is not critical. Only 5 out of 28 new employees were claimed to be needed urgently. These positions are for market specialists, technologists and visiting specialists. More generally, producers are willing to find and attract specialists at a more leisurely pace. At least 15 out of 28 new

[3] Hagenas Company did not want to share information about its vacancies
[4] Drying and evaporation specialist

employees may be attracted within the period of 3-12 months, or even more. This means that local pharmaceutical producers are not really suffering from the lack of qualified specialists and can operate without filling current vacancies for a quite long period. Problems may appear only if the company grows. The companies with the fastest growth will have the biggest problems; staff will work over-time for longer periods.

Causes of not filling the vacancies

Reasons for not attracting required specialists are quite various. Some pharmaceutical enterprises are expanding their production and adding new facilities: laboratories, production units, etc. or moving to new premises. For attracting new employees pharmaceutical enterprises often advertise the positions. They place their advertisement in media and/or with job agencies and wait for response.

Armenian pharmaceutical enterprises train necessary specialists for specific positions they may have currently or plan to open on-the-job. Usually, they have to attract employees with a minimum level of knowledge and skills (except of key positions, such as managers of production process and quality control). These employees are the trained on-the-job at the enterprises to gain necessary skills.

This situation is twofold: on the one hand producers get what they specifically need after that training; on the other hand, the remuneration demands of those employees notably increase after improving their experience and qualifications. In many cases producers cannot afford to pay significantly increased compensation to their employees and lose them. This circle is quite destructive; comparatively strong producers suggest higher remuneration and headhunt qualified specialists, whilst smaller competitors have to adopt alternative strategies.

Conformity of existing employment structure to current needs

Managers of the local pharmaceutical enterprises have responded to this question quite differently: some of them are more or less happy with the employment structure of their enterprises; others can see a lot of room for improvements. Nevertheless, the majority of interviewed top managers are quite satisfied with the current employment structure of their enterprises. In some cases managers want to attract new specialists in order to delegate some of their own responsibilities, or the structure was designed to meet much more requirements than it actually has.

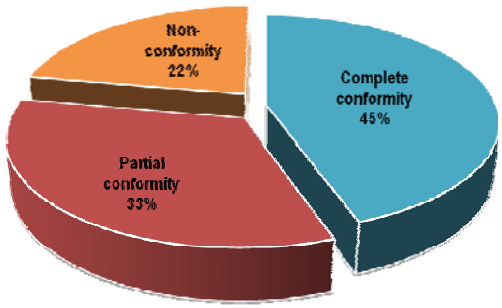

Chart 3 - Conformity of employment structure

Some of local producers are developing quite dynamically. In the near future they plan to apply certain modifications for meeting changing environment requirements, such as additional production premises, market conjuncture variations, changes in marketing policy, etc. That is why they state that they have only partial conformity.

Finally, more than one fifth of the respondents commented on the lack of conformity with the current needs of their enterprises. They believed their employees were too much overloaded, and urgent and notable changes are to be made. This may be initial signals of dissatisfaction with current structure, delegation of responsibilities and recruitment.

Delegation of responsibilities

Availability of job descriptions

Six out of the nine interviewed managers of pharmaceutical enterprises stated that they used job descriptions at their companies. Nevertheless, only one of the surveyed enterprises[5] agreed to share this information with the assessment team. Managers that ultimately refused to provide Job Descriptions of their enterprises explained their decision mainly on the basis of confidentiality issues. Some of them even went further and brought details: "28,000 Euros have been paid for developing those Job Descriptions and we can't share it with anybody[6]".

On the one hand, having no Job Descriptions for further analysis and comparison with international practices is quite sad and affect the assessment results negatively; on the other hand, it is very promising that producers are willing to spend such significant means on solving problems which may not be of first priority.

Pharmaceutical producers, that do not yet adopted Job Descriptions at their enterprises, explain it by following 2 reasons:

a) They are newly opened and are still developing their Job Descriptions,
b) Technologies and functions are changing all the time; it is difficult to develop final documents which will meet the requirements of changing environment.

Ways of delegating responsibilities to employees

In the analysis made above we saw that the overwhelming majority of pharmaceutical producers have adopted the system of Job Descriptions. In those cases, where producers have not completely developed the system of Job Descriptions a the method of oral instructions is employed. Although this practice is not effective and may be even dangerous in certain circumstances, this is the only alternative for some local companies. Nevertheless, in the situation of increased production volumes and product range producers will need to evaluate their operating procedures.

At least 3 local producers have declared that they don't have Job Descriptions, but we cannot say for sure that other 6 have these documents, we haven't seen them.

Qualification improvement needs

Employees' needs

All managers of pharmaceutical enterprises identified training needs. Some respondents think that all their personnel needs to be trained, others prefer to mention only a couple of positions, which they think are more important. Here is the complete picture with comments and priorities:

Table 4 - Training needs by the managers of pharmaceutical enterprises

Training needs	All specialists	Some specialists
Yereven CPF	a) **Especially** those who are engaged at GMP and other issues, i.e. the top management of the Company	
Arpimed	b) **Especially** engineers and technicians	

[5] Vitamax-E
[6] It should be mentioned that the mentioned amount was spent not only for developing Job Descriptions but for the set of consulting/certification services

	who operate the equipment, and specialists of R&D division at the laboratory	
Vitamax-E	c) All specialists without exceptions	
Esculap	d) **Especially** technologists, quality control supervisor, and marketing specialists	
Liqvor	e) All specialists without exceptions. Special budget should be developed for this purpose.	
Medical-Horizon		f) Head of Production, Quality Control Division specialists
Bizon-1	g) All specialists without exceptions	
Leiko-Alex		h) Production Operators, Packaging Operators
Hagenas		i) Storage Operators, Packaging Operators

Reasons for those needs

The assessment showed that the top managers of pharmaceutical enterprises completely understand their need for improving skills and knowledge of their personnel. They mentioned that continuous improvement of the qualification of specialists is the decisive factor for their success. As to reasons for those needs, respondents identified the following explanations:

a) Specialists' knowledge is outdated and employees are not familiar with modern technologies. There are no training programs in Armenia for improving the skills of pharmaceutical industry employees;
b) Where the producers do possess modern equipment, operators are not completely aware of the capability of that equipment and need to improve their training to operate the equipment more effectively;
c) There is a general lack of qualified specialists in Armenia. Producers usually attract general specialists and conduct on-the-job training for them;
d) Professional education and training at educational institutions is not adequate enough to allow the graduates to meet requirements of producers. Technologies are developing continuously, and producers have to train their specialists in order to keep them informed and skillful;
e) Employees trained on-the-job notably improve their qualifications, after which they usually request better remuneration. Producers cannot always afford to meet these demands and often lose their specialists to other companies without having other alternatives. Availability of training opportunities will increase the supply of the qualified workforce, *ceteris paribus.*

It can be concluded that improving the knowledge and skills of all staff will reduce the pressure, as there will be more qualified people available.

Ways of fulfilling needs

Since the improvement of employees' skills and knowledge is one of the most important challenges for Armenian producers of pharmaceuticals, various types of activities are applied for that purpose. Currently, the producers most often train their specialists in the process of production. This method is quite efficient, and does not require many resources. Nevertheless, some producers spend a lot of money on the training of their specialists outside of the production process. All respondents stated that

they would welcome a consolidated industry training programThey can see the organization of such training as follows:

Yereven CPF, Vitamax-E, Esculap, Liqvor	☞ Establishment of Training and Educational Center under the patronage of the Association of Medicine Producers and Importers
Arpimed, Medical-Horizon, Bizon-1	☞ Organization of trainings and practical seminars (especially abroad), or invitation of specialized trainers
Leiko-Alex	☞ On the-job training and provision of instructions
Hagenas	☞ Design and development of the Technical Assistance project which will provide financing for conducting special training for employees of pharmaceutical industry

Respondents think that the availability of centralized training opportunities will facilitate the training of specialists for employment in pharmaceutical enterprises, thus providing a set of minimum requirements for all potential employees.

Trainings' peculiarities

The assessment covered the following aspects of requested trainings: need, urgency, theme, place of the implementation, and trainers. The *combination of these factors* will allow us to make objective judgments about real training needs of pharmaceutical enterprises in Armenia. All factors are combined and illustrated in one general table (see below).

Themes

Almost all respondents stated that their personnel required training in GMP, GLP, and other professional pharmaceutical issues. This is legitimate, since currently almost all producers are planning to apply GMP requirements, and some of them have already initiated specific activities in this direction. Besides that, in the near future some legislative and regulatory changes are also imminent, with the aim to bring the pharmaceutical production closer to international GMP standards. Pharmaceutical enterprises understand all this very well, and try to react promptly and effectively.

Other themes for training are of more organizational and promotional by nature. Improvement of marketing skills and computer literacy has somewhat indirect connection with pharmaceutical production, although they are quite important, too.

Urgency

Assessment of the urgency of requested training has the aim to understand the importance that the pharmaceutical enterprises place on specific training programs. Some training programs should be conducted in the very short term; others can be left for a while. Again, professional pharmaceutical training programs are requested as a priority. According to top managers of the pharmaceutical enterprises, these training programs need to be conducted urgently.

Place of implementation

The place of the implementation of training sessions is another very important factor, which may affect the effectiveness and efficiency of trainings. Thus, for some trainees it is preferable to get training closer to their home and work: they try to keep in touch with their everyday agenda and complete other

tasks besides training. Other trainees prefer to participate in training programs at specially designed training centers, located quite far from their everyday life. It helps them to concentrate on the training topic and get maximum information in a short time.

Local training vs. overseas programs is another topic to discuss. On the one hand, training programs organized abroad are going to be more useful by default, since a lot of people from other countries participate in these training sessions and bring their successful experience. On the other hand, these training programs are usually quite expensive – many producers cannot afford such expenses.

Preferred trainers

There are many factors which characterize trainings, but the most important one is the trainer and his/her qualification. For the purpose of deepening the academic education theoretician trainers are to be attracted, for improving everyday working skills – practitioners are more preferable. In the case of pharmaceutical enterprises there is tendency towards the practical trainings. Skills and knowledge gained at these trainings, participants are going to apply in their own production process.

Table 5 - Combination of answers of top managers of the 9 pharmaceutical enterprises (number of responses)

Types of most required training	N of respondents	Urgency		Place of trainings			Trainers			
		Urgently	In coming months	At the workplace	In Armenia, out of the workplace	In abroad	Local specialist, theoretician	Local specialist, practitioner	Foreign specialist, theoretician	Foreign specialist, practitioner
GMP	9	6	3	3	6	4	1	3	3	8
GLP	9	6	3	3	6	4	1	3	3	8
Professional pharmaceutical themes	8	3	5	5	1	4	2	5	0	3
Marketing	4	1	3	2	2	1	2	2	0	2
Computer techniques	4	1	3	1	4	0	4	2	0	0
Accounting themes	1	0	1	0	1	0	1	1	0	0
Juridical themes	1	0	1	0	1	0	1	1	0	0

As we can see from the table above GMP/GLP and narrow professional themes are the most requested ones. These training programs are needed urgently for the majority of respondents. Training programs on different professional themes, as well as such “parallel” topics such as marketing and computer skills are also required, but not as urgently.

Respondents gave different answers to the question regarding the role of training. Anyhow, their majority prefers to get training in Armenia, but out of their workplace. As to trainers, respondents mainly require practical classes carried out by foreign specialists.

Relationship with educational institutions

Available cooperation

From the very beginning of the assessment we were thinking that there should be quite close cooperation between pharmaceutical enterprises and educational institutions. Concluding the results of

the assessment we can see that we were only partly right. Of course, there are some relations between producers and educational institutions, but those relations are limited to providing room for passing some practical classes for some students of medical and chemical educational institutions. In the table below the relations of producers and educational institutions are illustrated.

Table 6 - Relations of producers and educational institutions

1.	Yereven CPF	☞ Practical classes, internship, and diploma preparation classes for students of YSMU[7], Medical college, YSU[8] Pharmaceutical Faculty, etc.
2.	Arpimed	☞ Practical classes, internship, and diploma preparation classes for students of YSMU, YSU Pharmaceutical Faculty, etc. Have refurbished special premises for students
3.	Vitamax-E	☞ Practical classes and internship for students from Mehrabyan Medical Institute, Erebuni Medical College
4.	Esculap	☞ It is the main internship base for the YSMU
5.	Liqvor	☞ Practical classes for students of YSMU. The manager of the enterprise is a member of Examination Committee of the YSMU
6.	Bizon-1	☞ Working at the same territory with the Institute of Biotechnologies. Students visit the production premises once in each course
7.	Leiko-Alex	☞ Some practical classes from the non-medicinal educational institutions. Those classes are possible only via the recommendation of friends of the management of the enterprise
8.	Hagenas	☞ Have some cooperation with Armenian State Agrarian University, Academy of Science of RA. Have concluded cooperation agreements with YSMU on providing practical classes; practice presentations and other explanatory events for YSMU students

As it can be seen from the table above, the whole cooperation is limited to various types of practical classes. To our understanding, it is not enough and effective. No joint working groups, no research projects, no ventures, no planned labor-educating policy, no influence on educational disciplines and curricula, etc. In fact, the current situation is something like “relations” but not “cooperation”.

Industry expectations from educational institutions

In general, the producers’ major expectation from educational institutions is closer cooperation. Various producers see that cooperation in a different way, but all of them have their requirements. On the one hand, they are right: the educational system must try to meet requirements of the industry as much as possible. On the other hand, the producers are not very proactive, too. Here is the snapshot of Armenian pharmaceutical enterprises’ specific expectations from the educational institutions:

a) *Training of qualified GMP and related specialists.* GMP continuously increases its value in Armenia and around the world, and skillful GMP specialists have become just a necessity.
b) *Improvement of teaching and training quality.* Students of medical educational institutions (especially small ones) do not meet requirements of pharmaceutical producers. The theoretical knowledge students get in their classes is somewhat outdated, they strongly lack practical classes.
c) *Revision of educational disciplines and curricula.* There is a need for modifications in curricula, since the technologies are getting changed and modernized. Respective changes/deepening

[7] Yerevan State Medical University
[8] Yerevan State University

should be made at the educational level, otherwise we shall face a deep gap between pharmaceutical producers and educational institutions in the nearest future.

d) *Research and synthesis of new pharmaceuticals.* Some producers are not able to develop new pharmaceuticals, since that requires the availability of special infrastructure, analytical laboratory equipment, and R&D specialists. Normally, educational institutions possess these assets, and are able to develop new pharmaceuticals. However, they also have no means for organizing serial production. The mutual benefit of the real cooperation between educational institutions and pharmaceutical enterprises needs no more proof.
   - *Application and implementation labor projects.*
   - This involves the selection of the best students still studying, train them by special programs and curricula, prepare qualified specialists and ensure their employment. In fact this means investments in education.

e) In Armenia we have such examples in IT sector, and those examples turned to be success stories both for educational institutions and pharmaceutical enterprises.

Effectiveness of the cooperation

Although we tend to define the relations between pharmaceutical producers and educational institutions as non-effective, producers think that practical classes at their enterprises are very useful for students of various institutions. They are sure, that visiting practical classes students receive real pharmaceutical knowledge. “Even just one look at the production processes gives them more knowledge than many lectures”.

Producers stae that they quite often offer employment opportunities to students during those practical classes. Meantime, in Armenia students usually prefer to get employed in pharmacies instead of pharmaceutical enterprises. Nevertheless, Arpimed, Esculap, and other producers have already attracted tens of students. The necessary requirements are the completion of education and long-term commitments.

Demand for new employees

Number of newly requested employees in a short-term and 5-year prospective

Although the development preconditions in Armenia are not very promising, we are glad to report that almost all managers of the assessed pharmaceutical enterprises plan to develop quite extensively. Estimated ratios are presented at the table below.

Table 7 - Planned increase of the personnel in coming 12 months

Pharmaceutical enterprises	Planned increase of the personnel
Yereven CPF	☞ 27%
Arpimed	☞ 20%
Vitamax-E	☞ 79%
Esculap	☞ 14%
Liqvor	☞ 10%
Medical-Horizon	☞ 40%
Bizon-1	☞ 25%

Leiko-Alex	☞	25%
Hagenas	☞	123%

In total, respondent managers of the pharmaceutical enterprises mentioned about 170 potential openings / new jobs in coming 12 months. It is appropriate to note that the same 9 assessed enterprises currently employ 570 employees. In other words, the pharmaceutical industry in Armenia plans to increase employment figures by 30% in coming 12 months.

At the same time, we understand that the notable general development of the industry does not necessarily mean development for all enterprises. Some of them have much more preconditions for success than others. Thus, almost 65% of the planned increase of the number of employees is forecasted by only two enterprises – Yerevan CPF and Vitamax-E. Only 5 enterprises out of 9 have planned employment increase for more than 25%.

The figure of 170 new employees in coming 12 months stated by the managers of the pharmaceutical enterprises is quite impressive. At the first sight it may seem to be somewhat inflated, but managers know their businesses, and they hopefully are able to make accurate estimations. In a 5-year prospective estimations are a little conservative. 4 enterprises simply refused to estimate the potential number of new employees. The other 5 producers estimated that figure to be around 240 employees rather than the 170 of the first year. In a further analysis we compare these figures with the number of graduates of the educational institutions in the same period and trace the dynamics of the potential supply and demand of specialists in pharmaceutical industry.

Table 8 - Demand for new employees at local pharmaceutical enterprises

>1 year	Demand for new employees	1-5 years	Demand for new employees
Technologist	34	Technologist	40
Maintenance Staff	27	Worker	32
Production Operator	18	Pharmacist (for heading positions)	15
Packaging Operator	16	Lyophilization Specialists	12
Engineer-technician	15	Fireman	10
Marketing Specialist	6	Medical Representative	8
Laboratory technician	3	Marketing Specialist	5
Export specialist	1	Head of Workshop	5
Medical Representative	1	Production Operator	5
Quality Control Specialist	1	Laboratory technician	4
Essential oil specialist	1	Registration Specialist	2
Not specialized	47	Quality Control Specialist	1
		Export specialist	1
		HR Specialist	1
		Head of Storage	1
		Engineer	1
		General Specialist	1
		Responsible person	1
		Safety Engineer	1
		Not specialized	94

Total	170	Total	240

Respondents were not able to completely justify the specialization of all potential employees. The most requested positions mentioned by the managers of the pharmaceutical enterprises are: technologists, maintenance staff, packaging and production operators, etc. For some of requested employees the pharmaceutical education is not obligatory but desirable.

Possible ways of attracting employees

The assessment showed that the Armenian producers of pharmaceuticals do not usually practice sophisticated ways of attracting new employees. Producers usually attract general specialists from employment agencies that are not always graduates of medicinal educational institutions.

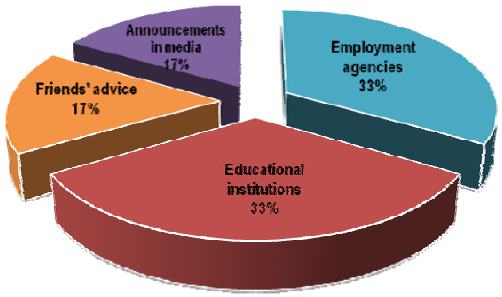

Chart 4 - Ways of attracting employees

Employees attracted from general educational institutions are comparatively cheap, but lack a lot of skills and knowledge due to short working experience or even a lack of such experience. Anyhow, producers really like the idea of attracting specialists exactly from the pharmacy faculties of educational institution, and this may become the first step towards the real cooperation between the educational institutions and producers.

The advice and recommendation of friends or other close people are still an effective and decisive factor for selecting employees. Although in -many cases such recommendations do not mean anything in a professional arena, Armenian employers still prefer to believe in their friends instead of judging people by their qualifications.

KNOWLEDGE SUPPLY PECULIARITIES BY REPRESENTATIVES OF EDUCATIONAL INSTITUTIONS

Educational institutions' profile and offered training

The assessment covered almost all academic institutions that suggest educational services in the field of pharmaceutical science and relative fields. The list of educational institutions comprises state and private entities, secondary vocational vs. high education. Assessed educational institutions and training and education suggested by them are presented in the table below.

Table 9 - Educational institutions and proposed trainings

Educational institutions	Type of education	Professions Specializations? add a separate column!
National Institute of Health named after academician S.Kh. Avdalbekyan SCJSC of the MOH of RA	☞ Refresher courses for pharmacists, ☞ Refresher courses for pharmacists with Higher education,	➢ Qualification Improvement and Training Courses for Pharmacists and Pharmaceutical scientists[9]

[9] **Pharmacists** are trained at higher education institutions and universities. Graduates of those institutions can engage top management positions at pharmaceutical enterprises. **Pharmaceutists** graduate vocational institutions and usually engage lower positions.

	☞ Specialization of pharmacists	
Yerevan State Medical University (YSMU) named after Mkhitar Heratsi of the MOES of RA	☞ Higher education, ☞ Internship, ☞ Post-graduate education, ☞ Specialization	➢ Pharmacist
Yerevan State University (YSU)	☞ Bachelor degree, ☞ Master degree, ☞ Post-graduated education,	➢ Pharmacist - Chemist
Yerevan State Engineering University (YSEU)	☞ Specialized secondary education, ☞ Bachelor degree, ☞ Master degree, ☞ Post-graduate education,	➢ Pharmaceutical scientist - Chemist
"Haybusak" Yerevan University	☞ Higher education,	➢ Pharmaceutical scientist
Yerevan Medical Institute after Mehrabyan	☞ Higher education, ☞ Specialized secondary education[10],	➢ Pharmaceutical scientist - the College ➢ Pharmacist - the Institute
Medical University named after Saint Teresa	☞ Higher education,	➢ Pharmaceutical scientist
Yerevan State Basic Medical College SNPO	☞ Specialized secondary education,	➢ Pharmaceutical scientist
"Grigoris" Medical-Humanities College	☞ Specialized secondary education,	➢ Pharmaceutical scientist
Yerevan State Medical College "Erebouni" SNPO of the MOH of RA	☞ Specialized secondary education,	➢ Pharmaceutical scientist

The major "player" from the side of educational institutions is the *YSMU*. This entity is the main "supplier" of specialists in the field of pharmaceutical production.

Number of places vs. applications

Current number of students

The purpose of the analysis of the current number of students at educational institutions is the understanding of labor supply and demand proportion in Armenia in a 5-year prospective. The task is complicated since it is impossible to combine all students in one final figure. The reason for that are the different types of the education: graduates of the colleges are potential applicants for higher education. Graduates of universities are potential applicants for internship and post graduate education. Nevertheless, the combined picture of the number of students is presented in the table below.

Table 10 – Distribution of pharmaceutical students by years (2008-2009)

Educational institutions	1st year	2nd year	3rd year	4th year	5th year	Intern-ship, etc	TOTAL
National Institute of Health named after academician S.Kh.	0	0	0	0	0	0	**0**

[10] 2-year education

Avdalbekyan SCJSC of the MOH of RA[11]							
Yerevan State Medical University (YSMU) named after Mkhitar Heratsi of the MOES of RA	156	51	57	61	61	25	**411**
Yerevan State University (YSU)	48	68	57	60	57	0	**290**
Yerevan State Engineering University (YSEU)	0	0	18	16	0	16	**50**
"Haybusak" Yerevan University	19	24	30	42	25	0	**140**
Yerevan Medical Institute after Mehrabyan	16	25	46	7	0	0	**94**
Medical University named after Saint Teresa	3	0	0	3	2	0	**8**
Yerevan State Basic Medical College SNPO	200	200	0	0	0	0	**400**
"Grigoris" Medical-Humanities College	18	18	0	0	0	0	**36**
Yerevan State Medical College "Erebouni" SNPO of the MOH of RA	67	67	0	0	0	0	**134**
TOTAL	**527**	**453**	**208**	**189**	**145**	**41**	**1563**

As it can be seen in the table, the total number of potential/future specialists of the pharmaceutical sector that are currently studying in various educational institutions of Armenia comprises 1,563 people/students. There is one important reservation to the information presented in the table: the same courses of vocational institutions and universities are presented in a combined figure, although in reality these are qualitatively different people[12]. Nevertheless, the total figure of students illustrates the approximate potential supply of pharmaceutical specialists.

Meantime, the type of education is also quite important. Secondary education may be enough for undertaking the responsibilities of operators or engage positions of the middle management, while for higher positions more educated and skillful specialists are to be attracted.

Coefficient of applications and places available

Educational opportunities in the field of the pharmaceutical science are another important issue to be discussed. Development of the pharmaceutical industry is going to create demand for qualified and skillful personnel. This demand can be met only via providing relevant educational opportunities at the field of pharmaceutical science.

Table 11 - Availability of educational places at institutions in the area of pharmaceutical science

Educational institutions	Coefficient of applications and places available		
	2006	2007	2008
Yerevan State Medical University (YSMU) named	0,6	0,6	1,4

[11] The education at the National Institute is organized in a cyclic manner. Cycles last 5-7 weeks

[12] Yerevan Medical Institute after Mehrabyan - 1st course: 9 students at higher school and 7 students at college, 2nd course: 5 vs. 20, 3rd course: 6 vs.40. Yerevan State Engineering University - 4 students at the 1st course of the master course and 12 students at the 2nd master course.

after Mkhitar Heratsi of the MOES of RA			
Yerevan State University (YSU)	1,2	1,2	0,8
Yerevan State Engineering University (YSEU)	6,7	5,3	5,7
"Haybusak" Yerevan University	0,3	0,4	0,5
Yerevan Medical Institute after Mehrabyan	2,2	1,0	1,3
Medical University named after Saint Teresa	1,0	1,0	0,2
Yerevan State Basic Medical College SNPO[13]	1,0	1,0	1,0
"Grigoris" Medical-Humanities College	1,5	1,5	1,5
Yerevan State Medical College "Erebouni" SNPO of the MOH of RA	1,0	1,2	1,0
Average	**1,08**	**1,04**	**1,15**

The average coefficients[14] of the availability of educational places at educational institutions are unexpectedly low. Bold coefficients mean that on average the demand for the pharmaceutical education is almost adequate to supply. Obviously, the coefficient is quite different for various educational institutions. Some institutions, such as YSEU, Yerevan Medical Institute after Mehrabyan, "Grigoris" Medical-Humanities College "were not able to meet the demand". In case of other institutions that are more famous and well-known, we can see significant shortage of applicants. Such authoritative institutions, as YSMU, YSU, and "Haybusak", were not able to complete their classes with students. The only reasonable explanation for the situation is the high cost of the education – only very small number of educational places is for free.

Another conclusion can also be made from the figures of the table. Pharmaceutical education is not currently required in Armenia as primary education. Applicants prefer to apply for other specialties, and mark the pharmaceutical science as secondary alternative.

At the same time, there is another very important point regarding pharmaceutical education. The overwhelming majority of students of pharmacy faculties don't even think about working at pharmaceutical enterprises. They prefer to find employment at pharmacies, where their work is going to be much easier, safer and well-paid. At pharmacies these specialists do not have good career opportunities, but the majority of specialists prefer today's better conditions at pharmacies.

Decision of the number of educational places

Results of the current assessment show that the number of educational places in pharmacy faculties in Armenian institutions has no relation with the relevant industry dynamics. Educational institutions operate separately, under the strict control of state regulatory authorities. Decision making on the number of educational places is made by the License issued by the Ministry of the Education and Science of Armenia. The Ministry makes licensing decisions based on the capacity of the certain institution, i.e. availability of classrooms and infrastructure, laboratories and equipment, etc. The only decision maker is the Ministry and the industry has no chance to influence. Fortunately, there is no notable gap between the number of places at educational institutions and the number of applications.

In ideal format, the licensing procedure could consider also the market conjuncture while opening educational places for certain institutions. The industry may not need so many professionals of specific specialty, and preparation of those specialists may turn to be a waste of time and resources. Meantime,

[13] Figures are approximately estimated
[14] Number of applicants was divided by the number of places at educational institutions

that would be very difficult to evaluate the real demand for pharmacists in Armenia for the following reasons:

a) Estimation of the market conjuncture is subjective process. Educational institutions may have their own understanding of the market[15].
b) There are hundreds of pharmacies in Armenia and they express demand for pharmacists.

Number of students graduating educational institutions in a 5-year prospective

Information on the number of students that will graduate their educational institutions in 12-month and for a 5-year prospective is important for the comparison of the demand of the pharmaceutical enterprises and supply of qualified labor from educational institutions. As mentioned above, pharmaceutical enterprises stated their demand for new employees in 2009 to be 170 specialists; in a 5-year prospective the total demand will comprise at least 410 employees[16]. The supply of the qualified labor is presented in the table below.

Table 12 - Projection of the number of students graduating pharmaceutical faculties in coming 5 years

Educational institutions	2009	2010	2011	2012	2013	TOTAL
Yerevan State Medical University (YSMU) named after Mkhitar Heratsi of the MOES of RA	61	61	55	50	150	**377**
Yerevan State University (YSU)	57	60	57	68	48	**290**
Yerevan State Engineering University (YSEU)	17	17	20	20	20	**94**
“Haybusak” Yerevan University	25	42	30	24	19	**140**
Yerevan Medical Institute after Mehrabyan	10	15	20	25	25	**95**
Medical University named after Saint Teresa	2	3	10	10	10	**35**
Yerevan State Basic Medical College SNPO	200	200	200	200	200	**1000**
“Grigoris” Medical-Humanities College	18	18	20	20	20	**96**
Yerevan State Medical College “Erebouni” SNPO of the MOH of RA	62	77	85	90	100	**414**
TOTAL	**452**	**493**	**497**	**507**	**592**	**2541**

It is very difficult to make unambiguous judgments about the sufficient availability of labor for pharmaceutical enterprises. At the first sight the supply completely covers demand, but we don’t know the demand that will be expressed by pharmacies. Secondly, pharmaceutical enterprises require not only pharmacologists, pharmaceutical scientists, chemists, and technologists, but also marketing specialists, engineers, managers, etc. The latter staff should not necessarily have medicinal education.

Curricula suggested at educational institutions

Adequacy of current curricula to the existing situation

During the interviews with the managers of the pharmaceutical enterprises they were asked about the sufficiency and adequacy of educational programs and curricula. The majority of respondents was strongly dissatisfied with the current educational system and suggests immediate changes to it. In order

[15] In this situation educational institutions have financial interest. They suggest their services for money and really don’t care about the demand for certain specialists in the labor market
[16] 5 pharmaceutical enterprises will request 240 employees in the period of 2nd – 4th years. 170 + 240 = 410 employees

to stay objective, we tried to find out the opinion of representatives of educational institutions on the topic.

It could be easily predicted that educational institutions are confident that current curricula and disciplines meet the requirements of industry. Nine respondents out of 10 replied that the education provided to students was completely adequate to meet the current needs of the pharmaceutical community. Only the representative of the YSEU expressed a different opinion. Reasons he expressed comprise *lack of theoretical and practical classes*[17]*, insufficiency of technical conditions and laboratory facilities, as well as lack of modern literature and knowledge exchange.*

Some managers of the pharmaceutical enterprises complained that educational programs and curricula have not been changed for up to 30 years. Representatives of almost all educational institutions stated that their curricula were adopted at 2005 and slightly changed, i.e. were broadened a little, during last 2-3 years. According to regulation, educational institutions are allowed to make up to 15% changes in curricula whilst staying within the frame of allowed characteristics defined by the state authorities.

Only one respondent noted that the curriculum at YSEU was reduced and these perceived negative changes were sourced from the transformation to Bologna system of education. Some disciplines were amended to masters programs, which were claimed to lower the quality of education at the bachelor degree.

Needs for curricula modifications

Although the majority of the educational institutions are quite happy with disciplines and curricula they apply and teach, they all understand that from time to time some changes are necessary. In some institutions the curricula are a matter of modifications once in 5 years, in others modifications are made once in up to 9 years. At the same time, slight ongoing changes may be applied almost every year. This means, that educational institutions are quite flexible, in fact.

Curricula modifications in almost all cases mean amendment of existing disciplines and introduction of new ones. Respondents named about 10 disciplines (in the fields of chemistry, biology, pharmaceutical science, etc.) that they are going to introduce, in order to improve curricula and the quality of education. The National Institute of Health is going to introduce GMP education for post-graduate students and interns.

Availability of the qualified lecturers

Training of the qualified specialists strongly depends on the availability of necessary resources. The most important resource in this process is the lecturer. All representatives of educational institutions replied that they have sufficient number of qualified lecturers for organizing the educational process.

As in case of curricula, there were discrepancies between answers of the representatives of educational institutions and managers of pharmaceutical enterprises. The latter group of specialists thinks that lecturers at educational institutions are more theoreticians and students need more practical classes, as well as problem and project based learning. Hence the need for cooperation between academic institutions and industry. Universities do not have production facilities and students can only get their experience in industry.

[17] Time factor

Relationships with pharmaceutical industry

Available cooperation

Cooperation between Armenian pharmaceutical enterprises and educational institutions is still one of the most important topics of the current assessment. From the analysis of the pharmaceutical enterprises managers' answers we understood that the cooperation is quite weak and restricted to providing practical classes and internship to students. Answers of the representatives of educational institutions are more encouraging.

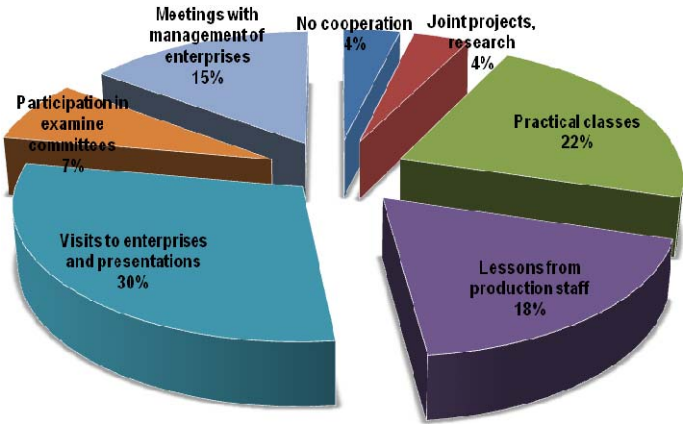

Chart 5 – Cooperation between pharmaceutical enterprises and educational institutions

Only 1 out of 10 respondents admitted that they have no cooperation with pharmaceutical enterprises. They are training pharmacists to work in pharmacies. Others seemingly have quite often a kind of cooperation.

As it can be seen from the chart, *Visits to pharmaceutical enterprises* are the most practiced type of cooperation. Meantime, the regularity of these visits is more important. Visits can be organized and paid much more often and not to the same company.

Practical classes and on-site training (lessons from production staff) are next prevailing answers. Some enterprises organize these events on commercial bases, others provide them for free. In some cases producers select some best students, organize special classes for them and even pay them some remuneration. The table below illustrates the cooperation between Armenian pharmaceutical producers and educational institutions.

Table 13 - Cooperation between educational institutions and pharmaceutical enterprises

Educational institutions		Partner producers
National Institute of Health named after academician S.Kh. Avdalbekyan SCJSC of the MOH of RA	☞	Arpimed, Pharmatec, Liqvor
Yerevan State Medical University (YSMU) named after Mkhitar Heratsi of the MOES of RA	☞	Liqvor, Esculap
Yerevan State University (YSU)	☞	Arpimed, Pharmatec, Liqvor, Noki, Yerevan CPF
Yerevan State Engineering University (YSEU)	☞	Yerevan CPF, Liqvor, Noki, Vitamax-E, Ariyak
"Haybusak" Yerevan University	☞	Liqvor, Esculap, Yerevan CPF
Yerevan Medical Institute after Mehrabyan	☞	Vitamax-E, Liqvor, Noki
Medical University named after Saint Teresa	☞	Noki
"Grigoris" Medical-Humanities College	☞	
Yerevan State Basic Medical College SNPO	☞	Yerevan CPF, Pharmatec
Yerevan State Medical College "Erebouni" SNPO of the MOH of RA	☞	

Implementation of joint projects and research is the rarest type of cooperation. Educational institutions are not looking for such cooperation very intensively, and pharmaceutical enterprises are not ready to

spend substantial financial means and much time[18] for that purpose. This inactivity is very problematic, since in developed countries the close cooperation between producers and scientific/educational institutions in research projects is an important prerequisite for the development of both counterparts.

Effectiveness of the cooperation

Representatives of educational institutions think that the cooperation with pharmaceutical producers is very effective and useful for their students. All respondents expressed their satisfaction with results of actual cooperation – practical classes, visits to enterprises, etc. They note that cooperation significantly contributes to developing experience and skills for students, justifying their theoretical knowledge with practical experience.

Although the representatives of educational institutions consider the current level of cooperation as very effective, we tend to hold another opinion. The cooperation is almost completely limited to the organization of practical classes for students. Moreover, this process has turned out to be somewhat like a responsibility, instead of being mutually beneficial process.

Assistance of students in getting employed

Employment and a future career is one of the most problematic issues for all graduates. The managers of educational institutions understand this very well and try to secure employment opportunities for their best students. Recommendations of educational institutions are quite valuable for business community and managers of both entities often keep quite close relations. Sometimes the employment of a student in Armenia is a matter of simple phone call for the dean or other manager of the educational institution.

Meantime, not all educational institutions do practice personal protectionism. Many institutions have established special units within their entities, which are engaged in job seeking operations for advanced students. For example, Yerevan Medical Institute after Mehrabyan, Medical University named after Saint Teresa, and some other institutions are keeping close relations with a wide network of pharmacies, Yerevan State Basic Medical College SNPO and YSU cooperate with Yerevan CPF and Noki and provide them with qualified workforce. Some educational institutions went further and established specialized career centers for their students.

Pharmaceutical industry influence on the educational processes

The purpose of the understanding of the pharmaceutical enterprises' influence on educational processes is another way of evaluating the intensiveness of cooperation between these producers and educational institutions. Although, representatives of educational institutions claim close and effective cooperation, we more agree with producers' opinion: the cooperation is just simply marginal.

In fact, pharmaceutical enterprises have no real influence on education processes. Producers are allowed to apply for an educational place for a student that will not participate in entry competition. In fact, producers purchase educational place, if they need. In some cases, managers of enterprises are invited to participate to examination committees; sometimes producers are invited to discuss *minor modifications* in educational programs (mainly editing). These relations are a very tiny part of potential cooperation opportunities.

[18] Some producers even complain that students are bothering their production process and create problems. Besides that not all producers possess proper facilities for conducting practical classes at their production sites

Awareness of the pharmaceutical industry

Awareness of educational institutions of the Armenian producers of pharmaceuticals is the last indicator within the current assessment that characterizes the cooperation between these two types of entities. Logically, all educational institutions that have pharmacy faculties must be well aware of local producers of pharmaceuticals. Unfortunately this statement is not true; only few institutions are well aware of producers.

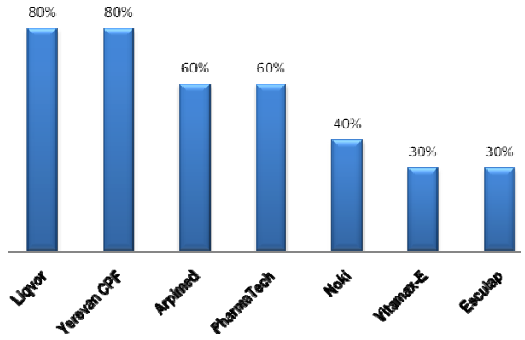

Chart 6 – Awareness of educational institutions about the pharmaceutical enterprises

As it is illustrated in the chart, Liqvor and Yerevan CPF are the most well-known enterprises – 80% of educational institutions are aware of them. Vitamax-E and Esculap are not very well known among Armenian educational institutions.

The most informed educational institution is the *National Institute of Health named after academician S.Kh. Avdalbekyan SCJSC of the MOH of RA*. The representative of this institution was aware of all producers. YSEU, YSMU, YSU, and Haybusak are also quite well informed: each of them was aware of at least 5-6 leading producers. At the same time, there are at least two educational institutions that are aware of only two producers.

APPENDICES

APPENDIX I: LIST OF ASSESSED PHARMACEUTICAL ENTERPRISES

NN	Name of the respondent	Enterprise	Position
1.	Sergey Matevosyan	Liqvor	Director
2.	Vachagan Ghazaryan	Arpimed	General Director
3.	Siraz Matevosyan	Yerevan CPF	Director
4.	Hrach Minasyan	Esculap	Director
5.	Shahe Qasis	Medical-Horizon	Assistant Director
6.	Eduard Dilanyan	Vitamax-E	Director
7.	Gagik Alexanyan	Leyko-Alex	Director
8.	Suren Harutyunyan	Bizon-1	Director
9.	Gevorgyan Xachik	Hagenas	Director

APPENDIX II: LIST OF ASSESSED EDUCATIONAL INSTITUTIONS

NN	Name of the respondent	Educational institution	Position
1.	Hasmik Hasratyan	Yerevan State Medical	Dean of Pharmacy Department

		University Named After Mkhitar Heratsi	
2.	Aida Avetisyan	Yerevan State University	Dean of Chemistry Department
3.	Geghetsik Hovhannisyan	State Engineering University of Armenia	Deputy Head of the Chemical Technologies Department
4.	Bogdan Gasparyan	"Haybusak" Yerevan University	Pro-rector (educational and scientific affairs)
5.	Larisa Hambardzumyan	Medical University Named After Saint Teresa	Rector
6.	Luiza Mehrabyan	Yerevan Medical Institute After Mehrabyan	Rector
7.	Donara Hakobyan	Yerevan N1 Medical College	Assistant Director (educational affairs)
8.	Marine Hayrapetyan	National Public Health Institute	Dean of Public Health Department
9.	Madlena Gevorgyan	“Erebuni” State Medical College	Assistant Director (educational affairs)
10.	Arthur Vardanyan	"Grigoris" Medical-Humanities College	Director

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Date: 08 December, 2008

Skills and Knowledge Needs Assessment For Pharmaceutical Industry

Report, Volume II

Skills and Knowledge Gap

Authored By: AM Partners Consulting Company

USAID FROM THE AMERICAN PEOPLE

CAPS

CONTENTS

EXECUTIVE SUMMARY

Introduction

The survey of employees of Armenian pharmaceutical enterprises has been conducted in the frame of the frame of "*Skills and Knowledge Needs Assessment*" among local pharmaceutical producers. In short, the purpose of the survey is the assessment of local employees' attitude towards the functions, job requirements, and skills and knowledge that are requested by advanced international producers for attracting specialists for their production. Within the survey, employees weighed the importance of each suggested function, requirement, skill and knowledge; they rank the level of application of those parameters at their enterprises; estimate their own skills and knowledge and uncover qualification improvement needs.

The survey of employees of pharmaceutical enterprises was carried out via the self-regulated survey. Respondents were distributed specially designed inquiry forms, filled them and delivered them to their direct supervisors for further elaboration. Direct supervisors commented on the responses of their subordinates and returned the filled-in inquiry forms to the consulting team.

The self-regulated survey of employees of pharmaceutical enterprises targeted employees of the abovementioned 15 key employment positions at local enterprises. Unfortunately, it was identified, that no enterprises meets the requirement of 15 key positions, and very few producers have even half of those positions. For clearer picture a table with companies and positions they have and they don't have is presented below.

Table 1 - Availability of positions and specialists at pharmaceutical enterprises

	Arpimed	Liqvor	Esculap	Yerevan CPF	Medical Horison	Vitamax - E	Bizon 1	Leyko Alex
Qualified person	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Head of Production	A	A	N/A	N/A	A	A	N/A	N/A
Head of quality control	A	A	A	A	N/A	A	N/A	N/A
Storage/warehouse person	A	A	A	A	A	A	N/A	N/A
Laboratory supervisor	A	A	A	N/A	N/A	A	N/A	N/A***
Head of technology/technologist	A	A	A	N/A	A	A	A	A
R&D specialist	N/A	N/A	N/A	N/A	N/A**	N/A	N/A	N/A
Quality control analyst, chemist	A	A	A	A	N/A	N/A	A	N/A
Microbiologist	A	A	N/A	A	N/A	A	N/A	N/A
Laboratory technician	A	A	N/A	A	A	N/A	N/A	N/A
Production operator	A	A	A	A	A	A	A	A
Packaging operator	A	A	A	A	A	A	A	A
Complaint and pharmacovigilence specialist	A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Registration specialist	A	A	N/A*	N/A	N/A	N/A	N/A	N/A
Marketing specialist	A	A	N/A	N/A	N/A*	N/A	N/A	N/A

A – Available (There is a position and it is engaged)
N/A – Not available (There is a position and it is not engaged)
NP – No position (There is no such a position)

* - Functions of the given position are carried out by specialized entity
** - Technologies are imported

*** - Functions are conducted out of the enterprise (sometimes even in abroad)

Survey tools and topics

Employees of pharmaceutical enterprises were suggested to answer the questions presented in the table below, and their direct supervisors have to confirm or reject those replies.

The questionnaire for interviewing the employees of pharmaceutical enterprises consisted of the following main sections:

a) Respondent's profile;
b) Importance of main duties and responsibilities;
c) Sufficiency of the education;
d) Importance of listed skills and knowledge;
e) Availability of listed skills and knowledge and improvement needs;
f) Importance of additional relevant requirements;
g) Practices of delegating responsibilities;
h) Acceptable training formats.

Main Findings and Conclusions

The survey of employees of local pharmaceutical producers uncovered a lot of important findings and provided good bases for making summarizing conclusions. 15 key positions were identified for further analysis. The survey of employees has been carried out among employees who engage those positions only. Respondents preferred to answer only those questions they found relevant for them, but still a lot of interesting findings were made. Here is a combination of more common and general conclusions that can be extracted from the analysis presented in further.

1. Only few local producers of pharmaceuticals are more or less staffed with the majority of specialists that present 15 key employment positions. More often duties and responsibilities of several positions are concentrated and tasked to the same employee. In fact, each employee at the key position coincides responsibilities of several specialists. There is one decisive reason for this: local producers are comparatively small. They produce narrow assortment and at relatively small volumes. In these circumstances they cannot afford themselves (sometimes also there is no need) to hire all mentioned specialists.

   Meantime, the situation may substantially change in case of rapid development of producers. They should be ready to attract or train specific specialists prior to the moment when they become absolutely necessary. From this point of view, assisting institutions (i.e. Association, technical assistance projects, etc.) may be very useful. They may create specialists database, organize centralized training, invite practical specialists for experience exchange, etc.

2. There is no certain regularity for delegating responsibilities to employees. Different companies practice different regularities starting from one week and ending with a year. Even more, various specialist of the same enterprise declared different regularities of discussing their functions with their supervisors. Regularity of discussing responsibilities with direct supervisors or top management varies from one week to one year. In some cases the delegation of responsibilities are made only once - at the moment of recruitment.

It can be concluded that local enterprises lack the culture of delegating responsibilities to their employees. In fact they don't pay much attention to this issue, maybe due to not comprehending the real importance of this function. Separate discussions may be organized with local producers for more detailed analysis of this issue, during which local producers may be introduced potential positive outputs of the regular delegation of duties of employees.

3. Respondents were presented duties and responsibilities selected for all 15 key positions that were picked up from the review of international best practice. They were suggested to rank the importance of those functions. Only very few functions were estimated to be not important, due to mainly subjective attitude of respondents towards specific skill or knowledge. This means that the best practice review has been carried out properly or depends on respondents not wanting to be seen as inqualified,

   The majority of estimates were distributed among the ranks of "*Very important*" and "*Important*". This is very positive finding: employees and their direct supervisors accept that presented functions, skills and knowledge are more or less important. Hopefully, they will not oppose to absorb some changes that may be applied in future and practice new functions.

4. Application of presented duties and responsibilities at local enterprises is partial. Almost half of functions regarding to narrow professional issues is currently practiced at local enterprises. Given the predicted development (that managers of pharmaceutical enterprises declared) the list of applied functions will be growing rapidly.

5. Direct supervisors of respondents agreed with their subordinates almost unanimously. Only few disagreements were observed throughout of the whole survey. There was an impression that supervisors did not want to argue with their subordinates.

   Outputs of the current assessment are going to be presented to the top management of pharmaceutical industry in Armenia. It may be useful to discuss with them the position of direct supervisors. Even more, in many cases those managers have played the role of those direct managers, and it would be useful to check their position once more.

6. Respondents were also presented the list of necessary skills and knowledge that were again collected from the international best practice. Respondents estimated the importance and availability of those skills and knowledge, as well as uncovered their need for improvements. Again respondents highly appreciate the importance of presented skills and knowledge. They made special emphasis on narrow professional skills, and did not pay much attention to personal skills, i.e. leadership, communication, team work, computer literacy, etc.

   In general, the position of employees is understandable: they are more interested in professional issues. Organizational, managerial and some "modern" themes (such as computers) may appear to be of secondary importance for them. Meantime, their attitude can be explained by conservatism; they don't want substantial changes, they may be "old style employees". Managers should pay attention to this issue, since modern organizational methods of business management allow to increase the productivity notably, and they have to try the application of those methods.

7. During the analysis respondents uncovered their needs for improving qualifications. Meantime, they were not able to select a training format that would be more or less convenient for the majority of respondents. This issue has to be discussed further with the management of local pharmaceutical enterprises in order to work out the most convenient type of training for each group of specialists.

SKILLS AND KNOWLEDGE GAP BY EMPLOYEES OF PHARMACEUTICAL ENTERPRISES

The Skills and Knowledge Gap Assessment has been implemented among the employees of 8 pharmaceutical enterprises in Armenia. The assessment has been conducted in a horizontal way: employees were divided into 15 key groups and analyzed separately. This separation was unavoidable since various groups of employees differ from each other by their responsibilities, functions they implement, required skills and knowledge etc. Distribution of respondents is presented in the table below.

Table 2 – Distribution of respondents by enterprises and key positions

Enterprise	Number of respondents														
	Marketing specialist	Complaint and pharmacovigilence specialist	R&D Specialist	Registration specialist	Storage/warehouse person	Production operator	Packaging operator	Head of production	Head of technology	Quality control analyst, chemist	Head of quality control	Laboratory supervisor	Microbiologist	Laboratory technician	T o t a l
Arpimed	1	1	1	1	1	2	2	1	1	1	1	1	1	1	**16**
Liqvor	1	1	1	1	1		1	1	1	1	1	1	1	1	**13**
Esculap					1	1	1	1	1	1	1	1			**8**
Yerevan CPF	1	1		1	1	2	2	1	1	1	1	1	1	1	**15**
Medical Horison				1	2	2	2	1	1	1		1	1	1	**13**
Vitamax - E		1		1	1	2	2	1	1		1	1	1		**12**
Bizon 1	1		1	1	1	1		1	1	1					**8**
Leyko Alex	1	1	1	1	1	2	2	1	1	1					**12**
Total	**5**	**5**	**4**	**7**	**9**	**12**	**12**	**8**	**8**	**7**	**5**	**6**	**5**	**4**	**97**

There is one important reservation, to be made before starting the analysis of polling results. Respondents sometimes rejected to provide answers/estimations to specific questions. That is not identified with negative answer, it is just a refuse to answer, or inability to answer. We preferred to leave the questionnaire as they are, and left some cells blank in our electronic database. That is why, in some cases the number of responses does not correspond to the number of respondents.

Below we start the analysis of the results of polling[1] of the employees of pharmaceutical enterprises on the theme of skills and knowledge gap.

[1] Self-regulated survey

QUALIFIED PERSON

According to the international best practice and GMP requirement each pharmaceutical enterprise must have the position for the *Qualified Person*. In fact, this specialist is a manager of the top range, and must ensure that each batch has been produced and tested/checked in accordance with the directives and the marketing authorization. Often the Qualified Person is the Head of Quality, but could also be the Head of Production. In fact the licensing of the whole enterprise is conducted after the name of these specialists. At the same time, this position is different from the director or the manager of the enterprise.

None of local producers of pharmaceuticals employ such specialist. The assessment accounted no respondent on this position, although all managers of pharmaceutical enterprises adopt the necessity of having such specialist.

HEAD OF QUALITY CONTROL

Respondents' profile

Only 5 enterprises out of 8 currently declared about implementing the responsibilities of the *Head of Quality Control*. Characteristics of respondents are presented in the table below. It should be mentioned, that all 5 enterprises are employing specialists who are conducting professional activities without coinciding the functions of quality control with other duties.

4 specialists out of 5 have relevant education. Only one of them has graduated the faculty of Radio physics at YSU, but this specialist further has participated a lot of training and certifications for completely meeting necessary requirements.

Table 3 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Responsible officer of the quality systematization division	Pharmaceutist	Internship	1
Liqvor	Quality control manager	Biophysics	Master	5-8
Esculap	Quality assurance specialist	Pharmaceutist – chemist	Candidate of science	1-3
Yerevan CPF	Deputy director on quality issues	Chemist	Bachelor	more than 8
Vitamax - E	Deputy director on quality issues	Radio physicist	Candidate of science	3-5

All respondents have sufficient scientific degrees for undertaking their responsibilities. The direct supervisors of respondents mentioned even lower requirements to scientific degrees. Professional working experience of heads of quality control at assessed enterprises is acceptable in general. Some enterprises are currently employing heads of quality control with professional experience of 1-2 years, which is not very sufficient, but it is much better than operating without any specialist. Leading enterprises, such as Liqvor and Vitamax - E are employing quite experienced specialists.

Duties and responsibilities

Duties and responsibilities have been drafted out on the basis of the international best practice. Local specialists of the quality control were asked to estimate the importance of specific operations as well as the application of those functions in practice.

Table 4 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties, responsibilities)				Practicing the functions	
	Very important	Important	Not so important	Unim-portant at all	Yes[2]	No
Approve or reject starting materials, packaging materials, and intermediate, bulk and finished products in relation to their specifications	3	1	0	0	3	2
Evaluate batch records	4	1	0	0	5	0
Ensure all necessary testing is carried out	3	1	0	0	3	2
Approve specifications, sampling instructions, test methods and other quality control procedures	3	2	0	0	4	1
Approve and monitor any contract analysts (if there are)	1	1	1	0	2	2
Check the maintenance of the department (lab), premises and equipment	3	1	0	0	3	0
Ensure that the appropriate validations, including those of analytical procedures, and calibrations of control equipment are carried out	3	1	0	0	3	1
Ensure that the required initial and continuing training of department personnel is carried out and adapted according to need	3	2	0	0	4	1
Manage activities of the Quality Testing Laboratories	2	1	0	0	2	2
Review of documentation for new product introduction, method validation, instrument validation and updating of testing standards, test methods, stability reports and SOPs	3	2	0	0	5	0
Liaising with QC, Technology, Production, Registration	2	3	0	0	5	0
Functions jointly exercised with the Head of Production; duties relating to quality. Authorization of written procedures and other documents	3	2	0	0	5	0

[2] Some of respondents simply rejected to answer the question: either they did not want to share internal information, or did not know the answer

Monitoring and control of the manufacturing environment	3	2	0	0	5	0
Plant hygiene	1	2	1	0	3	1
Process validation and calibration of analytical apparatus	3	2	0	0	4	1
Training including the application and principles of quality assurance	4	1	0	0	4	1
Approval and monitoring of suppliers of materials	1	2	0	0	3	1
Approval and monitoring of contract manufacturers (outsourcing) (if there is)	1	1	1	0	1	3
Designation and monitoring of storage conditions for materials and products	5	0	0	0	5	0
Performance and evaluation of in-process controls	4	1	0	0	5	0
Retention of records	3	2	0	0	5	0
Monitoring of compliance with the requirements of GMP	4	1	0	0	5	0
Inspection, investigation, and taking of samples, in order to monitor factors which may affect product quality	4	0	1	0	4	1
Development of the GMP documents' forms	1	0	0	0	1	0
Participation in all discussions on production processes	0	1	0	0	0	1

Almost all functions suggested from the international best practice were estimated by Heads of Quality Control of local enterprises as either "*Very important*" or "*Important*". This means that presented functions are completely accepted and evaluated by local specialists and may be applied in future, if they are not practiced currently. There is a strong correlation between importance of certain functions and implementation of those functions: those functions that are very important or important for respondents are currently practiced. Direct supervisors share the opinion of respondents – only in case of three functions presented in the table they disagree with estimates of respondents.

Skills and knowledge

Heads of quality control of 5 pharmaceutical enterprises declared that their education is sufficient enough for conducting functions presented in the previous section. Assessment of the international best practice has resulted in specific skills and knowledge that are necessary for conducting abovementioned duties and responsibilities. Employees of local pharmaceutical enterprises expressed their attitude towards those skills and knowledge in following way.

Table 5 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
Strong knowledge of Armenian pharmaceutical legislation and regulation (Medicines Law, Licensing Law, etc.) GMP,	4	1	0	0

Environmental and other regulatory compliance requirements				
Knowledge of GLP, GMP and Safety procedures	4	1	0	0
Knowledge of instrument and method validation	4	1	0	0
Ability or aptitude for continuous learning and analytical problem solving	4	1	0	0
Ability to manage multiple tasks simultaneously	1	4	0	0
Strong computer skills	3	2	0	0
Good verbal and written communication skills	1	4	0	0
Ability to work in a team environment	3	2	0	0

Skills and knowledge requirements that were picked up from the international best practice were estimated by local specialists only as "*Very important*" or "*Important*". GMP related skills and knowledge are again in a strong demand. This statement is confirmed by the respondents' direct supervisors, with a slight difference in estimation of the importance.

Respondents estimated their needs for improvement of skills and knowledge, too.

Table 6 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
Strong knowledge of Armenian pharmaceutical legislation and regulation (Medicines Law, Licensing Law, etc.) GMP, Environmental and other regulatory compliance requirements	0	2	3	0	5	0
Knowledge of GLP, GMP and Safety procedures	0	4	1	0	5	0
Knowledge of instrument and method validation	0	1	4	0	5	0
Ability or aptitude for continuous learning and analytical problem solving	1	4	0	0	1	4
Ability to manage multiple tasks simultaneously	0	4	1	0	1	4
Strong computer skills	1	2	2	0	1	3
Good verbal and written communication skills	0	5	0	0	1	4
Ability to work in a team environment	0	5	0	0	2	3

Almost all respondents noted that they have sufficient skills and knowledge for conducting their responsibilities. However, they think there is a place for improving those skills and knowledge, although that need is not declared to be urgent. Another interesting observation has been made – respondents do not need to improve more general skills, such as communication, computer literacy, team work, etc. Supervisors again confirmed the estimations of their employees. Only in 4 cases out of 64 they sharply disagree with their subordinates.

Almost all assessed pharmaceutical enterprises are practicing regular delegation of responsibilities. In some enterprises the regularity is declared to be once a quarter or month, in others – once a week. Meantime, some respondents declared nothing about the delegation of their responsibilities. They were informed about their duties on the moment of recruitment, and then receive some instructions as the need arises.

Relevant requirements

Aside from the responsibilities and duties, as well as the required skills and knowledge for conducting those responsibilities, employees usually are expected to meet additional relevant requirements. Those requirements usually refer to the experience and educational background. Respondents have been asked about some of additional requirements, and their responses are combined in the table below.

Table 7 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
University or College degree or diploma in a science related subject	2	2	1	0	3	0
Minimum University degree in Chemistry with 8+ years in analytical and microbiological pharmaceutical experience	2	0	1	0	2	0
Ph.D. in Chemistry with 4+ years of analytical and microbiological, pharmaceutical experience	1	1	1	0	2	0
Experience in a pharma lab with experience in analytical methods& instrumentation	2	2	0	0	3	0
Experience in GMP and SOPs	1	0	0	0	1	0

The most interesting from the analysis of the table, is the availability of the practice. Presented requirements are of importance for respondents and some of their enterprises do practice those requirements.

Organization of training

As it was illustrated in the analysis above, respondents declared their need for improving skills and knowledge that are necessary for conducting their duties and responsibilities. The best way of improving skills and knowledge are the training. Respondents were not able to select a format for trainings that is convenient for their majority.

Table 8 – Preferred formats for training

Training format	Convenient	Not convenient
Half a day	0	5
One full day	1	4
Several (2-3) days	1	4

One week	1	4
More than one week	0	5
Regular	2	3

HEAD OF PRODUCTION

Respondents' profile

All assessed pharmaceutical enterprises have special positions at the structure of their company that are responsible for the production process. Usually, these positions are hold by top managers, who organize and control the operation of whole enterprise. The profile of respondents that are responsible for production is presented in the table below.

Table 9 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Head of production	Chemist	Master	3 - 5
Liqvor	Production deputy director	Biochemist	Master	more than 8
Esculap	Deputy director	Builder – constructor	Bachelor	more than 8
Yerevan CPF	General engineer	Chemist	Candidate of science	more than 8
Medical-Horison	Production director	Pharmaceutist	Internship	1 – 3
Vitamax - E	Head of production	Coach - pedagogue	Master	5 -8
Bizon – 1	Director	Physicist	Candidate of science	more than 8
Leiko-Alex	Director	Economist	Master	5 - 8

Heads of production of the assessed pharmaceutical enterprises are not necessarily chemists or pharmaceutists. We can see from the table, that even specialists of quite different profession may handle duties of the Head of production. Almost all respondents have scientific degrees of master or candidate of science. This is important, since the higher the education the better skills of management specialists possess.

Professional experience at the current position is another important characteristic, necessary for effective management of the production process. We can see from the table that the majority of respondents have been engaging their positions for quite a long time.

Duties and responsibilities

The list of duties and responsibilities of the Head of production is one of the longest ones. This is legitimate, since the managers of this position controls the work of almost all units of the enterprise and closely cooperate with Quality Control divisions. International best practice suggest the following main functions for these specialists, and local employees are referring to those functions like follows in the table below.

Table 10 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties, responsibilities)				Practicing the functions	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Ensure that products are produced and stored according to the appropriate documentation	5	3	0	0	7	1
Establish guidelines for continuous risk reduction	3	5	0	0	7	1
Day to day management of the production floor	5	3	0	0	8	0
Approve the instructions relating to production operations and to ensure their strict implementation	3	5	0	0	7	1
Assures continuous improvement of production processes	3	5	0	0	8	0
Ensure that the production records are evaluated and signed by designed person before they are sent to the QC Department	6	1	1	0	7	1
Check the maintenance of the department, premises and equipment	5	3	0	0	8	0
Ensure that the appropriate process validations and calibrations of control equipment are performed and recorded and the reports made available	4	2	2	0	6	2
Ensure that the required initial and continuing training of production personnel is carried out and adapted according to need	1	6	1	0	6	2
Responsible for safety, regulatory and/or environmental compliance	4	4	0	0	7	1
Strong support linkage with the following departments: ▪ Systems - maintaining/upgrading manufacturing computer systems and network interfaces	0	5	3	0	3	5
▪ Plant Engineering - assisting with the design and commissioning of new equipment or equipment modifications to provide for new product introductions and continuous improvement activities	2	6	0	0	7	1
▪ Validation/Tech Support - in facilitating plant trials, new product activities and validation of existing and new procedures, equipment and computer systems	3	5	0	0	5	2
▪ Conducts training for new technologies,	0	7	1	0	1	6

new products and new associate processes						
Functions jointly exercised with the Head of Quality; duties relating to quality. Authorization of written procedures and other documents	4	4	0	0	8	0
Monitoring and control of the manufacturing environment	5	3	0	0	7	1
Plant hygiene	4	4	0	0	8	0
Process validation and calibration of analytical apparatus	3	5	0	0	7	1
Training including the application and principles of quality assurance	1	7	0	0	5	3
Approval and monitoring of suppliers of materials	3	5	0	0	4	4
Approval and monitoring of contract manufacturers (outsourcing) (if there is)	1	3	1	0	3	3
Designation and monitoring of storage conditions for materials and products	5	3	0	0	8	0
Performance and evaluation of in-process controls	2	5	1	0	5	2
Retention of records	4	3	1	0	3	3
Monitoring of compliance with the requirements of GMP	4	3	1	0	5	1
Conduct monthly planning and control the timely implementation of those plans	1	0	0	0	1	0

It is very promising that functions picked up from the successful international experience are adopted by local specialists in a quite responsive manner. Almost all functions have been marked as "Very *important*" or "*Important*". Real exceptions are the function of "*maintaining / upgrading manufacturing computer systems and network interfaces",* and also "*training for new technologies, new products and new associate processes*".

The objectivity of respondents' answers is proven by answers to the question about practicing presented functions. In many cases, those duties and responsibilities are already assigned to Heads of production in almost all enterprises. Again we have some functions that are not applied and will not be in near future. There are several reasons for that: adopted working style, local specificities, absence of some operational units at specific enterprises, etc.

Skills and knowledge

Requirements to the skills and knowledge for the specialists that engage positions of Heads of production are somewhat higher and can be compared with requirements that other top managers face. At the same time, the long list of skills and knowledge is not as important. The level of possessing those skills and knowledge by employees is more important. The combined picture is presented in the table below.

Table 11 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
Strong knowledge of Armenian pharmaceutical legislation and regulation (Medicines Law, Licensing Law, etc.) GMP, Environmental and other regulatory compliance requirements.	4	4	0	0
Good working knowledge of formulations and various process technologies.	4	4	0	0
Strong knowledge of all manufacturing operations, equipment, and SOP's.	2	6	0	0
Ability in providing proper solutions to problems that arise outside of normal procedures and to systems related issues.	3	5	0	0
Capable of adapting and managing in different technologies.	2	4	2	0
Ability to provide effective leadership to employees in manufacturing, engineering and operations.	3	3	1	0
Ability to interact with senior executives, senior technical managers, business heads, customers, and suppliers within and external to company.	2	4	2	0
Ability to pursue and manage process optimization.	2	4	2	0
Ability to coach, counsel, manage and direct personnel in appropriate division/business unit assignments.	2	4	2	0
Ability to interact and negotiate with regulatory agencies on routine compliance issues.	1	4	3	0
Ability to manage multiple tasks simultaneously	3	4	1	0
Strong computer skills	1	5	2	0
Good verbal and written communication skills	0	8	0	0
Ability to work in a team environment	4	4	0	0

As before, respondents again evaluate the importance of presented skills and knowledge. They gave the estimation of "*Not so important*" only in less than 15% of cases. The skills and knowledge related to GMP issues and production technologies are estimated to be of the most importance. The majority of the answers of respondents are confirmed by direct supervisors of respondents.

The level of possessing, as well as needs of local specialist for improving specific skills and knowledge, is presented in the following table.

Table 12 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
Strong knowledge of Armenian pharmaceutical legislation and regulation (Medicines Law, Licensing Law, etc.) GMP, Environmental and other regulatory compliance requirements.	1	4	2	2	6	0
Good working knowledge of formulations and	4	2	2	0	7	1

various process technologies.						
Strong knowledge of all manufacturing operations, equipment, and SOP's.	4	2	2	0	6	2
Ability in providing proper solutions to problems that arise outside of normal procedures and to systems related issues.	2	3	2	0	6	2
Capable of adapting and managing in different technologies.	3	3	1	0	7	1
Ability to provide effective leadership to employees in manufacturing, engineering and operations.	2	3	3	0	6	2
Ability to interact with senior executives, senior technical managers, business heads, customers, and suppliers within and external to company.	4	3	1	0	4	4
Ability to pursue and manage process optimization.	1	6	1	0	6	2
Ability to coach, counsel, manage and direct personnel in appropriate division/business unit assignments.	2	4	1	0	4	4
Ability to interact and negotiate with regulatory agencies on routine compliance issues.	1	3	3	0	4	4
Ability to manage multiple tasks simultaneously	3	3	2	0	3	5
Strong computer skills	3	2	2	1	4	3
Good verbal and written communication skills	2	5	1	1	3	4
Ability to work in a team environment	3	4	1	1	3	4

It can be concluded from the table that in general respondents are more or less self-confident. They really think that they possess almost all skills and knowledge necessary to fulfill their responsibilities. At the same time they tend to improve those characteristics, although they are not very eager to do that. In some cases, mainly non-related to professional issues, they even note that they need no improvements

In order to utilize skills and knowledge and successfully implement professional responsibilities employees must be well aware of those responsibilities. The assessment uncovered very interesting findings here. At first, respondents from 3 enterprises out of 8 did not answer at all. In other cases regularity of delegation of responsibilities vary from a week to a year. There is an impression that this practice is not conducted normally. Only during the recruitment it is conducted properly.

Relevant requirements

Additional requirements for the Heads of Production picked up from the international best practice are illustrated at the table below.

Table 13 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
PharmD 4-8+ years experience	2	1	4	1	2	4
PhD 2-6+ years experience	1	1	4	2	4	2
Experience in supervisory position	4	4	0	0	5	1
Pharmaceutical industry background in operations	1	5	1	1	5	1
Extensive experience in appropriate manufacturing processes	1	4	3	0	6	0
Flexibility to work overtime and some weekends	1	7	0	0	5	1
Ability to make well-based and fast decisions	1	0	0	0	1	0
Cooperation with similar production	2	0	0	0	1	0

Local specialists expressed a balanced attitude to presented requirements. In most cases they think that certain requirements are simply important. They are less exacting to the education, experience and scientific degrees, but require more flexibility and responsiveness at work. Respondents confirm their attitude to additional relevant requirements with practice.

Organization of training

The attitude of respondents to training is continuing to be somewhat problematic.

Table 14 – Preferred formats for training

Training format	Convenient	Not convenient
Half a day	1	7
One full day	3	5
Several (2-3) days	1	7
One week	2	6
More than one week	2	6
Regular	3	5

For various respondents formats of trainings significantly differ and this is going to cause problems in the process of organizing trainings.
Anyhow, this topic should be necessarily addressed in future, in order to conduct proper interventions.

HEAD OF TECHNOLOGY

Respondents' profile

Almost all assessed pharmaceutical enterprises have special positions of the Head of technology. This person is generally responsible for the smooth operation of the production facilities. The Head of

technology usually works under the strict control of the Head of production and Head of quality. The table below illustrates the profile of employees of local pharmaceutical enterprises that are responsible for the implementation of duties of the Head of technology.

Table 15 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Pharmaceutist	Pharmaceutist	Internship	3 - 5
Liqvor	Engineer	Radio technology engineer	Secondary vocational	3 – 5
Esculap	Technologist	Pharmaceutist	Master	1 - 3
Yerevan CPF	Head of workshop	Biochemist	Master	more than 8
Medical-Horison	Head of technical re-equipment division	Mechanic	Secondary vocational	1
Vitamax - E	General technologist	Engineer-mechanic	Master	5 – 8
Bizon – 1	Technologist	Chemist	Master	5 – 8
Leiko-Alex	Head of technical control	Organic chemist	Candidate of science	1

The profession of the majority of the respondents closely relates to chemistry and mechanic/engineering. At the same time, Head of technology operate the technological and technical part of facilities and must have some understanding and knowledge of engineering. In general, the profession of all respondents corresponds to their position.

The column of the scientific achievements illustrates a wide variety of degrees. One of the best pharmaceutical producers in Armenia – Liqvor, is employing a specialist with secondary vocational education, and this specialist is working for the enterprise for almost 5 years. This means that the education is not the first and most important criterion for getting employed.

Duties and responsibilities

As it was mentioned above duties and responsibilities of the Head of the technology mainly refer to technological processes and equipment, although these specialists also have some duties if contacting / cooperating with colleagues from other divisions and external counterparts, such as regulatory authorities. Duties and responsibilities of the Head of production, collected from the international best practice are presented in the table below.

Table 16 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties, responsibilities)				Practicing the functions	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Perform work in accordance with SOPs, GMPs and established safety procedures	5	3	0	0	8	0
Develop strategy, evaluation and selection of technology considering all needs	1	6	0	1	5	3

Responsible for evaluation, pilot/vendor testing and selection of process equipment, as well as associated clean utilities	2	3	3	0	6	2
Complete process engineering design	0	5	0	2	4	4
Set process engineering technical standards and standard practices	3	4	1	0	6	2
Development and maintain process descriptions, process block flow diagrams, specifications, and other process/equipment documents for engineering, design, operations and regulatory filings	1	5	1	1	4	4
Primary contact for process engineering and technology issues/questions of Regulatory Agencies	1	3	3	1	2	6
Responsible for continuous process improvement for highest efficiency	0	8	0	0	6	2
Integrate and contribute to cross-functional design, product and project teams	2	6	0	0	7	1

The proposed list of functions is not very long and almost all items of that list are quite to the point. Respondents find very few functions to be "*Unimportant at all*". Such functions as GMP related issues, cross functional design, strategy development, etc., are the most important ones for local employees. The same functions are widely practiced at local enterprises. Direct supervisors of respondents share this opinion with slight deviations.

There is no clear system of delegation of responsibilities at local pharmaceutical enterprises. Some employees are instructed weekly, others – once a year. There are specialists that were introduced their responsibilities only at the moment of recruitment. It is very difficult to make judgments on this topic: necessity of delegation of responsibilities is more internal task for the enterprise and cannot be criticized from aside without strong basis for that.

Skills and knowledge

The picture is adequate with required skills and knowledge. Local employees find the international best practice to be relevant to their needs. See the list of skills and knowledge, which has to be evaluated by respondents in the table below.

Table 17 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
Good knowledge of GMP regulatory requirements	5	3	0	0
Good knowledge, experience in novel, emerging and disposable process technology	3	5	0	0
Ability to manage multiple tasks simultaneously	1	6	1	0
Strong computer skills	1	3	4	0
Good verbal and written communication skills	1	6	1	0
Ability to work in a team environment	2	6	0	0

We would like to make special emphasis only on the computer skills. Half of the respondents don't think this skill is so important. The majority of direct supervisors share this opinion. This is probably because the equipment in some facilities pre-dates the computer era and has mainly mechanical control[3].

The attitude of employees towards the computer literacy is explainable. As it is shown in the table below, their majority lack this skill and need to improve it.

Table 18 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
Good knowledge of GMP regulatory requirements	0	6	2	2	5	1
Good knowledge, experience in novel, emerging and disposable process technology	0	4	4	1	6	1
Ability to manage multiple tasks simultaneously	0	5	3	0	5	3
Strong computer skills	0	2	5	1	7	0
Good verbal and written communication skills	0	7	1	0	3	5
Ability to work in a team environment	0	7	1	0	4	4

Respondents noted also other skills they would like to improve, such as GMP requirements, novel, emerging and disposable process technology, etc.

Relevant requirements

Aside from the specific group of the skills and knowledge, there are some additional requirements that are necessary for undertaking abovementioned duties for Heads of technology. Those requirements are presented at the table below.

Table 19 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
BS/MS or PHD in Chemical Engineering/PharmD	1	3	4	0	2	4
Experience in process engineering, manufacturing, trouble shooting, root cause analysis	0	5	3	0	3	3
Experience in discussion and inspections with Regulatory Agencies	1	4	3	0	2	4

[3] Comment of reviewers

Opinions of respondents are quite ambiguous regarding to requirements of education and experience. The same picture can be observed at the column illustrating the local practices. Again opinions are divided, and the main reason for that are current adopted practices, that are notably different from the international practice.

Organization of training

Heads of Technology also face difficulties in selecting convenient training format. The most convenient version is 1-week maturity, although it is acceptable for only half of the respondents.

Table 20 – Preferred formats for training

Training format	Convenient	Not convenient
Half a day	2	6
One full day	1	7
Several (2-3) days	3	5
One week	4	4
More than one week	1	7
Regular	2	5

Anyhow, trainings are the best way for the improvement of respondents' qualifications, and additional discussions should be organized for working-out the most convenient format of trainings.

LABORATORY SUPERVISOR

Respondents' profile

6 out of 8 assessed enterprises are employing Laboratory Supervisors. The name of the position is self-explanatory; these specialists are responsible for the smooth and effective operation of the laboratory. The profile of respondents is presented in the table below.

Table 21 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Head of Quality Control laboratory	Chemist	Master	5 - 8
Liqvor	Head of Quality Control laboratory	Engineer, chemist, technologist	Master	3 - 5
Esculap	Head of laboratory	Dispensing chemist, pharmaceutist	Bachelor	3 - 5
Yerevan CPF	Deputy Quality Director	Chemist	Master	5 - 8
Medical-Horison	Head of Quality Control division	Bio-physicist	Candidate of science	3 - 5
Vitamax - E	General specialist	Organic chemist	Candidate of science	5 - 8

In almost all assessed enterprises special specialists are employed for the laboratory supervision. In some enterprises these functions are coincided with functions of the Head of Quality Control. All respondents are narrow specialists by their background and profession. Respondents were asked about their education and the sufficiency of it. All respondents replied that their education is completely sufficient for meeting their professional requirements.

Almost all respondents have received higher education. Scientific degrees are paralleled with quite long professional experience. This experience varies from 5 years to longer maturity.

Duties and responsibilities

Duties and responsibilities of Laboratory Supervisors may be defined in a comprehensive manner as assurance of the smooth and effective work of the laboratory and related issues, such as GMP, documentation keeping, validation and calibration processes, equipment maintenance, etc. More detailed list of functions is presented in the table below.

Table 22 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties, responsibilities)				Practicing the functions	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Conducting tests and/or assaying of raw material, intermediates or finished products	6	0	0	0	5	1
Analysis of finished product, in-process, stability and validation samples	5	1	0	0	5	1
Supervision of employees performing testing and support activities	3	3	0	0	5	1
Evaluating data generated and recommend acceptance or rejection of samples, and performing lab work accurately and timely	6	0	0	0	6	0
Maintaining records, developing productivity improvement plans, maintaining adequate inventory of supplies, training records	0	6	0	0	2	4
Assure that the laboratories are in compliance with GMP; that the products and materials are tested as specified in the specifications and methodologies	4	2	0	0	6	0
Maintaining adequate instrumentation and laboratory facilities	1	4	1	0	4	2
Maintaining a safe working environment	3	2	1	0	5	1
Maintaining an awareness of technical developments in instrumentation analysis	0	5	1	0	3	3
Ensuring that equipment and services are kept in a safe condition	3	2	1	0	5	1
Approval of all work generated by analysts.	3	1	1	1	3	3

Approval of validation and calibration reports						
Updating SOPs, Process Specific Training Modules, Control procedures, etc	1	3	1	1	3	3
Training of the personnel	2	4	0	0	5	1
Control of laboratory investigation within the laboratory	4	1	1	0	4	2
Control of purchasing of laboratory equipment	1	4	1	0	2	4
Assists in internal and external audits	0	6	0	0	1	5

List of functions, i.e. duties and responsibilities, are designed based on the international best practice and successful experience of foreign producers. In overwhelming majority of cases the examples of the best practice were evaluated by local specialists. They marked the importance of listed functions as "*Very important*" and "*Important*". Respondents not only think that those functions are important but also confirm that position in practice. The majority of those functions are currently applied in local enterprises. There are some exceptions (such as assistance to audits, record maintenance, productivity improvement, control on purchases, etc.), but more generally the listed duties and responsibilities are practiced in Armenian enterprises. Direct supervisors of almost all assessed enterprises agreed with answers of their subordinates.

The presentation of duties and responsibilities in Armenian enterprises are conducted in a different manner. In case of Laboratory Supervisors the responsibilities are revised and renewed relatively often – once a week or once a month. But these modifications are usually made in orally, without any documentation.

Skills and knowledge

Proper implementation of the above mentioned duties and responsibilities requires the availability of certain skills and knowledge. In their majority those skills and knowledge are received from the basic and higher education, than confirmed by practical experience. All respondents are quite satisfied with their education; skills and knowledge gained via that education allows them to meet almost all requirements. The list of skills and knowledge, necessary for the implementation of duties of laboratory supervisor, is presented below.

Table 23 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
Strong knowledge of Armenian pharmaceutical legislation and regulation (Medicines Law, Licensing Law, etc.), Environmental and other regulatory compliance requirements	0	5	1	0
Knowledge of GLP, GMP and Safety procedures	4	2	0	0
Knowledge of instrument and method validation	3	3	0	0
Good interpersonal and supervisory skills	2	3	1	0
Ability or aptitude for continuous learning and problem solving	4	2	0	0
Ability to manage multiple tasks simultaneously	2	4	0	0
Strong computer skills	1	4	1	0

Good verbal and written communication skills	1	5	0	0
Ability to work in a team environment	3	2	1	0

Almost all presented skills and knowledge were estimated to be more or less important. Respondents especially emphasize the importance of GMP and GLP knowledge and sourcing skills, and the ability to improve the professional qualifications.

Estimation of their level of possession of specific skills and knowledge by employees of pharmaceutical enterprises aims to identify the real need for improving specific skills and knowledge, which are essential for conducting their responsibilities. The snapshot to the results of the combined analysis is presented below.

Table 24 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
Strong knowledge of Armenian pharmaceutical legislation and regulation (Medicines Law, Licensing Law, etc.), Environmental and other regulatory compliance requirements	0	4	2	0	4	2
Knowledge of GLP, GMP and Safety procedures	1	5	0	0	5	1
Knowledge of instrument and method validation	0	5	1	0	5	1
Good interpersonal and supervisory skills	2	4	0	0	0	6
Ability or aptitude for continuous learning and problem solving	3	3	0	0	2	4
Ability to manage multiple tasks simultaneously	1	4	1	0	1	5
Strong computer skills	0	3	3	0	5	1
Good verbal and written communication skills	2	3	1	0	0	6
Ability to work in a team environment	2	3	1	0	3	3

Again the respondents express demand for improving GMP and GLP knowledge, and other narrow professional skills, such as validation and computer literacy. Respondents expressed no need for improving their qualifications in interpersonal and supervisory relations, communication, and for solving multiple tasks simultaneously. Again the analysis of answers of direct supervisors of respondents shows that they agree with their subordinates almost completely.

Relevant requirements

In order to fit the position of the Laboratory Supervisor, and effectively conduct their responsibilities, employees of successful international pharmaceutical producers are essential to meet the following relevant requirements aside from the first bunch of skills and knowledge.

Table 25 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
University or College degree or diploma from a recognized institution in a science related subject	3	3	0	0	5	1
Minimum University degree in Chemistry with 8+ years in analytical and microbiological pharmaceutical experience	1	5	0	0	5	1
Ph.D. in Chemistry with 4+ years of analytical and microbiological pharmaceutical experience	0	3	2	1	4	2
Experience in a pharma lab with experience in analytical methods& instrumentation	4	2	0	0	6	0

As it can be seen from the table, respondents agree with international best practice referring to the additional requirements, i.e. education and experience. Only one respondent named the requirement "*Unimportant at all*". The position of respondents is confirmed by the practical application, too. Besides that, direct supervisors also agree with respondents with slight deviations.

Organization of training

Laboratory Supervisors also did not select commonly convenient format for trainings. Their responses distributed quite evenly.

Table 26 – Preferred formats for training

Training format	Convenient	Not convenient
Half a day	2	4
One full day	2	4
Several (2-3) days	0	6
One week	2	4
More than one week	1	5
Regular	1	4

REGISTRATION SPECIALIST

Respondents' profile

In assessed enterprises the responsibilities of the pharmaceuticals' Registration Specialist is conducted by various specialists who coincide those functions with their main duties. Only 3 out of 8 assessed enterprises employ specialists for registration purposes.

Table 27 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Registration division specialist	Pharmaceutist	Internship	more than 8
Liqvor	Head of registration division	Dispensing pharmaceutist	Master	3 – 5
Yerevan CPF	General engineer	Chemist	Candidate of science	more than 8
Medical-Horison	Deputy director	Pharmaceutist	Ordinator	more than 8
Vitamax - E	Medical representative	Physician radiologist	Ordinator	1 – 3
Bizon-1	Director	Physicist	Candidate of science	more than 8
Leiko-Alex	Director	Economist	Master	5 - 8

The majority of assessed pharmaceutical enterprises employ specialists with relevant profession for conducting registration functions. 2 enterprises are exceptional, where directors are implementing duties of registration specialists. We think that this will not last for a long time, and special employees will be attracted for those purposes.

All respondents have graduated high schools and were (will soon be) granted scientific degrees. The levels of those degrees are completely suitable to requirements. All respondents tell that their education is completely sufficient for conducting their professional tasks. What has not been via the education, was achieved by experience. Almost all respondents have quite a long experience with working at their current positions.

Duties and responsibilities

Duties and responsibilities of Registration Specialists are added up to coordination of the cooperation with regulatory authorities and monitoring of changes and modifications at the regulatory environment.

Table 28 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties, responsibilities)				Practicing the functions	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Facilitation of the regulatory aspects of projects/products, including documentation submitted to regulatory agencies and regulatory agency interactions.	6	1	0	0	4	0
Assurance that the documentation is complete and complies with applicable regulatory requirements	5	2	0	0	4	0
Assessment of documents incoming from	5	2	0	0	4	0

regulatory agencies						
Reviewing of documentation from other internal departments	4	3	0	0	4	0
Provides consultations regarding to required regulatory documents to other internal departments	1	6	0	0	3	1
Contribution to analyses of regulatory guidance documents, regulations, that impact Company products and operations	3	4	0	0	3	1
Analysis and advice to the business on existing and new regulatory requirements that may impact the development process and emerging trends. Balance ideas and practices against regulatory risks	3	4	0	0	4	0
Coordination of regulatory inspections and audits	1	6	0	0	3	1

The analysis of respondents' answers are quite impressive, they completely realize the importance of functions, listed in the table above, which illustrates the importance of each responsibility for Registration specialists. Respondents give only answers "Very important" and "Important". Moreover, their majority also practice those functions at their enterprises. Direct supervisors of respondents verified answers of their subordinates.

The majority of respondents told that they are told about their responsibilities either once a week, or once a month the latest. This means that local producers try to keep strong control and direct their employees as strict as possible. Meantime, some respondents were delegated their duties only once, at the moment of employment.

Skills and knowledge

Skills and knowledge required for the implementation of the responsibilities of the Registration Specialist are presented in the table below. They were picked up from the international best practice.

Table 29 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
Strong knowledge of regulatory requirements for Armenia and other countries (where company plan to export), including registration procedures	5	2	0	0
Strong knowledge of international guidelines	4	3	0	0
Demonstrated ability to evaluate, interpret and apply regulatory compliance requirements/guidelines to complex situations	3	4	0	0
Ability to manage multiple tasks simultaneously	2	4	1	0
Strong computer skills	1	6	0	0
Good verbal and written communication skills	1	6	0	0
Ability to work in a team environment	3	3	1	0

The rate of appreciation of mentioned skills and knowledge is again very high. Respondents have made special influence on such skills as knowledge of regulatory framework and international guidelines. Personal skills have received the lowest importance. Direct supervisors confirmed the opinion of their subordinates, although there were some slight deviation of the proportion of answers "*Very important*" and "*Important*".

Respondents have also estimated the level of their knowledge and uncovered their needs for improving specific qualifications.

Table 30 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
Strong knowledge of regulatory requirements for Armenia and other countries (where company plan to export), including registration procedures	2	2	2	3	4	0
Strong knowledge of international guidelines	1	1	3	1	6	0
Demonstrated ability to evaluate, interpret and apply regulatory compliance requirements/guidelines to complex situations	0	4	2	0	7	0
Ability to manage multiple tasks simultaneously	2	2	2	0	4	3
Strong computer skills	0	5	2	0	5	2
Good verbal and written communication skills	1	4	2	0	3	4
Ability to work in a team environment	3	2	2	0	4	3

This time respondents were quite modest. Their majority marked their skills and knowledge to be "*Good*" and expressed need for improvement of qualifications. Knowledge of regulatory issues is prioritized by respondents and they think that improvements are needed urgently. Not all supervisors of respondents agreed with their estimations and required urgency for improvements. Disagreements are especially valid at the latter case.

Relevant requirements

In parallel to skills and knowledge additional requirements that are relevant to the position of Registration specialists are to be met by them. The list of those relevant requirements is presented in the table below.

Table 31 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Bachelor Degree in Pharmacy, Chemistry,	5	2	0	0	3	1

Pharmacology or related subject						
3+ years experience in the registration and re-registration of pharmaceutical products in international markets	3	2	1	0	3	1

The situation with other relevant requirements is self-explanatory. Both requirements are considered to be of importance. Meantime, only 3 out of 8 assessed enterprises noted that they practice those requirements. Supervisors answered in a same way. We hope that those respondents who agreed with the importance of those requirements will try to apply them in their enterprises.

Organization of training

Selection of training format is again difficult.

Table 32 – Preferred formats for training

Training format	Convenient	Not convenient
Half a day	1	6
One full day	3	4
Several (2-3) days	2	5
One week	2	5
More than one week	0	7
Regular	2	5

The best opportunity is 1-daytraining which is convenient for only 3 enterprises out of assessed 8 ones.

PRODUCTION OPERATOR

Respondents' profile

Production Operators are directly engaged in the production (synthesis) of various pharmaceuticals. This is one of the key positions, although requirements to the employees engaging these positions are not too high in comparison with the management staff. The list of respondents from the assessed enterprises is presented below.

Table 33 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Operator	Dispensing Pharmaceutist	Internship	1
Arpimed	Operator Pharmaceutist	Dispensing Pharmaceutist	Internship	1
Esculap	Staff and process manager of the packaging division	Accoucheur (Nurse)	Secondary vocational	3 – 5
Yerevan CPF	Technologist	Agro - chemist	Master	5 - 8

Yerevan CPF	Master	Commodity expert	Secondary vocational	more than 8
Medical-Horison	Production operator	Pianist	Secondary vocational	1
Medical-Horison	Production operator	N/A	N/A	1
Vitamax-E	Production operator	N/A	N/A	1 - 3
Vitamax-E	Production operator	Tourism manager	Master	1 - 3
Bizon-1	Production operator	Chemist	Master	more than 8
Leiko-Alex	Cutter and cleaner	N/A	N/A	1
Leiko-Alex	Accountant	Economist	Bachelor	1

All pharmaceutical enterprises do employ Production Operators. It is almost impossible to coincide effectively functions of the Production Operator with other duties at normal enterprises. There are varieties of the position of the Producing Operator depending on the type of manufactured pharmaceutical, i.e. tablets, liquids, or ointments.

As we can see from the table, no special educational background is needed for undertaking the responsibilities of the Production Operator for the majority of local producers[4]. This can be explained by the technical nature of the work the Production Operator does. That is why; even employees with secondary (not vocational) education are able to works at this position. Similarly, working experience is not of great importance, too. Usually, it takes a couple of months to train a newcomer to be a professional operator.

Direct supervisors of interviewed employees complain that they have to change those operators quite often. At the moment of employment, these operators are not asking for high wages since they have no education and qualifications. In a couple of months, they gain some skills and professionalism and start requesting higher remuneration. In many cases, the enterprises cannot afford themselves to pay such remuneration and they lose their already qualified employees.

Duties and responsibilities

Although we mentioned that function of the Production Operators are somewhat technical, their implementation requires some personal features to be available. Duties and responsibilities of these employees are quite various (starting from working in accordance with GMP standards and ending up with cleaning of facilities) and contains a lot of routine work. The list of duties and responsibilities is presented in the table below.

Table 34 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties, responsibilities)				Practicing the functions	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
To work as part of a team performing the pharmaceutical production as defined by GMP, SOPs and safety procedures	9	3	0	0	11	1

[4] Meantime, if it is required to do a synthesis of various pharmaceuticals, there *must* be a person with strong chemical background.

Perform duties of operating assigned machinery consisting of servicing machines with materials, removing finished materials from machine	8	3	0	1	11	1
Report any deviations from standards to team leader promptly	9	3	0	0	12	0
Complete and review on-line batch records. In case of problems identification immediately report to area management	8	4	0	0	12	0
To work to a manufacturing schedule and ensure all documentation is completed accurately, legibly and on time and maintain records as required	5	7	0	0	11	1
Sterile gowning qualification for sterile core operators. Operators will also have an understanding of aseptic behaviors, and have a basic knowledge of viable and non-viable monitoring equipment	7	4	0	0	8	4
Perform visual and physical checks of in-process and finished materials	8	4	0	0	11	1
Follow batch and SOP instructions to perform in-process and finished product sampling. Label and deliver samples to appropriate locations (laboratory, etc.)	9	3	0	0	8	4
Performing end-of-day cleaning of the equipment, the manufacturing facility, especially the aseptic areas	9	3	0	0	10	2
Taking responsibility for assembling, testing, disassembling , and sanitizing various filling and packaging equipment	1	10	1	0	8	4
Being familiar with job related hazards	8	4	0	0	11	1
Contribution to the continues improvement of processes, procedures and quality	6	6	0	0	10	2
Perform inventory control and reconciliation activities	7	4	1	0	10	2
Flexibility in conducting filling, inspection and packaging functions	7	4	0	1	10	2
Assist technical staff with preventive maintenance procedures	3	9	0	0	10	2

The list of duties and responsibilities taken from the international best practice was approved by respondents. They accepted the necessity of those responsibilities almost completely. Slight deviations (functions that are estimated as “Not so important”), mainly relate to specificities of the production process of certain producers. Functions of tablet producers are not appreciated by those specialists who are engaged in production of liquids, and vice a versa. The picture is adequate in case of the application of listed duties and responsibilities in at local enterprises. The majority of respondents currently undertake responsibilities we mentioned at their enterprises. This statement is confirmed by their direct supervisors, too.

Production officers are informed about their responsibilities very well. All enterprises are practicing delegation of responsibilities on a weekly basis. At first sight it may seem to be too often and useless, but deeper look shows that this measure allows the managers of pharmaceutical enterprises to keep their employees well informed and in line with the objectives of the enterprise.

Skills and knowledge

It was already mentioned that not all respondents have graduated professional educational institutions and some of them have received just simple secondary education. Meantime, they all think that their education is quite sufficient for meeting their job requirements. Nevertheless, implementation of responsibilities requires some specific skills and knowledge, that are presented in the table below.

Table 35 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
Excellent understanding of the requirements of GMP	9	3	0	0
Basic knowledge of sterile room techniques, chemical handling and usage	4	6	1	1
Mechanical/technical aptitude	0	8	3	1
Working knowledge of automated and semi-automated inspection equipment	1	9	1	1
Ability to independently read and comprehend documents such as safety rules, operating and maintenance instructions, and procedure manuals	6	5	1	0
Ability to select the correct actions when operational conditions change. (i.e. ability to follow 'if-then' statements)	3	7	2	0
Knowledge of product security controls including controlled substance handling	7	5	0	0
Ability of eye-controlling the tests	4	6	2	0
Attention to details, accurate record keeping, and math skills	5	7	0	0
Ability to manage multiple tasks simultaneously	3	7	2	0
Strong computer skills	1	5	5	1
Good verbal and written communication skills	5	6	1	0
Ability to work in a team environment	7	5	0	0

Again we can see that presented skills and knowledge are appreciated by respondents in general. The only exception is again the computer literacy. We can't agree with this statement, and would recommend the managers of pharmaceutical enterprises to pay more attention to this factor. Technologies will continuously develop and involvement of computers is going to be more and more. Strong computer skills are to be of the first necessity. It should also be noted that direct supervisors share the opinion of their subordinates in the majority of cases.

Production Officers tried to estimate their skills and knowledge and identify improvement needs. Results of that operation are presented below.

Table 36 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
Excellent understanding of the requirements of GMP	0	6	4	4	8	0
Basic knowledge of sterile room techniques, chemical handling and usage	0	6	5	0	11	1
Mechanical/technical aptitude	0	3	8	0	11	1
Working knowledge of automated and semi-automated inspection equipment	0	6	5	2	7	3
Ability to independently read and comprehend documents such as safety rules, operating and maintenance instructions, and procedure manuals	5	6	1	0	8	4
Ability to select the correct actions when operational conditions change. (i.e. ability to follow 'if-then' statements)	3	6	3	0	11	1
Knowledge of product security controls including controlled substance handling	1	7	4	0	11	1
Ability of eye-controlling the tests	1	8	2	0	8	4
Attention to details, accurate record keeping, and math skills	1	9	2	0	10	2
Ability to manage multiple tasks simultaneously	1	8	3	0	9	3
Strong computer skills	0	5	2	1	8	3
Good verbal and written communication skills	5	5	2	0	7	5
Ability to work in a team environment	5	7	0	1	6	5

The majority of respondents estimated their skills and knowledge as “Good”, although for some requirements some of them positioned themselves less modestly. Nevertheless, they expressed needs for improvement of almost all skills and knowledge they possess. Exceptions have been made only for communication skills, team working, and a couple of personal characteristics. The highest demand has been expressed for GMP related issues, technological / mechanical processes, and security practices.

Relevant requirements

Educational and experience requirements for the Production operators are presented in the table below. International practice may not be completely applicable to local enterprises, but it may provide some guidance.

Table 37 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very	Important	Not so	Unim-	Yes	No

	important		important	portant at all		
Vocational education at least	9	2	1	0	9	2
Two to five years experience in the pharmaceutical industry	3	5	4	0	7	4
Experience with machine changeovers and use of hand tools strongly preferred	6	3	3	0	9	2

Answers of Production Operators to this block of questions are not surprising. The majority of respondents think that presented requirements are quite important. Moreover, in many enterprises those requirements are applied. Meantime, the application of those requirements does not yet mean that managers always follow them. In Armenia it is very difficult to find skillful employees and sometimes employers have to accept the available supply.

Organization of training

In case of Production Officers the selection of training formats is more effective. Training with the maturity of one week and slightly more may have some demand but only half of respondents are going to participate those training.

Table 38 – Preferred formats for training

Training format	Convenient	Not convenient
Half a day	3	9
One full day	3	9
Several (2-3) days	1	11
One week	7	5
More than one week	2	10
Regular	2	10

The request of one week is legitimate. In a shorter period it is impossible to get properly acquainted to GMP procedures, or technical innovations. Both theoretical and practical classes are needed for that purpose, and in a period of a couple of days it impossible to ensure serious achievements.

PACKAGING OPERATOR

Respondents' profile

The Packaging Operator in pharmaceutical industry is a quite important position, since for many types of pharmaceuticals packaging comprises the major part of the manufacturing process. As in case of the Production Operators, in Armenia currently is not possible to organize the work of the pharmaceutical enterprise without Packaging Operators. Snapshot to the profile of Packaging Operators at local enterprises is presented below.

Table 39 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Packaging Operator	Pharmaceutist	Vocational	1

Arpimed	Packaging Operator	Pharmaceutist	Vocational	1 - 3
Liqvor	Packaging Operator	Radio-mechanic	Vocational	more than 8
Esculap	Packaging Operator	Accountant	Vocational	3 - 5
Yerevan CPF	Packaging Operator	Agronomist	Vocational	more than 8
Yerevan CPF	Packaging Operator	Agronomist	Vocational	more than 8
Medical-Horison	Packaging Operator	Nurse - cosmetologist	Vocational	1
Medical-Horison	Packaging Operator	Laboratory chemist	Vocational	1
Vitamax-E	Packaging Operator	Nurse	Vocational	1
Vitamax-E	Packaging Operator	Accoucheur (Nurse)	Vocational	1
Leiko-Alex	Packaging and Weighing Operator	N/A	Secondary	1
Leiko-Alex	Packaging and Cutting Operator	Agric entrepreneur	Vocational	1

The majority of respondents declared that there is no need for special background for undertaking the responsibilities of the Packaging Operator. Employees of great variety of professions and with just vocational (maybe even simple secondary) education successfully operate the packaging equipment and conduct other relevant functions if they clearly understand and strictly work under their SOPs and other guidelines.

The working experience is also of not much importance. The situation is very similar the one with Production Operators. Meantime, in case of production operators, it is more important to have scientifically closer background as production operators are directly involved in preparation of pharmaceutical compositions while packaging operators are mainly responsible for filling procedures and do not deal with formulations. Again the majority of employees has just one-year experience, and achieved their qualification within a couple of months. Specialists' turnover (mainly due to changing remuneration requirements) is again a valid problem for employees engaging this position.

Duties and responsibilities

Duties and responsibilities of Packaging Operators are slightly similar to those of Production Operators. Specific functions that should be conducted by Packaging Operators, that were picked up from the international best practice are presented below.

Table 40 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties, responsibilities)				Practicing the functions	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Follow all SOP's, GMP regulations and safety guidelines and company policies and procedures relative to production	5	6	1	0	11	1
Reading and following packaging instructions	6	6	0	0	12	0
Perform in-process testing and finished goods inspection to ensure all product	6	5	1	0	8	3

produced meets established quality criteria						
Complete all necessary production and maintenance paperwork	7	4	0	1	7	4
Set-up, operate and adjust packaging equipment to maximize quality and output	8	4	0	0	8	2
Perform minor troubleshooting and corrections	3	7	1	0	11	0
Handle all packaging process stages (packaging and labeling)	7	5	0	0	11	0
Room and facility cleaning, inspection, assembly, case packing, material handling	6	6	0	0	10	1
Generate and/or support new ideas/ways to increase productivity and efficiencies	5	5	1	0	5	6
Performs other duties as requested	4	6	2	0	11	0

High importance of almost all responsibilities has been accepted by the overwhelming majority of respondents. Some of functions were prioritized, such as exploitation of the packaging equipment, completion of necessary documents, following adopted instructions strictly. No function can be exampled as one that respondents (at least the notable part of them) noted as unimportant. This approach is confirmed by respondents' answers regarding the application of those functions at their enterprises. The rate of application is very high, which means that Packaging Operators of local enterprises are quite well aware of international practices. Respondents' answers have been checked with their direct supervisors; in almost all cases the latter group of specialists confirmed the information provided by their subordinates.

Delegation of responsibilities (and reminding of duties) to the Packaging Operators are implemented in different enterprises by different regularity. Majority of Packaging operators is informed about their tasks weekly, but there are some producers that don't pay much importance to that[5].

Skills and knowledge

Table 39 illustrates that Packaging Operators have not graduated high schools or completed special courses. They all declared that their education is vocational, but we think that some of them may have completed the secondary school the best. Even so, they declare that their education is sufficient for conducting their professional responsibilities sufficiently. Below we present those specific skills and knowledge that Packaging Operators must have according to international practice.

Table 41 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
General knowledge of state laws, acts and/or regulations as pertaining to regulated industries	4	6	2	0
Strong knowledge of GMP procedures	3	9	0	0
Good math skills	0	9	3	0

[5] Only at moment of recruitment or once a year (practiced by Arpimed and Vitamax)

Ability and willingness to learn new things (i.e., hand tool use, use of manuals)	4	7	0	0
Ability to adjust quickly to new responsibilities and tasks	6	5	0	0
Must be able to lift, push and pull up to 35-50 pounds	1	7	4	0
Must have the ability to stand, bend and walk for up to 8-10 hour daily	2	9	1	0
Mechanical aptitude	0	7	4	1
Excellent hand-eye coordination. Good eyesight for inspection of finished product	8	4	0	0
Ability to manage multiple tasks simultaneously	2	8	1	0
Strong computer skills	0	4	5	2
Good verbal and written communication skills	1	10	1	0
Ability to work in a team environment	8	4	0	0

Respondents have agreed with the main part of required skills and knowledge. They made special emphasis on the necessity of knowledge of regulations and GMP, as well as such personal features as quick adjustment to new environment, coordination on work, team working ability. Mechanical aptitude, physical abilities, and computer literacy are estimated to be less important. Direct supervisors have almost completely agreed with their subordinates.

Packaging Operators seem to be quite self-assured. Some of them think that they completely possess all necessary skills and knowledge for the implementation of their duties. Availability of necessary skills and improvement needs are presented below.

Table 42 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
General knowledge of state laws, acts and/or regulations as pertaining to regulated industries	1	8	2	1	10	1
Strong knowledge of GMP procedures	0	7	4	1	10	1
Good math skills	0	4	7	0	6	6
Ability and willingness to learn new things (i.e., hand tool use, use of manuals)	2	8	1	0	11	1
Ability to adjust quickly to new responsibilities and tasks	3	7	2	0	7	4
Must be able to lift, push and pull up to 35-50 pounds	3	6	3	0	4	8
Must have the ability to stand, bend and walk for up to 8-10 hour daily	3	7	2	0	6	6
Mechanical aptitude	0	4	5	0	8	4
Excellent hand-eye coordination. Good eyesight for inspection of finished product	4	6	1	0	3	8

Ability to manage multiple tasks simultaneously	2	8	2	0	7	3
Strong computer skills	0	4	5	0	10	1
Good verbal and written communication skills	1	10	1	0	6	6
Ability to work in a team environment	7	4	1	1	2	9

It is legitimate that respondents expressed urgent improvement need only for the knowledge of regulatory issues and GMP. Recently these two aspects are discussed among the professional community very intensively. Respondents see no need for improving such skills as team working, coordination, physical abilities, and knowledge of mathematics. It is difficult to make judgments; there are too many factors to consider starting from subjective attitude of the managers and ending with local peculiarities of pharmaceutical production.

Relevant requirements

Other relevant requirements for the Packaging Operators are presented in the table below.

Table 43 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Secondary vocational education or equivalent (Pharmacy technician)	3	5	4	0	9	0
1 year (recent/contiguous) experience operating filling/packaging equipment	4	4	4	0	4	6
Experience with machine changeovers and use of hand tools preferred	3	6	3	0	7	1
Flexibility to work weekends, overtime and on all shifts	3	6	2	0	6	2

Respondents' opinions about the relevant requirements have distributed almost evenly. No requirement has been marked as unimportant, but we have no strong tendency towards real appreciation of those requirements either.

Organization of training

Packaging Operators are not very successful in selecting training formats, too. Nobody likes training that last more than one week, but shorter maturity is also not very requested,

Table 44 – Preferred formats for training

Training format	Convenient	Not convenient
Half a day	3	8
One full day	2	9

Several (2-3) days	1	10
One week	4	7
More than one week	0	11
Regular	3	8

The preferred format of training can be explained by the same reason as in case of Production Operator. Specialists think that one week is enough for getting acquainted with any new technology and equipment.

CHEMIST (QUALITY CONTROL ANALYST)

Respondents' profile

Responsibilities of this position often coincided by the QC specialists or by the Laboratory employees. The profile of chemists included in the assessment is presented below.

Table 45 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Chemist-Analyst	Biochemist	Master	3 - 5
Liqvor	Manager	Biophysicist	Master	5 - 8
Esculap	Analyst	Dispensing Chemist, Pharmaceutist	Bachelor	3 - 5
Yerevan CPF	Chemist	Chemist	Master	more than 8
Medical-Horison	Head of Quality Control Division	Biophysicist	Candidate of science	1
Bizon-1	Chemist, Quality Control Analyst	Chemist	Master	3 - 5
Leiko-Alex	Head of Technical Control Division	Organic Chemist	Candidate of science	1

All assessed enterprises are employing qualified specialists with relevant profession, i.e. chemists, bio…s, pharmaceutists. Employment at the position of the Chemist requires higher education and background. Chemists of 6 out of 8 assessed pharmaceutical enterprises have scientific degrees and quite a long experience.

Duties and responsibilities

In general, the main responsibility of Chemists is the control of manufactured pharmaceuticals' quality and organization of the laboratory operations. List of duties relevant to this position according to the best practice is presented below.

Table 46 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties,	Practicing the

	responsibilities)				functions	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Testing of all laboratory samples including in-process, finished products, validation, stability, environmental	6	1	0	0	7	0
Observe GLP/GMP at all times	5	2	0	0	7	0
Recording of analytical results accurately	4	3	0	0	6	1
Operation, maintenance and calibration of laboratory instruments	4	2	1	0	6	1
Preparation and execution of instrument qualification and method validation protocols	2	5	0	0	5	2
To ensure that the laboratory is kept clean, tidy and safe at all times	3	4	0	0	6	1
Report any non-conformance, instrument malfunction, accident or other abnormal occurrence to immediate superior	4	3	0	0	6	1
Verify analytical data of other analysts within the lab as requested	1	6	0	0	5	2
Review and interpretation of data for conformance to procedures, standards and protocols and/or real-time recognition of aberrant data and results	3	3	0	1	5	2
Initiate change controls and deviations	3	3	0	1	6	1
Troubleshoot equipment and methods as required	3	3	0	1	5	2
Assist in improvement of quality systems by creating or revising worksheets and other lab documentation systems	3	3	1	0	6	1
Comply with and implement safety standards	3	4	0	0	4	3
Executes notification to management when required by procedures or standards	2	5	0	0	6	1
Participate fully in cross functional training	0	5	2	0	3	4
Develop training materials, train and mentoring others	1	5	1	0	3	4

We are glad to ascertain again that local employees' attitude towards the best practices is very receptive. Only few functions were estimated by a couple of respondents as unimportant ones. Others have noted as "*Very important*". Special emphasis was made on laboratory processes and GMP related issues. These very important functions are already applied at many pharmaceutical enterprises. This was declared by respondents and confirmed by their direct supervisors.

According to respondents, delegation of responsibilities and duties at their enterprises is conducted regularly, every week or every month. We think that this is quite effective regularity; employees are informed about their tasks and not burdened with too often discussions.

Skills and knowledge

The international best practice outlines the following list of skills and knowledge that are necessary for successful implementation of responsibilities.

Table 47 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
Strong knowledge GLP/GMP requirements	6	1	0	0
Ability to read, analyze, interpret and communicate technical data, technical procedures or regulations	4	3	0	0
Strong technical ability and the ability to troubleshoot testing methods	4	3	0	0
Ability to working in a lab environment including wearing appropriate PPE and other safety required equipment (such as a respirator)	1	6	0	0
Excellent organization, planning and judgment skills and will be able to positively achieve results through and with others	1	6	0	0
Ability to manage multiple tasks simultaneously	1	5	1	0
Strong computer skills	0	6	1	0
Good verbal and written communication skills	0	7	0	0
Ability to work in a team environment	0	6	1	0

Respondents did not really argue the importance of any skill and knowledge. They told that their education is quite sufficient for meeting requirements of their profession. Meantime, they estimate their skills and knowledge as “Good” and declare about need for improving some of discussed skills.

Table 48 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
Strong knowledge GLP/GMP requirements	1	4	2	0	6	1
Ability to read, analyze, interpret and communicate technical data, technical procedures or regulations	0	6	1	0	2	5
Strong technical ability and the ability to troubleshoot testing methods	1	4	2	0	5	2
Ability to working in a lab environment including wearing appropriate PPE and other safety required equipment (such as a respirator)	3	3	1	0	2	5
Excellent organization, planning and judgment skills and will be able to positively achieve results through and with others	1	4	2	0	2	5
Ability to manage multiple tasks simultaneously	0	6	1	0	4	3

Strong computer skills	0	3	4	0	6	1
Good verbal and written communication skills	2	5	0	0	2	5
Ability to work in a team environment	2	4	1	0	3	4

Improvement of GMP related skills, equipment testing, and computer literacy are the most requested topics for improvement. Meantime respondents don't think they have to improve their communication, organizational and planning skills, and ability of working with process documents.

Relevant requirements

Other relevant requirements for the Chemists are presented in the table below.

Table 49 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Higher education in chemistry, analytical chemistry or a related subject	6	1	0	0	7	0
Relevant laboratory experience	3	4	0	0	7	0
Experience in pharmacopeial testing, along with method development, validation experience and working knowledge of GMP	4	3	0	0	7	0

Respondents adopted the importance of additional relevant requirements completely. Direct supervisors of respondents share this opinion. This is normal, since requirements listed here are already applied at local pharmaceutical enterprises.

Organization of training

Chemists would like to participate regularly organized training. The regularity of those training sessions is another theme to discuss. Again short-lasting training are not of much demand.

Table 50 – Preferred formats for training

Training format	Convenient	Not convenient
Half a day	3	4
One full day	2	5
Several (2-3) days	2	5
One week	3	4
More than one week	3	4
Regular	5	2

LABORATORY TECHNICIAN

Respondents' profile

Surprisingly, only 4 enterprises have declared about having laboratory technicians. It is difficult to imagine a pharmaceutical enterprise without this specialist. Maybe, in some enterprises responsibilities of these specialists are coincided by other employees. The combined profile of respondents is presented below.

Table 51 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Chemist	Chemist	Master	1
Liqvor	Laboratory analyst	Pedagogue-chemist	Bachelor	5 - 8
Yerevan CPF	Senior laboratory analyst	Chemist	Bachelor	5 - 8
Medical-Horison	Laboratory analyst	Chemist-technologist	Bachelor	1

All respondents have professional background and necessary scientific degrees. Direct supervisors of respondents note that for conducting responsibilities of Laboratory Technicians even the secondary education is sufficient. Deviation of working experience is quite big. Supervisors again insist that for this position the experience is not a decisive factor.

Duties and responsibilities

Laboratory Technicians conduct various types of testing, maintains QC Laboratory equipment and instruments. Specific responsibilities may be quite different, but we tried to gather the most relevant ones that are applied at international practice.

Table 52 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties, responsibilities)				Practicing the functions	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Responsible for performing full QC testing on starting and packaging materials, in-process, Batches and Finished Product	3	0	0	0	1	0
Maintain and utilize instrumentation for analytical purposes	0	2	1	0	1	0
Support Manufacturing in a timely manner by analyzing all intermediates and finished product that enters the laboratory	1	2	0	0	1	0
Prepare and keep records on analysis of intermediates, finished batches and packaged products	1	2	0	0	1	0

Assist the Chemist(s) in special projects, including Plant Trial and Process Validation testing	0	3	0	0	1	0
Conduct cleaning responsibilities of workplace	3	0	0	0	1	0
Daily instrument calibration	1	2	0	0	1	0
Washing of glass instruments	1	0	0	0	1	0

Local specialists and their supervisors completely adopted the importance of listed responsibilities. This may be explained by limited number of duties and their exact nature. Special emphasis was made on issues related to Quality Control Systems.

Respondents told that they are discussing their duties and responsibilities with their supervisors either once a week, or once a month. This regularity is quite effective; employees are promptly informed about their duties and relevant details of operations they are expected to conduct.

Skills and knowledge

Some respondents declare that availability of specific skills and knowledge are not the first priority for Laboratory Technicians. According to them, "*taking compassion on the work and facilities is prior to professional skills*".

Table 53 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
Experience with GMP and GLP	3	0	0	1
Detail oriented record keeping skills	2	1	0	1
Ability to manage multiple tasks simultaneously	1	2	0	1
Strong computer skills	0	2	1	1
Good verbal and written communication skills	0	3	0	1
Ability to work in a team environment	2	2	0	0

Respondents gave most importance to the knowledge of GMP and related issues. Surprisingly, there is a respondent thinking that presented skills and knowledge are not of any importance. This is very subjective approach; working in such manner is risky and not professional.

All respondents declared that their education ensured quite sufficient base for them in order to meet the minimum requirements of the position. Respondents are satisfied with their skills in general, but they would not reject opportunities of improving their skills (see the table below).

Table 54 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
Experience with GMP and GLP	0	1	2	1	2	0
Detail oriented record keeping skills	1	1	1	0	2	1

Skills and Knowledge Needs Assessment for Pharmaceutical Industry				Skills and Knowledge Gap		
Ability to manage multiple tasks simultaneously	0	2	1	0	1	2
Strong computer skills	0	1	1	0	3	0
Good verbal and written communication skills	1	1	1	0	1	2
Ability to work in a team environment	1	0	3	0	2	2

As it was noted, respondents pay much importance to GMP related issues; they also think that their knowledge of this theme is not sufficient enough and they need to improve it. Respondents' knowledge of computers also has a room for improvements. Direct supervisors of respondents agree with their subordinates completely.

Relevant requirements

As it was already mentioned, the list of requirements to Laboratory Technicians is not very long. The same refers to additional relevant requirements. They are not too tough.

Table 55 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Vocational education in general chemistry	3	0	0	0	2	0
Equivalent experience in pharmaceutical laboratories	3	0	1	0	2	1

Respondents find both requirements to be very important. Some of them even practice those requirements at their enterprises. Again, supervisors share the opinion of their subordinates.

Organization of training

Laboratory Technicians prefer regular training of not very short maturity. Unfortunately, respondents did not explain their motivation for regular sessions, and did not specify the regularity.

Table 56 – Preferred formats for training

Training format	Convenient	Not convenient
Half a day	0	4
One full day	0	4
Several (2-3) days	1	3
One week	2	2
More than one week	1	3
Regular	4	0

MICROBIOLOGIST

Respondents' profile

In general, the responsibilities of Microbiologists consist of various microbiological analyses at the QC Laboratory, validation, development of the QC Systems, etc. Although microbiologists are very important part of the Quality Control system, we identified that not all local enterprises employ these specialists. Some small producers that manufacture non-sterile products can outsource microbiological services to specialized entities.

Table 57 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Microbiologist	Biochemist	Bachelor	3 - 5
Liqvor	Microbiologist	Biologist	Master	5 - 8
Yerevan CPF	Bacteriologist	Biologist	Master	more than 8

Medical - Horison	Head of Quality Control Division	Biophysicist	Candidate of science	1
Vitamax - E	Microbiologist	Microbiologist and biotechnologist	Master	1

All respondents are professionally engaged in microbiological investigations and relevant activities. They have appropriate scientific degrees, sometimes even higher than it is necessary. Professional working experience is different for various enterprises, but specialists estimate the minimum required maturity to be up to 3 years.

Duties and responsibilities

Duties and responsibilities presented in the table below have been selected at the international best practiced. Their conformity with local realities will be estimated by local specialists.

Table 58 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties, responsibilities)				Practicing the functions	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Work in accordance to SOP, GMP and GLP requirements	4	1	0	0	5	0
Sampling and the microbiological analysis of samples and environmental monitoring	5	0	0	0	5	0
Validation of Test Methods	2	3	0	0	5	0
Documentation of results or inputting of data onto the LIMS (Laboratory Information Management Systems)	4	1	0	0	5	0
Isolation and identification of micro-organisms	3	2	0	0	5	0
Trending and review of results	3	2	0	0	4	1
Report out-of-trend or out-of-specification results	0	4	1	0	4	1
Completion of Laboratory Investigation and the preparation of associated reports	2	3	0	0	5	0
Development, execution and maintenance of Quality Control systems, standards, practices and procedures for raw materials, utilities, in-process and final product testing	2	3	0	0	4	1
Support continuous process performance evaluation and continuous process improvement for highest efficiency	1	3	1	0	3	2
Integrate, contribute, and/or lead cross-functional project teams as required	0	3	2	0	2	3
Primary contact for all QC Microbiology	0	5	0	0	3	2

related filings and inspections of Regulatory Agencies						

Respondents found the listed duties and responsibilities to be more or less important from the viewpoint of the position they engage at their enterprises. They especially value the importance of such responsibilities as sampling and analysis, GMP procedures, documentation of investigation outputs and computerized analysis of data. Respondents mentioned only few functions that are not so important from their point of view. Respondents also informed that the overwhelming majority of listed duties and responsibilities are practiced at their enterprises. This is very good, since it means that local practices are in line with internationally accepted performance. Respondents' direct supervisors agree with their subordinates completely.

Microbiologists have been asked about the regularity of discussing their responsibilities with their supervisors. In other words, how often the higher management reminds them about their duties and functions. Responses are quite various: once a week, once a month, and even once a quarter.

Skills and knowledge

To the question about the sufficiency of education respondents replied traditionally. They think their education is completely sufficient in order to undertake their duties successfully. Meantime, only the education is still not enough, and special skills and knowledge is required. Best practice review suggests the following list.

Table 59 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
Good Knowledge of GMP, GLP and Safety requirements	5	0	0	0
Strong knowledge of microbiology and the GMP as applied in the area of microbiological control of production	5	0	0	0
Current knowledge or proven interest in starting-up and qualifying new facilities, tech transfers and manufacturing operations	2	2	1	0
Knowledge of laboratory instrumentation and methods	4	1	0	0
Ability to manage multiple tasks simultaneously	2	3	0	0
Strong computer skills	0	4	1	0
Good verbal and written communication skills	1	4	0	0
Ability to work in a team environment	0	5	0	0

Respondents found important almost all skills and knowledge presented above. They make special influence on the knowledge of GMP and microbiological investigations and control. In general, the importance of the narrow knowledge was accented. Again, direct supervisors agree with their subordinates with slight deviations.

Table 60 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
Good Knowledge of GMP, GLP and Safety	1	3	1	1	3	1

requirements						
Strong knowledge of microbiology and the GMP as applied in the area of microbiological control of production	3	2	0	1	3	1
Current knowledge or proven interest in starting-up and qualifying new facilities, tech transfers and manufacturing operations	0	4	1	0	3	2
Knowledge of laboratory instrumentation and methods	3	2	0	0	2	3
Ability to manage multiple tasks simultaneously	3	1	1	0	1	4
Strong computer skills	1	2	1	0	2	3
Good verbal and written communication skills	3	2	0	0	0	5
Ability to work in a team environment	3	1	1	0	1	4

Estimates of the possession of listed knowledge and the availability of skills were not monotonous. Although respondents think they have not bad knowledge and skills they would like to somewhat improve their qualifications. It is interesting that they don't think they need to improve their personal features, but prefer to discuss opportunities for upgrading their professional skills and knowledge.

Relevant requirements

The list of additional relevant requirements is quite short: again education and experience.

Table 61 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
University or advanced degree in Microbiology or related science with 5+ years of appropriate experience	2	3	0	0	4	0
Minimum of 6+ years GMP quality control and/or QC related experience, at least 3 years of which are direct microbiology laboratory experience	2	2	1	0	2	2

Both requirements were appreciated by respondents. University degree requirements are quite common in Armenia, too, but GMP related issues are very new for our country. The understanding of GMP and application of this system in local pharmaceutical enterprises has just started. There simply was no opportunity of 6 and more year experience for GMP related issues locally.

Organization of training

Training with the maturity of one week and more have the biggest demand among the microbiologists of local enterprises. Meantime, some of them require also some regularity for those training.

Table 62 – Preferred formats for training

Training format	Convenient	Not convenient
Half a day	1	4
One full day	2	3
Several (2-3) days	1	4
One week	4	1
More than one week	1	4
Regular	3	2

At last, we face strong demand for specific format of training. At least 4 out of 5 respondents mentioned the period of training to be one week.

STORAGE (WAREHOUSE) PERSON

Respondents' profile

Pharmaceutical enterprises usually require separate storage facilities for raw and packaging materials, semi-finished and in-process goods. There may also be requirements for the storage of materials such as narcotics, hazardous and flammable materials. At small enterprises, where the range of products is not long and only few inputs are used, storage facilities may not be as complicated, but still safety issues must be of the first priority. Management of storage facilities is quite a sophisticated function, which requires special knowledge and skills for successful implementation of the complicated responsibilities.

Table 63 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Storage responsible officer	Chemist-Technologist	Bachelor	1 - 3
Liqvor	Head of Final Product Storage	Economist	Bachelor	3 - 5
Esculap	Head of Storage	Chemist, Pharmaceutist	Bachelor	1
Yerevan CPF	Head of Storage	Chemist	Vocational	more than 8
Medical - Horison	Head of Final Product Storage	N/A	Secondary	1
Medical - Horison	Head of Storage	Dental Technician	Vocational	1
Vitamax - E	Storage responsible officer	Engineer - Electrician	Master	1 - 3
Bizon - 1	Director	Physicist	Candidate of science	more than 8
Leiko - Alex	Director	Economist	Master	3 - 5

6 out of 8 assessed pharmaceutical enterprises employ Storage Persons that are responsible for storages' operation. In other 2 enterprises that function is conducted by the managers of enterprises in parallel with their duties. The position of the Head of Storage requires special background and skills, but as we can see from the table those functions may be conducted by employees with different profession.

Specialists note that the working experience of about 3 years is quite sufficient for conducting responsibilities of the Storage Person. As to local reality, only half of assessed enterprises can meet this requirement.

Duties and responsibilities

At first sight duties of the Storage Person may seem to be quite limited and easy to perform. This opinion is not right: the position requires wide knowledge in various areas, some personal skills and responsiveness. Specific duties and responsibilities for the Storage Person picked up from the practice of advanced international producers of pharmaceuticals are presented in the table below.

Table 64 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties, responsibilities)				Practicing the functions	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Implement procedures for maintaining accurate inventories, proper storage of the various products: starting and packaging materials, finished products, products in quarantine, and released, expired, rejected, returned or recalled products	8	0	0	1	8	1
Implement procedures designed to maintain accurate inventories, proper storage of radioactive materials, narcotics and other hazardous, sensitive and/or dangerous pharmaceutical products, and products of special risks of abuse, fire or explosion, should be stored in a dedicated area	5	2	0	2	3	6
Responsibility for monitoring and enforcing quality and productivity standards	4	3	0	1	4	4
Coordination and management of the flow of materials, ensuring proper receipt, storage, picking, shipping and documentation	6	3	0	0	9	0
Adhering to and improving the SOPs and promoting regulatory and safety compliance	3	4	0	1	5	3
Supply of components and raw materials to the respective departments	5	3	0	1	7	2
Load and unload all domestic and export production	2	6	1	0	7	2
Maintain forklift trucks according to established procedures	2	4	0	3	1	8

Coordinate housekeeping tasks (e.g. sweeping, product consolidation) to maintain neat, clean, dry and maintain acceptable temperature limits	6	3	0	0	8	1
Utilization of computerized material tracking system to locate components and maximize warehouse space	6	1	1	1	5	4
Input data into receiving system and shipping system	5	4	0	0	7	2
Provision of daily direct supervision to warehouse and distribution activities	4	4	1	0	8	1
Provision of strong leadership, coaching and training of warehouse colleagues	4	3	1	1	4	5
Overseeing the operations of designated warehousing and distribution functions to ensure that all functions comply with government and corporate requirements	4	5	0	0	7	2
Assist with assuring that proper building and equipment maintenance	2	5	2	0	6	3
Provision of a strong emphasis on safety for the warehouse and facility environment	4	5	0	0	8	1

The majority of respondents noted that almost all duties and responsibilities are quite important. Some of listed functions, such as performance of proper and accurate storage procedures, organization of materials' flow, keeping storage facilities in proper condition, and application of computerized management systems are marked to be "Very Important". The only function respondents don't like is the ability of exploiting forklift trucks. The situation with application of listed functions at local enterprises is different and ambiguous. Some functions are applied at local enterprises very intensively, others are practiced very weakly. Providing respondents' estimation of the importance of listed duties and responsibilities, some positive changes may be awaited in near future. Direct supervisors of respondents approved the position and opinion of their subordinates almost unanimously.

Delegation of responsibilities of Storage Persons is also carried out differently in various enterprises. Some respondents declare that they discuss their functions with their supervisors every week or every month at least. Others tell, that they have been informed about their duties and responsibilities once a year, or even only at the moment of recruitment. The first option is surely better, since the environment of the enterprise changes and certain modifications of duties are unavoidable.

Skills and knowledge

All respondents declared that their education is completely sufficient for performing their professional duties as Storage Persons. Some additional skills and knowledge they gain at the practical work. The conformity of the available skills and knowledge with international practice is presented below.

Table 65 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
Knowledge of Armenian and international regulations on narcotics	1	3	4	1

Knowledge of GMP, Good Storage Practices and Good Distribution Practices	2	6	0	1
Willingness and ability to operate a forklift and hand trucks	0	4	2	3
Ability to wear respiratory protection to perform specific tasks	2	6	1	0
Ability and willingness to train others	1	7	0	1
Ability to lift, bend and move heavy objects	0	5	2	2
Ability to manage multiple tasks simultaneously	3	5	1	0
Strong computer skills	2	5	2	0
Good verbal and written communication skills	2	6	1	0
Ability to work in a team environment	3	4	2	0

Very few skills and knowledge were estimated to be “Very important” or “Unimportant”. Respondents think that the majority of skills and knowledge are simply important, and may be requested from employees in general. There is only one special point that we would like to pay attention. Half of the respondents think that knowledge of regulation on narcotics is “Not so important”. Direct supervisors agreed with their subordinates with slight deviations between the columns of “Very important” and “Important”.

Respondents answers to questions regarding the possession of mentioned skills and knowledge is quite surprising. Almost half of respondents think that their knowledge is just tolerable, and some of them even estimate their skills and knowledge to be unsatisfactory. This is very important finding that should be necessarily explored further.

Table 66 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
Knowledge of Armenian and international regulations on narcotics	0	1	5	0	4	5
Knowledge of GMP, Good Storage Practices and Good Distribution Practices	0	2	6	0	7	2
Willingness and ability to operate a forklift and hand trucks	1	1	2	0	1	8
Ability to wear respiratory protection to perform specific tasks	1	2	5	0	4	5
Ability and willingness to train others	1	7	1	0	2	7
Ability to lift, bend and move heavy objects	1	2	4	0	0	9
Ability to manage multiple tasks simultaneously	2	3	4	0	2	7
Strong computer skills	1	3	2	0	6	3
Good verbal and written communication skills	2	6	1	0	1	8
Ability to work in a team environment	2	6	1	0	1	8

Respondents expressed no “Urgent” need for improving their skills and knowledge. They also rejected the need for improving special skills completely. Examples of such skills are physical abilities, exploitation of forklift truck, as well as personal skills, i.e. communication and team work. Again the majority of direct supervisors agreed with their subordinates. Exceptions were made for the same physical abilities and skills of exploiting forklift trucks.

Relevant requirements

Relevant additional requirements come to amend the list of required skills and knowledge. See the list below.

Table 67 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
PharmD	0	5	4	0	5	1
Warehouse and pharmaceuticals’ shipping related experience	0	4	5	0	4	1
Knowledge of Safety requirements and Transportation rules	0	7	2	0	4	1
Warehouse Management System experience	0	7	2	0	4	2
Flexibility to work 12 hour days (including weekends), overtime and all shifts is required. Commitment to safety	3	4	2	0	4	2

The most important finding that was made from the survey was the respondents answer regarding to flexibility of working time. Respondents think that this factor is of the most importance. Meantime, half of respondents do not think that higher education (PharmD) and relevant experience are not so important for the Storage Person. Direct supervisors agree with their subordinates with only one exception, supervisors think that the experience is of much importance.

Organization of training

Storage Persons are more disposed to training than other employees whose answers were analyzed above.

Table 68 – Preferred formats for training

Training format	Convenient	Not convenient
Half a day	2	7
One full day	3	6
Several (2-3) days	1	8
One week	6	3
More than one week	1	8

Regular	1	8

Again the sessions with the maturity less than one week are not convenient for the overwhelming majority of respondents. The same refers to those longer than one week. Any reasons for such preferences were not brought.

MARKETING SPECIALIST

Respondents' profile

Only 5 enterprises out of 8 currently declared about implementing marketing functions. Characteristics of respondents are presented in the table below. It should be mentioned, that only 2 enterprises are employing specialists who are conducting professional marketing activities. In other cases marketing functions are coincided with other responsibilities (usually with duties of the top management).

None of the marketing specialists has marketing education. Only one of them has graduated the Institute of National Economy with the relevant profession of economist. Meantime, some of specialists argue that marketing specialists at pharmaceutical enterprises should be pharmaceutists.

Table 69 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Marketing manager	Pharmaceutist	Internship	more than 8
Liqvor	Head of marketing and sales division	Pharmaceutist	Internship	1 - 3
Yerevan CPF	General engineer	Chemist	Candidate of science	more than 8
Bizon-1	Director	Physicist	Candidate of science	3 - 5
Leiko-Alex	Director	Economist	Master degree	1 - 3

All respondents have scientific degrees. Direct supervisors of respondents think their education is more or less sufficient for undertaking their responsibilities. This statement is confirmed by the respondents' direct supervisors, too. Professional working experience of marketing specialists is also quite sufficient. The shortest experience accounts 3 years.

Duties and responsibilities

Duties and responsibilities have been drafted out on the basis of the international best practice. Local marketing specialists of the pharmaceutical enterprises were asked to estimate the importance of specific operations as well as the application of those functions in practice.

Table 70 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties, responsibilities)	Practicing the functions

	Very important	Important	Not so important	Unim-portant at all	Yes[6]	No
Operation in accordance with Armenian pharmaceutical legislation and regulation, company Policies and Procedures	2	3	0	0	2	0
Operation in accordance with internal the Marketing Operating Practices and Procedures	4	1	0	0	2	0
Development of marketing strategy, tactics and via the market research	2	3	0	0	2	0
Annual marketing planning	2	3	0	0	2	0
Development of the product marketing plan and proactive alignment the product's promotional requirements	3	2	0	0	2	0
Development and managing advertising, educational and other material	1	4	0	0	2	0
Work across functions to coordinate development of marketing materials and ensure consistent delivery of brand message to consumers	2	3	0	0	2	0
Regularly perform professional analysis and qualitative/quantitative research of the market,	3	2	0	0	2	0
Conduct competitors' research	2	3	0	0	2	0
Conduct consumers' targeting by groups	0	4	0	0	1	0
Provides product briefings and training to sales specialists	0	5	0	0	2	0
Perform field visits to monitor implementation of marketing strategy by the sales specialists	0	5	0	0	2	0
Participates in budgeting of promotional activities	0	0	0	0	0	0

As it can be seen in the table above, all functions suggested from the international best practice were estimated by local marketing specialists as either "*Very important*" or "*Important*". This means that presented functions are completely accepted and evaluated by local specialists and may be applied in future. Moreover, some of the suggested functions are already conducted by local producers of pharmaceuticals. Another interesting observation – direct supervisors agreed with answers of respondents completely.

Skills and knowledge

Marketing specialists of 5 pharmaceutical enterprises declared that their education is sufficient enough for conducting functions presented in the previous section. Meantime, basic education may not ensure sufficient skills and knowledge for undertaking certain responsibilities.

[6] Some of respondents simply rejected to answer the question: either they did not want to share internal information, or did not know the answer

Table 71 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
Strong knowledge of Armenian drug regulation concerning medicines promotion (Medicines Law, Advertisement Law, etc)	1	4	0	0
Strong knowledge of international guidelines concerning medicines promotion (WHO, EU, etc)	1	3	1	0
Strategic thinking and analytical skills	3	1	1	0
Be self-directed and inquisitive	2	3	0	0
Ability to motivate others	2	2	1	0
Excellent communication skills (written and oral)	2	3	0	0
Ability to work effectively within changing environment	3	2	0	0
Strong project management, budget management and prioritization skills	2	3	0	0
Strong decision-making skills and experience preferred	4	1	0	0
Knowledge of Project Management, Marketing & Promotion techniques	2	2	1	0
Strong computer skills	1	3	1	0

Again we have many answers under the columns of *very important* and *important*. As we can see from the table, some skills and knowledge were not prioritized, although in some cases these answers are difficult to understand. It is difficult to imagine, that strategic thinking and analytical skills or knowledge of marketing and project management can be "*not so important*".

Table 72 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
Strong knowledge of Armenian drug regulation concerning medicines promotion (Medicines Law, Advertisement Law, etc)	0	2	3	1	3	1
Strong knowledge of international guidelines concerning medicines promotion (WHO, EU, etc.)	0	4	1	0	3	2
Strategic thinking and analytical skills	0	4	1	0	3	2
Be self-directed and inquisitive	2	2	1	0	4	1
Ability to motivate others	0	4	1	0	4	1
Excellent communication skills (written and oral)	1	3	1	0	2	3
Ability to work effectively within changing environment	1	3	1	0	2	3
Strong project management, budget management and prioritization skills	0	3	2	0	3	2

Strong decision-making skills and experience preferred	1	4	0	0	3	2
Knowledge of Project Management, Marketing & Promotion techniques	1	2	2	0	4	1
Strong computer skills	1	2	2	2	0	3

Marketing specialists are quite modest in estimating their skills and knowledge. At the same time, they are not very eager to improve their skills and knowledge. Some of them simply refuse to improve their qualifications. It would not be so strange, if the answers of direct supervisors were not so strictly confirmative. Only one supervisor did not agree with an employee: he thought that the employee really needs to improve its skills and knowledge.

Some of assessed pharmaceutical enterprises are practicing regular delegation of responsibilities. In some enterprises the regularity is declared to be once a month, in others – weekly. Meantime, some respondents declared nothing about the delegation of their responsibilities. They are informed about their duties on the moment of recruitment, and then receive some instructions as the need arises.

Relevant requirements

Aside from the responsibilities and duties, as well as the required skills and knowledge for conducting those responsibilities, employees usually are awaited to meet additional relevant requirements. Those requirements usually refer to the experience and educational background. Respondents have been asked about some of additional requirements, and their responses are combined in the table below.

Table 73 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Bachelors degree, marketing or related field	4	0	1	0	2	1
3+years in packaged goods or consumer marketing experience	2	3	0	0	3	0
Experience with advertising, production processes, and/or media planning preferred	1	2	2	0	2	1
MBA Preferred	1	1	3	0	1	2

Respondents paid more attention to the availability of higher education, i.e. bachelor degree. Some experience in the exact field of their activity is also important. In fact, we understood that only few of pharmaceutical enterprises in Armenia raise *other relevant requirements* on the moment of employing specialists.

Organization of training

Table 74 - Preferred formats for training

Training format	Convenient	Not convenient
Half a day	1	3
One full day	2	2
Several (2-3) days	0	4
One week	0	4
More than one week	1	3
Regular	1	3

As it was illustrated in the analysis above, respondents declared their need for improving skills and knowledge that are necessary for conducting their duties and responsibilities. The best way of improving skills and knowledge are the training.

Unfortunately, respondents were not able to identify any format for trainings that is convenient for the majority of them. This is quite a problematic issue, since it will be impossible to organize training sessions for just a couple of participants and conduct those sessions on a continuing basis.

COMPLAINT AND PHARMACOVIGILENCE SPECIALIST

Respondents' profile

Pharmacovigilence Specialist deals with all kinds of complaints regarding to pharmaceuticals and carries out investigations. This specialist cooperates closely with regulatory authorities on safety issues. But all this is some cut-off information from the international practice. In Armenia, local enterprises don't employ specialists for performing only pharmacovigilence related duties. In fact, specialists of local enterprises coincide these duties with other responsibilities. This is mainly due to small sizes and production volumes of local companies. Nevertheless, the profile of those specialists who undertake the responsibilities of Pharmacological Specialists is presented in the table below.

Table 75 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Medical Representative	Pharmaceutist	Candidate of science	3 - 5
Liqvor	Quality Control Manager	Biophysicist	Master	5 - 8
Yerevan CPF	Technical Control Manager	Engineer - Technologist	Master	3 - 5
Vitamax - E	Pharmaceutist	Pharmaceutist	Bachelor	more than 8
Leiko - Alex	Deputy Director on Scientific Issues	Chemist	Candidate of science	3 - 5

We can see from the table that no local enterprise currently employs a pharmacovigilence specialist. These responsibilities are performed by other employees of general pharma- or bio- professions. All of them have relevant education and sufficient working experience. At least respondents' supervisors think so. The only thing that disturbs is the engagement of mentioned specialists on several positions; this lowers their effectiveness and efficiency and provides possibilities for making mistakes.

Duties and responsibilities

International best practice uncovers some specific duties and responsibilities that are to be applied for the Pharmacovigilence Specialists at the moment of recruitment in their Job Descriptions. Local specialists attitude (estimation) of those responsibilities see bellow.

Table 76 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties, responsibilities)				Practicing the functions	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Follow all SOP's, appropriate regulations and company procedures, relative complaints including the need to consider a recall and adverse reactions monitoring of products	4	1	0	0	3	1
Record any complaint concerning a product defect with all the original details and report to designed person for appropriate action	3	2	0	0	4	1
Investigate whether a complaint was caused because of counterfeiting	4	1	0	0	4	1
Contact person for communication with Regulatory Authorities on drug safety issues	1	4	0	0	2	3
Review and reporting of spontaneous adverse events internally to assigned person and externally to regulatory authority	0	4	0	0	3	2
Investigation and follow up international and Armenian adverse event reports	1	4	0	0	1	4
Review and submit Periodic Safety Update Reports (PSURs) and Annual Safety Reports (ASRs) to regulatory authorities	0	4	0	0	1	3
Define evaluation plan with partners to appropriately assess and complete responses for inquiries from regulatory authorities regarding product safety	2	1	1	0	3	2
Training of affiliate personnel on relevant drug safety responsibilities	2	3	0	0	2	3
Responsibility for preparation and maintenance of pharmacovigilence plans	1	0	3	0	1	4
Identify and propose process improvements	1	3	1	0	3	2
Utilize available tools to identify, clarify and communicate safety signals from multiple data sources; consult and coordinate with safety physicians and other personnel to ensure thorough evaluation of safety signals	0	4	0	0	4	1

Only the function of the preparation and maintenance of pharmacovigilence plans was ranked as “Not so important” by some of respondents. Almost all other functions have been estimated to be of importance for local enterprises, too. Special emphasis was made on narrow professional issues. Although some notable part of listed functions is already applied at local enterprises, there are still others that are considered to be more or less important but are not practiced, yet. Direct supervisors agreed with their subordinates almost unanimously.

Skills and knowledge

As before, all respondents declare that their education is sufficient for them and allows to meet requirements of their employment positions. Aside from basic education, some additional skills and knowledge listed below are required at advanced enterprises.

Table 77 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
Strong knowledge of Armenian pharmaceutical legislation and regulation	2	3	0	0
Strong knowledge of GMP procedures	3	2	0	0
Strong knowledge of Product Safety within Pharmaceuticals	4	1	0	0
Strong knowledge and experience of the adverse event reporting	2	2	1	0
Strong communication skills (written and oral)	2	3	0	0
Excellent organizational skills	2	3	0	0
Excellent team working skills	1	4	0	0
Project management skills	0	4	1	0
Ability to manage multiple tasks simultaneously	0	5	0	0

Almost all presented skills and knowledge are estimated by respondents as “Very important” or “Important”. Responses are divided almost evenly between these two positions of importance. Safety issues and GMP are again of higher importance. Answers of direct supervisors are very similar.

Table 78 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
Strong knowledge of Armenian pharmaceutical legislation and regulation	1	3	1	0	3	2
Strong knowledge of GMP procedures	1	4	0	1	2	2
Strong knowledge of Product Safety within Pharmaceuticals	3	2	0	0	2	3
Strong knowledge and experience of the adverse event reporting	1	3	1	0	2	3
Project management skills	0	3	2	0	2	3
Ability to manage multiple tasks simultaneously	1	3	1	0	1	4

Strong communication skills (written and oral)	2	3	0	0	1	4
Excellent team working skills	2	3	0	0	1	4
Strong computer skills	0	2	3	1	3	1

Respondents did not express urgent need for improving any of their professional skills and knowledge, but they don't mind to improve their qualification regarding some general aspects of their activity. Regulatory issues are the most required aspect for the improvement. Supervisors again share respondents' opinion.

Relevant requirements

The table below illustrates local specialists' attitude towards the relevant additional requirements. The list is very short and estimations are self-explanatory.

Table 79 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Life Sciences background	4	1	0	0	2	0
PharmD Required	1	1	2	1	1	0
Working experience available	3	2	0	0	1	0

Organization of training

The table below shows that again we again face the situation when respondents are not able to select a format for training that will be convenient for their majority.

Table 80 – Preferred formats for training

Training format	Convenient	Not convenient
Half a day	1	4
One full day	1	4
Several (2-3) days	0	5
One week	1	4
More than one week	2	3
Regular	2	3

The only recommendation to be made in these circumstances is the closer discussion of the topic with the management of local enterprises and development of the most - attractive type of the training for various groups of employees.

SCIENTIST (RESEARCH AND DEVELOPMENT SPECIALIST)

Respondents' profile

Employment of Scientists that are engaged at the performance of specific responsibilities regarding to the improvement of existing products and investigation/formulation of new pharmaceuticals is not affordable for every producer. These specialists are expensive due to not only their salaries, but also for high expenses their work requires. That is why, no local producer of pharmaceuticals employs exactly scientists; they even don't have such a position in their structure. Functions of Scientists are coincided by other specialists.

Table 81 – Respondents profile

Enterprise	Respondent's position	Respondent's profession	Respondent's scientific degree	Working experience, years of practice
Arpimed	Head of Quality Control Laboratory	Chemist	Master	3 - 5
Liqvor	Head of Quality Control Laboratory	Engineer, Chemist - Technologist	Master	more than 8
Bizon - 1	Accountant	Biophysicist	Master	1 - 3
Leiko - Alex	Head of Technical Control Division	Pharmaceutist	Candidate of Science	1

We can see from the table, that specialists engaged in various types of control are engaged in the performance of Scientist's functions. To our opinion this is not going to be very effective, since the control of the product quality is already very difficult task to carry out, and it will not leave much time for the sufficient and effective performance of other duties.

Nevertheless, 4 local enterprises introduced their specialists engaged in carrying out duties and responsibilities of Scientists, and they all have relevant professions and scientific degrees. Working experience of different specialists is different; to our understanding this characteristic should exceed 3 years at least, and specialists agree with us.

Duties and responsibilities

Set of duties and responsibilities of Scientist at advanced international producers of pharmaceuticals contains the following main functions that are suggested to be evaluated by local specialists.

Table 82 – Importance and application of specific functions, duties and responsibilities

Functions	Importance of functions (duties, responsibilities)				Practicing the functions	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
Improvement of current pharmaceuticals and contribute to development of future products	2	2	0	0	3	1
Design and conduct R&D experiments for new product development	1	3	0	0	4	0
Write and or review R&D and product	1	3	0	0	3	1

evaluation protocols						
Review stability practices, evaluate stability data, and make recommendations for extending shelf life of the current products	1	2	1	0	3	1
Troubleshoot existing products to find areas for improvements and cost reductions.	1	3	0	0	3	1
Provide scientific and technical support to senior staff members, as required, in the identification and development of new opportunities, leading to commercially viable proprietary formulation and process technologies	1	3	0	0	2	1
To identify and implement new (and/or streamline current) equipment, process and documentation systems and procedures	1	3	0	0	3	1
To support the development of the R&D and GLP documentation	2	1	1	0	2	1
Provide analytical testing support at all stages of production	3	0	1	0	3	1
To take the primary analytical role in R&D development programs from early process development experimental studies through clinical batch release, registration, scale-up and tech transfer to the validation stages	1	2	1	0	2	1
Preparation and/or review of documentation including but not limited to SOP's, SAM's (standard analytical methods, both development and validation documents), master batch records and protocols for stability, sampling and equipment validation	3	1	0	0	4	0

Respondents declare that almost all duties and responsibilities listed in the table above are quite important. Moreover, the majority of presented functions are currently applied at local enterprises[7]. A reservation should be made: the understanding of respondents on listed functions may somewhat differ from their real nature.

Skills and knowledge

Availability of relevant skills and especially knowledge is the main characteristic of the Scientist. Meantime, specialists usually pay appropriate attention to only those skills that they think are important.

Table 83 - Importance of skills and knowledge

Skills and knowledge	Very important	Important	Not so important	Unimportant at all
Ability to troubleshoot and solve scientific and technical challenges either alone or in a team environment	1	3	0	0

[7] We mean at enterprises that think they have the position of the Scientist

Thorough understanding of current product attributes and manufacturing processes	3	1	0	0
Working knowledge of mathematical / statistical design and modeling	0	2	1	1
Strong leadership	1	1	1	0
Ability to think critically and creatively	1	3	0	0
Ability to influence and motivate others	1	3	0	0
Ability to manage multiple tasks simultaneously	1	3	0	0
Strong computer skills	0	4	0	0
Good verbal and written communication skills	1	3	0	0

Respondents think that almost all skills and knowledge we picked up from the best practice are quite important. Only one respondent estimated the knowledge of mathematics and statistics as “Unimportant at all”. This may be explained by the specificities of the activity of their enterprise and also by their unawareness of usage of statistics as a scientific research tool.

Table 84 – Availability/possession of skills and knowledge and improvement needs

Skills and knowledge	Availability / Possession			Improvement needs		
	Excellent	Good	Tolerable	Urgent need	Need	No need
Ability to troubleshoot and solve scientific and technical challenges either alone or in a team environment	1	3	0	0	1	3
Thorough understanding of current product attributes and manufacturing processes	1	3	0	0	4	0
Working knowledge of mathematical / statistical design and modeling	0	2	1	0	3	1
Strong leadership	1	1	2	0	0	4
Ability to think critically and creatively	1	3	0	0	1	3
Ability to influence and motivate others	0	2	2	0	0	4
Ability to manage multiple tasks simultaneously	0	3	1	0	2	2
Strong computer skills	0	2	2	0	4	0
Good verbal and written communication skills	0	4	0	0	1	3

Although respondents stay quite modest while estimating the availability of their knowledge, they don’t express “Urgent need” for improving any skills and knowledge. Moreover, they mention only few skills they would like to improve. Special emphasis was made on narrow professional skills, academic knowledge of mathematics and statistics and computer literacy. In general, direct supervisors agreed with the estimates of availability of specific skills and knowledge, but suggested some corrections, too.

Relevant requirements

The list of relevant requirements is limited to only two factors: education and experience. Below three varieties of the combination of these two parameters are suggested.

Table 85 – Importance and application of relevant requirements

Requirements	Importance of requirements				Practicing the requirements	
	Very important	Important	Not so important	Unim-portant at all	Yes	No
BS degree in Chemistry, Pharmacy, Biochemistry or life science with 6+ years' proven experience in product development	1	3	0	0	2	1
MS degree in Chemistry, Pharmacy, Biochemistry or life science with 4+ years proven experience in product development	0	4	0	0	4	0
Ph.D. in chemistry or life science with 2+ years experience in product development	1	1	2	0	2	1

Respondents' answers distributed almost evenly between the first two options. This is legitimate and understandable. Deviation of the answers can be explained by differing features of assessed enterprises, such as the volume of production and assortment, availability of fixed assets, etc.

Organization of training

The most convenient format for training that respondents expressed is the maturity of 2-3 days. We are not going to discuss the effectiveness of this format, but this maturity is more relevant for some types of seminars and conferences.

Table 86 – Preferred formats for training

Training format	Convenient	Not convenient
Half a day	1	3
One full day	2	2
Several (2-3) days	3	1
One week	2	2
More than one week	2	2
Regular	1	3

Date: 08 December, 2008

Skills and Knowledge Needs Assessment For Pharmaceutical Industry

Report, Volume III

Job Description Templates

Authored By: AM Partners Consulting Company

USAID FROM THE AMERICAN PEOPLE

CAPS

CONTENT

POSITION:

Qualified person

SUMMARY:

Ensures that each batch has been produced and tested/checked in accordance with the directives and the marketing authorization. Often the Qualified Person is the Head of Quality, but could also be the Head of Production. Key specialist for contacting internal and external audits, report to the management and shareholders of the enterprise.

DUTIES AND RESPONSIBILITIES:

1. Prior batch to release should ensure:
   - manufacture has been carried out in accordance with Good Manufacturing Practice SOPs
   - the principal manufacturing and laboratory testing processes have been validated
   - any deviations or planned changes in production or quality control have been authorized by the persons responsible
   - all the necessary checks and tests have been performed
   - all necessary production and quality control documentation has been completed and endorsed by the staff authorized to do so
   - the batch and its manufacture comply with the provisions of the marketing division.
2. Participate in establishing and maintaining a validation program for all company.
3. Handle the complaints concerning potentially defective products and execute and coordinate product recalls.
4. Ensure that all inspection issues raised by internal and external bodies are comprehensively resolved to the agreed timescales.
5. Participate in development and review different departmental SOPs.
6. Be a member of the company management team, including its strategic direction.
7. Manage the training process of employees.
8. Create methods and procedures for continuous improvement of production.
9. Preparation for and management of Regulatory Inspections.
10. Design criteria for an effective QMS.
11. Monitoring of documentation and record keeping.
12. Conduct production planning, scheduling, and inventory control.

JOB REQUIREMENTS:

1. Education to degree level in one of the following spheres: pharmacy, medicine, chemistry, pharmaceutical chemistry and technology, biology.
2. Practical experience over at least two years in management in either Production or Quality Control.

SKILLS AND KNOWLEDGE:

1. Comprehensive knowledge of Armenian pharmaceutical legislation (as well as EU, WHO) relating to the manufacture, storage and supply of medicinal products.

2. Knowledge of principles and practice of GMP and QA.
3. Interpersonal skills (leadership, delegation, communication, etc).
4. Knowledge of principles of design, selection, qualification and maintenance of premises, equipment, utilities, and services.
5. Knowledge of calibration, preventative maintenance and training processes.
6. Good statistical and math skills.
7. Knowledge of key therapeutic drug classifications.
8. Knowledge of disease states and their treatment with pharmaceuticals.
9. Knowledge of the major processing techniques, their limitations and control parameters.
10. Knowledge of the principles of process validation and control.
11. Knowledge of the principles of laboratory analysis.
12. Knowledge of pharmaceutical microbiology.
13. Knowledge of Good Laboratory Practices.
14. Ability to manage multiple tasks simultaneously,
15. Computer skills.
16. Good verbal and written communication skills.
17. Ability to work in a team environment.

POSITION:

Head of Production

SUMMARY:

Organizes the manufacturing process and control all stages of it, starting from the procurement of inputs and finishing with release of final products. Together with the Head of Quality Control implements the operational supervision of the operation of the enterprise.

DUTIES AND RESPONSIBILITIES:

1. Ensure that products are produced and stored according to the appropriate documentation.
2. Establish guidelines for continuous risk reduction.
3. Day to day management of the production floor.
4. Approve the instructions relating to production operations.
5. Assures continuous improvement of production processes.
6. Ensure that the production records are evaluated and signed by designed person before they are sent to the Quality Control Department.
7. Check the maintenance of the department, premises and equipment.
8. Ensure that the appropriate process validations and calibrations of control equipment are performed and recorded and the reports made available.
9. Ensure that the required initial and continuing training of production personnel is carried out and adapted according to need.
10. Responsible for safety, regulatory and/or environmental compliance.
11. Strong support linkage with the following departments:
    - Systems - maintaining/upgrading manufacturing computer systems and network interfaces
    - Plant Engineering - assisting with the design and commissioning of new equipment or equipment modifications to provide for new product introductions and continuous improvement activities
    - Validation/Tech Support - in facilitating plant trials, new product activities and validation of existing and new procedures, equipment and computer systems
    - Conducts training for new technologies, new products and new associate processes.
    - Marketing department – in reviewing sales levels and planning new yearly production rate.
12. Responsible for yearly production planning

Functions jointly exercised with the Head of Quality Control; responsibilities relating to quality.

13. Authorization of written procedures and other documents.
14. Monitoring and control of the manufacturing environment.
15. Maintain and control plant hygiene.
16. Process validation and calibration of analytical apparatus.
17. Training including the application and principles of quality assurance.
18. Approval and monitoring of suppliers of materials.
19. Approval and monitoring of contract manufacturers (outsourcing) (if there is).
20. Designation and monitoring of storage conditions for materials and products.
21. Performance and evaluation of in-process controls.
22. Retention of records.

23. Monitoring of compliance with the requirements of GMP.

JOB REQUIREMENTS:

1. Higher education in respective fields and 4+ years experience.
2. Bachelor degree in respective fields and 2+ years experience.
3. Experience in supervisory position.
4. Pharmaceutical industry background in operations.
5. Experience in appropriate manufacturing processes.
6. Flexibility to work overtime and some weekends.

SKILLS AND KNOWLEDGE:

1. Strong knowledge of Armenian pharmaceutical legislation and regulation (Medicines Law, Licensing Law, etc.) GMP, Environmental and other regulatory compliance requirements.
2. Strong knowledge of work and safety procedures.
3. Good working knowledge of formulations and various process technologies.
4. Strong knowledge of all manufacturing operations, equipment, and SOP's.
5. Ability in providing proper solutions to problems that arise outside of normal procedures and to systems related issues.
6. Capable of adapting and managing different technologies.
7. Ability to provide effective leadership to employees in manufacturing, engineering and operations.
8. Ability to interact with senior executives, senior technical managers, business heads, customers, and suppliers within and external to company.
9. Ability to pursue and manage process optimization.
10. Ability to coach, counsel, manage and direct personnel in appropriate division/business unit assignments.
11. Ability to interact and negotiate with regulatory agencies on routine compliance issues.
12. Ability to manage multiple tasks simultaneously,
13. Computer skills.
14. Good verbal and written communication skills.
15. Ability to work in a team environment.

POSITION:

Head of Quality Control

SUMMARY:

Controls the quality issues (Maintains production and product's quality); manage the work of the QC Laboratory and its staff. Together with the Head of Production implements the operational supervision of the operation of the enterprise.

DUTIES AND RESPONSIBILITIES:

1. Approve or reject starting materials, packaging materials, and intermediate, bulk and finished products in relation to their specifications.
2. Evaluate batch records.
3. Ensure that all necessary laboratory testing is carried out.
4. Approve specifications, sampling instructions, test methods and other quality control procedures.
5. Approve and monitor any contract analysts (if there are).
6. Check the maintenance of the department (lab), premises and equipment.
7. Ensure that the appropriate validations, including those of analytical procedures and calibrations of control equipment are carried out.
8. Ensure that the required initial and continuing training of department personnel is carried out and adapted according to need.
9. Manage activities of the Quality Testing Laboratories.
10. Review of documentation for new product introduction, method validation, instrument validation and updating of testing standards, test methods, stability analytical reports and SOPs.
11. Liaising with QC, Technology, Production and Registration.

Functions jointly exercised with the Head of Production; responsibilities relating to quality.

12. Authorization of written standard operational procedures and other documents.
13. Monitoring and control of the manufacturing environment.
14. Maintain and control plant hygiene.
15. Process validation and calibration of analytical apparatus.
16. Training including the application and principles of quality assurance.
17. Approval and monitoring of suppliers of materials.
18. Approval and monitoring of contract manufacturers (outsourcing) (if there is).
19. Designation and monitoring of storage conditions for materials and products.
20. Performance and evaluation of in-process controls.
21. Retention of records.
22. Monitoring of compliance with the requirements of GMP.
23. Inspection, investigation, and taking of samples, in order to monitor factors which may affect product quality.

JOB REQUIREMENTS:

1. University or College degree or diploma from a recognized institution in a science related subject.

2. University degree in Chemistry with 4+ years in analytical and microbiological pharmaceutical experience.
3. Ph.D. in Chemistry with 4+ years of analytical and microbiological pharmaceutical experience is desirable.
4. Experience in a pharma lab with experience in analytical methods& instrumentation.

SKILLS AND KNOWLEDGE:

1. Strong knowledge of Armenian and international pharmaceutical legislation and regulation (Medicines Law, Licensing Law, etc.) GMP, Environmental and other regulatory compliance requirements.
2. Knowledge of GLP, GMP and Safety procedures, including those pertinent to them.
3. Knowledge of work and safety procedures.
4. Knowledge of instrument and method validation.
5. Ability or aptitude for continuous learning and analytical problem solving.
6. Ability to manage multiple tasks simultaneously,
7. Computer skills.
8. Good verbal and written communication skills.
9. Ability to work in a team environment.

POSITION:

Storage/Warehouse Person

SUMMARY:

Organizes proper stocking of inputs, intermediate products, final pharmaceuticals and their release. Special emphasis is made on safety and hazard issues.

DUTIES AND RESPONSIBILITIES:

1. Implement and maintain procedures designed to maintain accurate inventories, proper input and storage of the various categories products: starting and packaging materials, finished products, products in quarantine, and released, expired, rejected, returned or recalled products.
2. Implement and maintain procedures designed to maintain accurate inventories, proper storage of radioactive materials, narcotics and other hazardous, sensitive and/or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion, (e.g. combustible liquids and solids and pressurized gases) should be stored in a dedicated area that is subject to appropriate additional safety and security measures.
3. Responsibility for monitoring and enforcing quality and productivity standards.
4. Coordination and management of the flow of materials, ensuring proper receipt, storage, picking, shipping and documentation of these processes.
5. Adhering to and improving the standard operating policies and promoting regulatory and safety compliance.
6. Supply of components and raw materials to the respective departments.
7. Load and unload all domestic and export production.
8. Maintain forklift trucks according to established procedures.
9. Coordinate and record housekeeping tasks (e.g. sweeping, product consolidation) to maintain neat, clean, dry and maintain acceptable temperature limits.
10. Utilization of computerized material tracking system to locate components and maximize warehouse space.
11. Input data into receiving system and shipping system.
12. Provision of daily direct supervision to warehouse and distribution activities.
13. Provision of strong leadership, coaching and training of warehouse colleagues.
14. Overseeing the operations of designated warehousing and distribution functions to ensure that all functions comply with government and corporate requirements while striving to continually improve.
15. Assist with assuring that proper building and equipment maintenance.
16. Provision of a strong emphasis on safety for the warehouse and facility environment.

JOB REQUIREMENTS:

1. At least vocational education in relevant spheres.
2. Warehouse related experience.
3. Knowledge of Safety requirements and Transportation rules.
4. Warehouse Management Automatized Systems using experience.
5. Flexibility to work 12 hour days (including weekends), overtime and all shifts is required.

SKILLS AND KNOWLEDGE:

1. Knowledge of Armenian and international regulations on narcotics and psychoactive drugs.
2. Knowledge of GMP, Good Storage Practices and Good Distribution Practices.
3. Knowledge of work and safety procedures.
4. Willingness and ability to operate a forklift truck.
5. Ability to wear respiratory protection to perform specific tasks.
6. Ability and willingness to manage train others.
7. Ability to lift, bend and move heavy objects.
8. Ability to manage multiple tasks simultaneously,
9. Computer skills.
10. Good verbal and written communication skills.
11. Ability to work in a team environment.

POSITION:

Laboratory Supervisor

SUMMARY:

Conducts direct supervision of the QC Laboratory. Ensures the proper retention of all documents and effective operation of the equipment and instruments.

DUTIES AND RESPONSIBILITIES:

1. Organization of activities involved in conducting tests and/or assaying of raw material, intermediates or finished products.
2. Organization of analysis of finished product, in-process, stability and (where necessary) validation samples.
3. Organization of production process validation.
4. Supervision of employees performing testing and support activities.
5. Critically evaluating data generated and recommend acceptance or rejection of samples, and performing lab work accurately and timely.
6. Maintaining records, developing productivity improvement plans, maintaining adequate inventory of supplies, training records.
7. Assure that the laboratories are in compliance with GMP and GLP regulations as well as company procedures; that the products and materials are tested as specified in the specifications and methodologies.
8. Maintaining adequate instrumentation and laboratory facilities.
9. Maintaining a safe working environment.
10. Maintaining an awareness of technical developments in instrumentation analysis.
11. Ensuring that equipment and services are kept in a safe and validated condition.
12. Approval of all work generated by analysts. Approval of laboratory validation and calibration reports.
13. Updating SOPs, Process Specific Training Modules, Control procedures, etc.
14. Training personnel to ensure employees are competent and qualified.
15. Control of laboratory investigation within the laboratory.
16. Control of purchasing of laboratory equipment and chemicals.
17. Assists in internal and external audits.

JOB REQUIREMENTS:

1. University degree in Chemistry with 4+ years in analytical and microbiological pharmaceutical experience.
2. Ph.D. in Chemistry with 4+ years of analytical and microbiological pharmaceutical experience is desirable.
3. Experience in a pharma lab with experience in analytical methods& instrumentation.

SKILLS AND KNOWLEDGE:

1. Strong knowledge of Armenian pharmaceutical legislation and regulation (Medicines Law, Licensing Law, etc.) GMP, Environmental and other regulatory compliance requirements.
2. Knowledge of GLP, GMP and Safety procedures.
3. Knowledge of instrument and method validation.
4. Good interpersonal and supervisory skills.
5. Ability or aptitude for continuous learning and analytical problem solving.
6. Ability to manage multiple tasks simultaneously,
7. Computer skills.
8. Good verbal and written communication skills.
9. Ability to work in a team environment.

POSITION:

Head of Technology/Technologist

SUMMARY:

Deals with technological aspects of the manufacturing of pharmaceuticals. Engaged in engineering design, selection and maintenance of the technological equipment, and process improvement.

DUTIES AND RESPONSIBILITIES:

1. Develop and perform work in accordance with SOPs, GMPs and established safety procedures.
2. Develop strategy, evaluation and selection of production process technology considering current and future needs.
3. Responsible for evaluation, pilot/vendor testing and selection of process equipment, as well as associated clean utilities.
4. Responsible for process validation
5. Complete process engineering design.
6. Set process engineering technical standards and standard practices.
7. Development and maintain process descriptions, process block flow diagrams, specifications, and other process/equipment documents for engineering, design, operations and regulatory filings.
8. Primary contact for process engineering and technology issues/questions of Regulatory Agencies.
9. Responsible for continuous production process improvement for highest efficiency.
10. Responsible for production process modification and upgrades.
11. Integrate and contribute to cross-functional design, product and project teams.
12. Responsible for establishment and maintenance of disposal processes

JOB REQUIREMENTS:

1. Qualification of BS/MS Chemical Engineering
2. Technology leadership in the pharmaceutical Industry.
3. Experience in discussion and inspections with Regulatory Agencies.

SKILLS AND KNOWLEDGE:

1. Good knowledge of GMP regulatory requirements, including the specifications pertinent to them..
2. Good knowledge, experience in novel, emerging and disposable process technology.
3. Knowledge of work and safety procedures.
4. Ability to manage multiple tasks simultaneously,
5. Computer skills.
6. Good verbal and written communication skills.
7. Ability to work in a team environment.

POSITION:

R&D Specialist

SUMMARY:

Conducts intensive R&D with the purpose of improving characteristics (especially the shelf life and stability) of existing range of pharmaceuticals, and synthesize new varieties. Also conduct analytical assessments and assist other employees in preparation and retention of various documents.

DUTIES AND RESPONSIBILITIES:

1. Participate in development of current pharmaceuticals and contribute to development of future products.
2. Design and conduct R&D experiments for new product development.
3. Write and or review R&D and product evaluation protocols.
4. Review current stability practices, evaluate stability data, and make recommendations for improvements and extending shelf life of the current products.
5. Optimize the composition of the current products and new product developments.
6. Trouble shoot existing products to find areas for performance improvements and product cost reductions.
7. Provide scientific and technical support to senior staff members, as required, in the identification and development of new opportunities, leading to commercially viable proprietary formulation and process technologies.
8. Identify and implement new (and/or streamline current) equipment, process and documentation systems and procedures or improve the existing ones.
9. Assist in the preparation of the GLP documentation.
10. Provide analytical testing support for raw material release, in-process, experimental studies and clinical batch release, and stability testing programs.
11. To take the primary/supporting analytical role in R&D development programs from early formulation/process development experimental studies through clinical batch release, registration, scale-up and tech transfer to the validation stages for new pharmaceutical products using the company's technology platforms.
12. Preparation and/or review of documentation including but not limited to SOP's, SAM's (standard analytical methods, both development and validation documents), master batch records and protocols for stability, sampling and equipment validation.

JOB REQUIREMENTS:

1. BS degree in Chemistry, Pharmacy, Biochemistry or life science with 6+ years' proven experience in product development.
2. MS degree in Chemistry, Pharmacy, Biochemistry or life science with 4+ years' proven experience in product development is desirable.
3. Ph.D. in Chemistry, Pharmacy, Biochemistry or life science with 2+ years experience in product development is desirable.

SKILLS AND KNOWLEDGE:

1. Ability to troubleshoot and solve scientific and technical challenges either alone or in a team environment.
2. Thorough understanding of current product attributes and manufacturing processes.
3. Knowledge of work and safety procedures.
4. Working knowledge of mathematical / statistical design and modelling.
5. Strong leadership.
6. Ability to think critically and creatively.
7. Ability to influence and motivate others.
8. Ability to manage multiple tasks simultaneously,
9. Computer skills.
10. Good verbal and written communication skills.
11. Ability to work in a team environment.

POSITION:

Quality Control Analyst, Chemist

SUMMARY:

Conducts laboratory analysis and testing at all stages of the manufacturing of pharmaceuticals. Ensures the proper work of the laboratory equipment and instruments. Prepares various documents and protocols and ensure their proper retention.

DUTIES AND RESPONSIBILITIES:

1. Testing of all laboratory samples including raw materials, in-process, finished products, validation, stability, environmental (as per written procedure or as per pharmacopeia).
2. Observe GLP/GMP at all times.
3. Recording of analytical results accurately.
4. Operation, maintenance and calibration of laboratory instruments.
5. Maintains usage of laboratory chemicals and keeping records.
6. Preparation and execution of instrument qualification and method validation protocols.
7. To ensure that the laboratory is kept clean, tidy and safe at all times.
8. Report any non-conformance, instrument malfunction, accident or other abnormal occurrence to immediate superior.
9. Verify analytical data of other analysts within the lab as requested.
10. Review and interpretation of data for conformance to procedures, standards and protocols and/or real-time recognition of aberrant data and results.
11. Troubleshoot equipment and methods as required.
12. Assist in improvement of quality systems by creating or revising worksheets and other lab documentation systems.
13. Comply with and implement safety standards.
14. Executes notification to management when required by procedures or standards.
15. Participate fully in cross functional training.
16. Develop training materials, train and mentoring others.

JOB REQUIREMENTS:

1. At least BS in Chemistry, Analytical chemistry or a related subject.
2. Relevant laboratory experience.
3. Experience in pharmacopeial testing, along with method development, validation experience and working knowledge of GMP.

SKILLS AND KNOWLEDGE:

1. Strong knowledge GLP/GMP requirements, including the specifications pertinent to them.
2. Ability to read, analyze, interpret and communicate technical data, technical procedures or regulations.
3. Knowledge of work and safety procedures.
4. Knowledge of laboratory instrumentation

5. Strong technical ability and the ability to troubleshoot GC, HPLC and Dissolution testing methods is essential.
6. Ability to working in a lab environment including wearing appropriate PPE and other safety required equipment (such as a respirator).
7. Excellent organization, planning and judgment skills.
8. Ability to manage multiple tasks simultaneously,
9. Computer skills.
10. Good verbal and written communication skills.
11. Ability to work in a team environment.

POSITION:

Microbiologist

SUMMARY:

Conducts various microbiological analyses at the QC Laboratory, implements validation, develops QC Systems, etc. Primary contact for all Microbiology related issues and inspections of Regulatory Authorities.

DUTIES AND RESPONSIBILITIES:

1. Work in accordance to SOP, GMP and GLP requirements.
2. Sampling and the microbiological analysis of samples and environmental monitoring functions.
3. Validation of Test Methods.
4. Documentation of results or inputting of data onto the LIMS (Laboratory Information Management Systems).
5. Isolation and identification of micro-organisms.
6. Trending and review of results.
7. Report out-of-trend or out-of-specification results.
8. Completion of Laboratory Investigation and the preparation of associated reports.
9. Responsible for development, execution and maintenance of Quality Control systems, standards, practices and procedures for raw materials, utilities, environmental, in-process and final product testing.
10. Support continuous process performance evaluation and continuous process improvement for highest efficiency.
11. Integrate, contribute, and/or lead cross-functional project teams as required.
12. Primary contact for all QC Microbiology related filings and inspections of Regulatory Agencies.

JOB REQUIREMENTS:

1. University or advanced degree in Microbiology or related sciences.
2. Minimum of 2+ years GMP quality control and/or QC related experience, at least 1 year of which are direct microbiology laboratory experience.

SKILLS AND KNOWLEDGE:

1. Good Knowledge of GMP, GLP and Safety requirements.
2. Strong knowledge of microbiology and the GMP as applied in the area of microbiological control of production.
3. Current knowledge or proven interest in starting-up and qualifying new facilities, tech transfers and manufacturing operations.
4. Knowledge of laboratory instrumentation and methods.
5. Ability to manage multiple tasks simultaneously,
6. Computer skills.
7. Good verbal and written communication skills.
8. Ability to work in a team environment.

POSITION:

Laboratory Technician

SUMMARY:

Conducts various types of testing, maintains QC Laboratory equipment, instruments and glassware.

DUTIES AND RESPONSIBILITIES:

1. Responsible for performing full QCS testing on starting and packaging materials, in-process, Batches and Finished Product.
2. Maintain and utilize instrumentation for analytical purposes.
3. Support Manufacturing in a timely manner by analyzing all intermediates and finished product that enters the laboratory.
4. Prepare and keep records on analysis of intermediates, finished batches and packaged products.
5. Assist the Chemist(s) in special projects, including Plant Trial and Process Validation testing.
6. Conduct cleaning responsibilities of workplace.
7. Daily instrument calibration.

JOB REQUIREMENTS:

1. Vocational education in General Chemistry or related subject
2. Experience in pharmaceutical laboratories.

SKILLS AND KNOWLEDGE:

1. Good Knowledge of GMP and GLP.
2. Knowledge of work and safety procedures.
3. Detail oriented record keeping skills.
4. Ability to manage multiple tasks simultaneously,
5. Computer skills.
6. Good verbal and written communication skills.
7. Ability to work in a team environment.

POSITION:

Production Operator

SUMMARY:

Immediately engaged in the process of pharmaceuticals' manufacturing. Conducts servicing and maintenance of manufacturing equipment, controls the exploitation of equipment and instruments.

DUTIES AND RESPONSIBILITIES:

1. To work as part of a team performing the various stages of pharmaceutical production as defined by GMP, SOPs, established safety procedures and company policies and procedures relative to production, testing/inspection, and documentation of quality products..
2. Perform duties of operating assigned machinery consisting of servicing machines with materials, removing finished materials from machine, and assuring smooth flow of product.
3. Report any deviations from standards to team leader promptly.
4. Complete and review on-line batch records. In case of problems identification immediately report to area management.
5. To work to a manufacturing schedule and ensure all documentation is completed accurately, legibly and on time and maintain records as required.
6. Sterile core operators will also have an understanding of aseptic behaviors; media fills including line interventions, and have a basic knowledge of viable and non-viable monitoring equipment. This will include performing sampling both inside and outside the sterile core.
7. Perform visual and physical checks of in-process and finished materials.
8. Follow batch and SOP instructions to perform in-process and finished product sampling. Label and deliver samples to appropriate locations (laboratory, etc.).
9. Performing end-of-day cleaning of the equipment, the manufacturing facility, especially the aseptic areas.
10. Taking responsibility for assembling, testing, disassembling, and sanitizing various filling and packaging equipment.
11. Being familiar with job related hazards. Report all discrepancies to process facilitator.
12. Contribution to the continuous improvement of processes, procedures and quality.
13. Perform inventory control and reconciliation activities.
14. Flexibility in conducting filling, inspection and packaging functions.
15. Assist technical staff with preventive maintenance procedures.

JOB REQUIREMENTS:

1. Vocational education at least.
2. 2+ years experience in the pharmaceutical industry.
3. Experience with machine changeovers and use of hand tools strongly preferred.
4. Ability for visual test verification.

SKILLS AND KNOWLEDGE:

1. Excellent understanding of the requirements of GMP, including the specifications pertinent to them.
2. Strong knowledge of sterile room techniques, where appropriate, and chemical handling and storage.
3. Mechanical/technical aptitude.
4. Strong knowledge of work and personal safety requirements.
5. Working knowledge of automated and semi-automated inspection equipment.
6. Ability to independently read and comprehend documents such as safety rules, operating and maintenance instructions, and procedure manuals.
7. Ability to select the correct actions when operational conditions change (i.e. ability to follow 'if-then' statements).
8. Knowledge of product security controls including controlled substance handling.
9. Ability of visual control of testing process.
10. Good attention to details. Individual must be capable of keeping accurate records and performing mathematical calculations.
11. Ability to manage multiple tasks simultaneously,
12. Computer skills.
13. Good verbal and written communication skills.
14. Ability to work in a team environment.

POSITION:

Packaging Operator

SUMMARY:

Conducts packaging processes of pharmaceuticals, checks the exactness of the technological packaging equipment, makes inspections of packaging materials.

DUTIES AND RESPONSIBILITIES:

1. Handle all packaging process stages (packaging and labeling).
2. Follow necessary SOP's, GMP regulations and safety guidelines and company policies and procedures relative to production, testing/inspection, and documentation of quality products.
3. Reading and following packaging instructions.
4. Perform in-process testing and finished goods inspection as required in SOPs and batch documentation.
5. Complete all necessary production and maintenance paperwork.
6. Set-up, operate and adjust packaging equipment to maximize quality and output.
7. Perform minor troubleshooting and corrections.
8. Performs tasks to support room cleaning, inspection, assembly, case packing, material handling and facility cleaning.
9. Generate and/or support new ideas/ways to increase productivity and efficiencies.
10. Performs other duties as requested.

JOB REQUIREMENTS:

1. Vocational education at least.
2. 1 year (recent/contiguous) experience operating filling/packaging equipment.
3. Experience with machine changeovers and use of hand tools preferred.
4. Flexibility to work weekends, overtime and on all shifts.

SKILLS AND KNOWLEDGE:

1. Strong knowledge of GMP procedures, including the specifications pertinent to them.
2. Knowledge of work and safety procedures.
3. Good math skills.
4. Ability and willingness to learn new things (i.e., hand tool use, use of manuals).
5. Ability to adjust quickly to new responsibilities and tasks.
6. Must be able to lift, push and pull up to 15-25 kg.
7. Must have the ability to stand, bend and walk for up to 8-10 hour daily.
8. Mechanical aptitude.
9. Excellent hand-eye coordination. Good eyesight for inspection of finished product.
10. Ability to manage multiple tasks simultaneously,
11. Computer skills.
12. Good verbal and written communication skills.
13. Ability to work in a team environment.

POSITION:

Complaint & Pharmacovigilence Officer

SUMMARY:

Keeps records on complaints and conducts investigations. Cooperates closely with regulatory Authorities on safety issues. Follows the changes and modifications at local and international markets, reviews analytical materials.

DUTIES AND RESPONSIBILITIES:

1. Follow all SOP's, appropriate regulations and company policies and procedures, relative complaints including the need to consider a recall and adverse reactions monitoring of products.
2. Record any complaint concerning a product defect with all the original details and report to designed person for appropriate action.
3. Investigate whether a complaint was caused because of counterfeiting.
4. Contact person for communication with Regulatory Authorities on drug safety issues.
5. Review and reporting of spontaneous adverse events internally to assigned person and externally to regulatory authority.
6. Investigation and follow up international and Armenian adverse event reports.
7. Review and submit Periodic Safety Update Reports (PSURs) and Annual Safety Reports (ASRs) to regulatory authorities.
8. Define evaluation plan with partners (physicians, team members, business partners) to appropriately assess and complete responses for inquiries from regulatory authorities and internal and other external sources regarding product safety.
9. Training of affiliate personnel on relevant drug safety responsibilities.
10. Responsibility for preparation and maintenance of pharmacovigilence plans.
11. Identify and propose process improvements.
12. Receive and clarify drugs' safety signals and communicate relevant safety information to the appropriate persons.

JOB REQUIREMENTS:

1. BS/MS degree in Pharmacy or Clinical education.
2. 2+ years of relevant experience.

SKILLS AND KNOWLEDGE:

1. Strong knowledge of Armenian and international pharmaceutical legislation and regulation.
2. Strong knowledge of GMP procedures.
3. Strong knowledge of Product Safety within Pharmaceuticals and other safety procedures.
4. Strong knowledge and experience of the adverse event reporting.
5. Project management skills.
6. Ability to manage multiple tasks simultaneously,
7. Computer skills.

8. Good verbal and written communication skills.
9. Ability to work in a team environment.

POSITION:

Registration Specialist

SUMMARY:

Primary contact for the Regulatory Authorities. Preparation, submission, analysis and retention of various documents. Contribution to development of new products' descriptions, guidance and instructions,

DUTIES AND RESPONSIBILITIES:

1. Facilitation of the regulatory aspects of projects/products, including documentation submitted to regulatory agencies and regulatory agency interactions.
2. Assurance that the documentation is complete and complies with applicable regulatory requirements.
3. Assessment of documents incoming from regulatory agencies.
4. Reviewing of documentation from other internal departments.
5. Provides consultations regarding to required regulatory documents to other internal departments.
6. Contribution to analyses of regulatory guidance documents, regulations that impact Company products and operations.
7. Monitoring, analysis and advice to the business on existing and new regulatory requirements that may impact the development process and emerging trends. Balance ideas and practices against regulatory risks.
8. Coordination of regulatory inspections and audits.

JOB REQUIREMENTS:

1. Master Degree in Pharmacy, Chemistry, Pharmacology or related subject.
2. Ph.D. in Pharmacy, Chemistry, Pharmacology or related subject.
3. 3+ years experience in the registration and re-registration of pharmaceutical products with good track records and references.

SKILLS AND KNOWLEDGE:

1. Strong knowledge of regulatory requirements for Armenia and other countries (where company plan to export), including registration procedures.
2. Strong knowledge of international guidelines.
3. Knowledge of work and safety procedures.
4. Ability to coordinate Company's operations with the requirements of regulatory agencies.
5. Ability to manage multiple tasks simultaneously,
6. Computer skills.
7. Good verbal and written communication skills.
8. Ability to work in a team environment.

POSITION:

Marketing Specialist

SUMMARY:

Development of the Marketing Strategy and Policies, implementation of marketing research, application of various promotional tools, analyses of market share and position, initiation of various events.

DUTIES AND RESPONSIBILITIES:

1. Operation in accordance with Armenian and other countries (where export is going to be done) pharmaceutical legislation and regulation, company Policies and Procedures.
2. Operation in accordance with internal the Marketing Operating Practices and Procedures.
3. Development of marketing strategy, tactics and via the market research.
4. Annual marketing planning.
5. Development of the product marketing plan and proactive alignment the product's promotional requirements.
6. Development and managing advertising, educational and other material.
7. Work across functions to coordinate development of marketing materials and ensure consistent delivery of brand message to consumers.
8. Regularly perform professional analysis and qualitative/quantitative research of the market. Conduct competitors' research.
9. Conduct market segmentation and consumers' targeting.
10. Provides product briefings and training to the sales specialists.
11. Perform field visits to monitor implementation of marketing strategy by the sales specialists.
12. Participates in the preparation of sales, market share, patient, promotional – and promotional budget – objectives.

JOB REQUIREMENTS:

1. Bachelors degree, marketing or related field.
2. 3+ years experience in marketing or promotion fields.
3. Experience in advertising fields and working with mass media.
4. MBA Preferred.

SKILLS AND KNOWLEDGE:

1. Strong knowledge of Armenian drug regulation concerning medicines promotion (Medicines Law, Advertisement Law, etc).
2. Strong knowledge of international guidelines concerning medicines promotion (WHO, EU, etc).
3. Strategic thinking and analytical skills.
4. Be self-directed and inquisitive.
5. Ability to motivate others.
6. Ability to work effectively within changing environment.
7. Strong project management, budget management and prioritization skills.
8. Strong decision-making skills and experience.

9. Knowledge of Marketing & Promotion techniques.
10. Ability to manage multiple tasks simultaneously,
11. Computer skills.
12. Excellent verbal and written communication skills.
13. Ability to work in a team environment.