# ISO 9001:2015 Quality Self-Assessment

including

## Rx-360 Supplier Assessment Questionnaire
Module 1, Company Information

Relevant for

## Life Science business

The purpose of this document is informing our customer about the quality management system of our Life Science business of Merck KGaA, Darmstadt, Germany.

The table of content of this document is aligned to „Contents of ISO 9001:2015 Quality Management Systems“. The company profile is aligned to „RX 360 Supplier Assessment Questionnaire, Module 1“.

We trust that our quality measures meet our customer‘s and industry expectations and exceed general standards.

As a trusted partner of our customers, we deliver quality - always.

RX 360 An International Pharmaceutical Supply Chain Consortium

Merck KGaA, Darmstadt, Germany is an active member of the Rx 360 Consortium.

Merck KGaA, Darmstadt, Germany
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany
Phone +49 6151 72-0

Sigma-Aldrich Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
3050 Spruce Street
St. Louis, MO 63103, USA
Phone +1 (800) 521-8956 / +1 (314) 771-5765

EMD Millipore Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive Burlington,
MA 01803, USA
Phone +1 (781) 533-6000

# Table of Contents

# I Company Profile

Our purpose is to solve the toughest problems in life science by collaborating with the global scientific community and through that, we aim to accelerate access to better health for people everywhere.

Please find attached our company profile according to RX 360 Supplier Assessment Questionnaire Module 1, Version 2

| SECTION 1. General Company Information--Rx 360 | |
|---|---|
| 1.1 | Company Name:<br>Merck KGaA, Darmstadt, Germany has a Life Science business |
| 1.2 | Company Address:<br>The legal entities that make up the Life Science business are listed below:<br>1. Merck KGaA, Darmstadt, Germany<br>Corporation with General Partners<br>Frankfurter Str.250, 64293 Darmstadt, Germany<br>2. EMD Millipore Corporation<br>A subsidiary of Merck KGaA, Darmstadt, Germany<br>400 Summit Drive, Burlington, MA 01803, USA<br>3. Sigma-Aldrich Corporation<br>A subsidiary of Merck KGaA, Darmstadt, Germany<br>3050 Spruce Street St. Louis, MO 63103 U.S.A.<br>GPS Coordinates:<br>1. Merck KGaA, Darmstadt, Germany: Coordinates (main entrance): Latitude 49.89510\| Longitude 8.65384<br>2. EMD Millipore Corporation: Latitude: 44.9048126 \| Longitude:-73.2972118<br>3. Sigma-Aldrich Corporation, St. Lois USA: Latitude: 38.627156 \| Longitude: -90.223748 |
| 1.3 | Phone:<br>1. Merck KGaA, Darmstadt, Germany Phone +49 6151 72-0<br>2. EMD Millipore Corporation Phone +1 (781) 533-6000<br>3. Sigma-Aldrich Corporation Phone +1 (800) 521-8956 +1 (314) 771-5765 |
| 1.4 | Respondent or General Quality Department Email:<br>please refer to 1.5 |
| 1.5 | Fax:<br>please contact us via the local offices listed on<br>Home>About Us>Worldwide offices |
| 1.6 | Website:<br>https://www.merckgroup.com/en/company/who-we-are/life-science.html |

| | |
|---|---|
| 1.7 | Facility Establishment Identifier:<br>1. Merck KGaA, Darmstadt, Germany: 3002806906 (pharma), 9610140 (medical device)<br>2. EMD Millipore, Burlington, USA : 3009432145 (medical device)<br>3. Sigma-Aldrich Corporation 3300 S Second St, Saint Louis, Missouri (MO) 63118-3306, USA: 1937990 (medical device) |
| 1.8 | DUNS Number:<br>1. Merck KGaA, Darmstadt, Germany: 342249299<br>2. EMD Millipore Corporation, Burlington, USA: 00-105-0152<br>3. Sigma-Aldrich Corporation 3300 S Second St, Saint Louis, Missouri (MO) 63118-3306, USA: 829643423<br>Sigma-Aldrich Corporation, St. Louis USA: 079928354 |
| 1.9 | If there is an individual contact for the following areas, please provide name and preferred contact information (at a minimum, name and telephone number or email):<br><br>Quality:<br>please refer to the description of the leadership team on the internet Home>About Us>Leadership Team<br><br>Technical Services:<br>please refer to the description of the leadership team on the internet Home>About Us>Leadership Team<br><br>Commercial/Business/Sales:<br>please refer to the description of the leadership team on the internet Home>About Us>Leadership Team<br><br>Preferred Primary Contact:<br>please contact us via the local offices listed on the internet Home>About Us>Worldwide offices<br><br>merckmillipore.com or sigmaladrich.com |
| 1.10 | Please list other subsidiaries operating under the company:<br><br>subsidiaries are listed in our ISO 9001:2015 certificate, please request certificate from your local sales office |
| 1.11 | Is your company and affiliates willing to have Rx-360 conduct audits on behalf of your customers according to the RX 360 audit program?<br>yes, please refer to the internet: rx-360.org>audit-programs |
| 1.12 | If Rx-360 has performed audits at your sites, please state site and date of the audit:<br>Audit reports are available for the sites listed below:<br>Merck Darmstadt, Germany Merck SLU, Barcelona, Spain Merck Altdorf, Switzerland<br>SAFC Irvine, UK SAFC St. Louis, USA, SAFC Sinking spring, USA SAFC Lenexa, USA<br>Sigma Aldrich, Inc. Buchs, Switzerland Sigma Aldrich, Inc. St. Louis, USA<br><br>Audit dates can be retrieved from https://rx-360.org/license-audits-in-database/ enter "Merck" or"SAFC" and "Sigma" in the filter field |
| 1.13 | Please list the general product groups manufactured by the company:<br>Our 300,000 products range from lab water systems to gene editing tools, antibodies, cell lines and end-to-end systems and raw materials to manufacture drugs. |

| | |
|---|---|
| | On addition we offer chemicals for research, diagnostic use for analytics and chromatography purposes, customized solutions and services and much more. Please refer to the website as indicated in1.6 of this questionnaire. |
| Additional comments: | |

| SECTION 2. General Company Operating Information-- Rx 360 | |
|---|---|
| 2.1 | What year was the company established?<br>In 2015, Merck KGaA, Darmstadt, Germany acquired Sigma-Aldrich Corporation. Sigma-Aldrich Corporation combined with Merck Millipore create the Life Science business of Merck KGaA, Darmstadt, Germany. |
| 2.2 | Is the legal ownership structure of the company public or private? If other, please eleborate.<br>Life Science is a business of Merck KGaA, Darmstadt, Germany. Merck KGaA is German business entity with General partners, partly public and partly private. |
| 2.3 | If public, what is the company's stock symbol and on which exchanges is it listed?<br>Ticker symbol: MRK;<br>Official trading: Xetra, Frankfurt (Germany);OTC (Germany): Regional stock exchanges<br>Additional info: The Merck KGaA established a Sponsored Level I American Depository Receipt (ADR) program on 26 July 2017, which trades over-the-counter (OTC) in the United States (Ticker: MKKGY) |
| 2.4 | How many manufacturing sites does the company have?<br>60 manufacturing sites worldwide |
| 2.5 | Does the company have a corporate Quality Assurance Division?<br>yes |
| 2.6 | Does the company have any of the following written policies at the corporate level? If so, please provide policy number and title<br>Written site-specific policies can be reviewed within an audit |
| 2.6a | Environmental?<br>EHS Group Policy (20050155) |
| 2.6b | Quality Assurance?<br>Quality Mission Statement for Life Science (00005042POL) |
| 2.6c | Health and Safety?<br>EHS Group Policy (20050155) |
| 2.6d | Global Citizenship/Corporate Responsibility?<br>Please download corporate responsibility reports from Home>Company> Responsibility>Responsibility at Merck>Publications>CR Reports on http://www.merckgroup.com |
| Additional comments: | |

Our Life Science business brings together the legacy expertise of Merck's life science portfolio and Sigma-Aldrich, which was acquired by Merck KGaA, Darmstadt, Germany in 2015.

Link to publications: http://www.merckgroup.com/en/company/publications/publications.html

The purpose of this document is to describe processes, maintenance and improvement of the quality system, which is based on ISO 9001:2015 (Title: "Quality Management Systems –Requirements").

Please refer to our Regulations and Guidelines page on the internet which includes the ISO 9001 and other ISO certificates:

# II Responsible Personnel from our Life Science Leadership Team

Please refer to section 1.9 of the RX 360 company profile

# III Terms and Definitions

The terms and definitions given in ISO 9000:2015 apply to this document.

The relationship between the different phases of the PDCA (Plan, Do, Check, Act) cycle and the chapters of this document is shown in the following table:

| Step | Chapter |
|---|---|
| Plan | 4 Purpose and context of the organization<br>5 Leadership<br>6 Planning<br>7 Support |
| Do | 8 Operation |
| Check | 9 Performance Evaluation |
| Act | 10 Improvement |

# IV. Purpose and Context of the organization

## IV.1. Understanding the organization and its context

| | Yes | No |
|---|---|---|
| 1. Is the quality management system based on the "Plan – Do – Check – Act" (PDCA) cycle? | ☒ | ☐ |
| 2. Is there an understanding of the context of the organization via defining, monitoring and reviewing the key factors, which influence the organizations' purpose and objectives? | ☒ | ☐ |
| 3. The context of organization is not determined once, but is monitored, reviewed and updated as necessary on a regular basis, for example during management reviews with regard to? | | |
| a. Strategic direction of the organization | ☒ | ☐ |
| b. Purpose of the organization | ☒ | ☐ |
| c. Intended result of the QMS | ☒ | ☐ |
| d. Scope of the QMS | ☒ | ☐ |
| e. Definition of Risks and Opportunities | ☒ | ☐ |
| f. Definition of Quality Policies/ Objective | ☒ | ☐ |

## IV.2. Needs and expectations of interested parties

| | Yes | No |
|---|---|---|
| 1. Is there a definition and listing of interested parties to recognize and understand? | | |
| a. Who these parties are | ☒ | ☐ |
| b. What their needs and expectations are | ☒ | ☐ |
| c. Which of them are relevant and pose a significant risk to the organization | ☒ | ☐ |
| d. Which actions are needed to mitigate these risks? | ☒ | ☐ |
| 2. Is the information about interested parties monitored in different ways for example in? | | |
| a. Annual reports | ☒ | ☐ |
| b. Strategic consideration | ☒ | ☐ |
| c. Customer and employee surveys | ☒ | ☐ |
| d. Supplier evaluation and contract | ☒ | ☐ |
| e. Customer and internal audits | ☒ | ☐ |
| f. Management reviews | ☒ | ☐ |
| 3. Is it intended to keep a good relationship with the neighbourhood? | ☒ | ☐ |
| 4. Is there a global procedure available on the determination of the context of the organization and the interested parties? | ☒ | ☐ |

## IV.3. Scope of the QMS

| | Yes | No |
|---|---|---|
| 1. Does the QMS include the following? | | |
| a. Quality Policy and Quality Objectives | ☒ | ☐ |
| b. Quality Manual | ☒ | ☐ |
| c. Management Procedures | ☒ | ☐ |
| d. Documented Procedures and Records | ☒ | ☐ |
| e. Documents/ Records necessary to ensure the effective planning, operation and control of processes | ☒ | ☐ |
| 2. Does the Quality Manual include the following? | | |
| a. Establish the scope of the QMS | ☒ | ☐ |
| b. A description of the interaction between the processes of the QMS | ☒ | ☐ |
| c. Definition of Risk management and derived actions of the QMS | ☒ | ☐ |
| d. A description of tools to maintain organizational knowledge | ☒ | ☐ |
| 3. Is the Quality Manual available to customers upon request during a customer audit? | ☒ | ☐ |
| 4. Are global QMS requirements shared and aligned with local and regional QMS requirements? | ☒ | ☐ |

## IV.4. Management of Business processes

| | Yes | No |
|---|---|---|
| 1. Does the organization define and differentiate between the following processes? | | |
| a. Group function processes | ☒ | ☐ |
| b. Management processes | ☒ | ☐ |
| c. Strategic and operational management processes | ☒ | ☐ |
| d. Support processes | ☒ | ☐ |
| e. Packaging materials? | ☒ | ☐ |
| f. Rejected materials? | ☒ | ☐ |
| 2. Are risks and opportunities addressed in documents to ensure that: | | |

| | | | |
|---|---|---|---|
| a. | The business process descriptions are kept up to date | ☒ | ☐ |
| b. | The required resources for these processes are determined and are available | ☒ | ☐ |
| c. | The processes are evaluated and any necessary changes are implemented to ensure that these processes achieve their intended results and that the QMS is improved | ☒ | ☐ |
| d. | The risks and opportunities associated with these processes are determined and addressed in an appropriate way | ☒ | ☐ |
| e. | The responsibilities and authorities within these processes are determined and addressed in an appropriate way | ☒ | ☐ |
| f. | Key Performance Indicators (KPIs) are defined and monitored by the departments for which they are relevant. They are reviewed regularly. By monitoring and reviewing KPIs it is ensured that processes deliver their intended outputs, or, if not, that the processes can be improved as necessary | ☒ | ☐ |

# V Leadership

## V.1. General

| | | Yes | No |
|---|---|---|---|
| 1. | Does top management establish and support leadership principles in form of values for unity of purpose and direction of the organization at all levels? | ☒ | ☐ |
| 2. | Is a quality and regulatory culture maintained based on these values? | ☒ | ☐ |
| 3. | Does top management provide evidence of its commitment to the development and implementation of the QMS and continually improve its effectiveness? | ☒ | ☐ |
| 4. | Is top management accountable for the quality and regulatory compliance of the products and ensures that effective quality and regulatory systems are in place? | ☒ | ☐ |
| 5. | Has top management appointed members of the management organization, who shall ensure that Quality and continual improvement is considered as a strategic pillar of the organization by: | | |
| | a. Establishing a global quality management system based on ISO 9001 and other applicable quality and regulatory requirements, | ☒ | ☐ |
| | b. Formulating a set of documents that include this commitment, | ☒ | ☐ |
| | c. Setting the framework to establish quality objectives in line with the global group objectives, | ☒ | ☐ |
| | d. Principles, charters and the Quality Policy | ☒ | ☐ |
| | e. Establishing the purpose and context of related organizations and supporting their strategic direction, and | ☒ | ☐ |
| | f. Creating and maintaining a work environment in which our employees become fully involved in achieving the objectives. | ☒ | ☐ |
| 6. | Does top management ensure that the QMS achieves its intended results (e.g. by regular reviews, evaluation and communication of results, customer surveys etc.) | ☒ | ☐ |
| 7. | Are regular management reviews conducted? | ☒ | ☐ |
| 8. | Does top management communicate the importance of effective quality management and of conforming to the QMS requirements? | ☒ | ☐ |

## V.2. Customer Satisfaction

| | | Yes | No |
|---|---|---|---|
| 1. | Does top management ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction? | ☒ | ☐ |
| 2. | Does top management ensure that this customer focus is promoted throughout the whole organization, e.g. during employee meetings or by publications? | ☒ | ☐ |
| 3. | Does top management communicate the importance of meeting customer as well as statutory and regulatory requirements? | ☒ | ☐ |
| 4. | Are objectives and KPIs established to focus on enhancement of customer satisfaction? | ☒ | ☐ |

## V.3 Quality Mission Statement

| | | Yes | No |
|---|---|---|---|
| 1. | Does the Quality Mission statement set the framework for the quality objectives and form the basis for all employees' daily work? | ☒ | ☐ |
| 2. | Is the Quality Mission Statement reviewed at least annually as part of management review for adequacy and continued suitability? | ☒ | ☐ |
| 3. | Is the Quality Mission Statement made known to all employees through induction, ongoing training, and postings displayed in appropriate locations? | ☒ | ☐ |

# VI Planning

| | Yes | No |
|---|---|---|
| 1. Is there a formal risk management program? | ☒ | ☐ |
| 2. Are risk and opportunities identified to investigate all relevant aspects which may affect the achievement of quality objectives? | ☒ | ☐ |
| 3. Are actions defined to mitigate the risk and pursue the opportunities? | ☒ | ☐ |
| 4. Are data resulting from actions evaluated to check for the effectiveness of those actions? | ☒ | ☐ |
| 5. Does top management ensure that quality objectives, including those needed to meet requirements for products, are established at relevant functions and levels within the organization? | ☒ | ☐ |
| 6. Are personnel made aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives? | ☒ | ☐ |
| 7. Does change management ensure that the integrity of the QMS is maintained, when changes are planned and implemented? | ☒ | ☐ |

# VII Support

## VII.1 - VII.4 Resources, Competence, Awareness, Communication

| | Yes | No |
|---|---|---|
| 1. Are well-trained, engaged and motivated personnel considered as a decisive asset for the success of the company? | ☒ | ☐ |
| 2. Are there written job descriptions for all critical positions? | ☒ | ☐ |
| 3. Is training provided or are other actions taken to achieve the necessary competence of employees in their positions? | ☒ | ☐ |
| 4. Are appropriate records of education, training, skills and experience maintained? | ☒ | ☐ |
| 5. Do employees undergo periodic performance reviews? | ☒ | ☐ |
| 6. Does management ensure that appropriate infrastructure (buildings, workspace, utilities, and process equipment, supporting services) is available to achieve product conformity? | ☒ | ☐ |
| 7. Is an adequate protection level of all employees established based on all relevant aspects from occupational health and safety requirements? | ☒ | ☐ |
| 8. Are workers having the potential to come into direct contact with exposed product required to wear clean clothing appropriate for their duties? | ☒ | ☐ |
| 9. Are workers required to keep personal belongings away from immediate production areas? | ☒ | ☐ |
| 10. Are there facilities for eating, smoking, restrooms, and lockers separate from production? | ☒ | ☐ |
| 11. Is measuring and monitoring of equipment either verified or calibrated by internal personnel or by qualified sub-contractors as applicable? | ☒ | ☐ |
| 12. Are calibration records maintained during the life of the equipment and archived per record retention policies? | ☒ | ☐ |
| 13. Does the organization maintain a variety of tools to convert individual knowledge of employees into organizational knowledge and to make this knowledge available within the organization to the extent necessary? | ☒ | ☐ |

## VII.5. Documented Information

| | Yes | No |
|---|---|---|
| 1. Are documents required by the QMS controlled? | ☒ | ☐ |
| 2. Is a document hierarchy defined which is aligned to the levels of the organization? | ☒ | ☐ |
| 3. Are minimum requirements for documents defined? | ☒ | ☐ |
| 4. Is an electronic document control system utilized? | ☒ | ☐ |
| 5. Is the document system centralized (by site)? | ☒ | ☐ |
| 6. Are knowledge management systems established to maintain internal knowledge? | ☒ | ☐ |
| 7. Are documented procedures established to define the controls for the following? | ☒ | ☐ |
| a. Approval of documents for adequacy prior to issue | ☒ | ☐ |
| b. Review and update of documents as necessary with re-approval | ☒ | ☐ |
| c. Ensuring changes and current revision status of documents are identified | ☒ | ☐ |
| d. Ensuring that relevant versions of applicable documents are available at points of use | ☒ | ☐ |
| e. Ensuring that documents remain legible and readily identifiable | ☒ | ☐ |
| f. Ensuring that documents of external origin are identified and distribution is controlled | ☒ | ☐ |
| g. Preventing unintended use of obsolete documents with appropriate identification if they are retained for any purpose | ☒ | ☐ |

| | | |
|---|---|---|
| 8. Are documents managed through the following stages of quality document lifecycle as applicable? | | |
| a. Evaluation of Need | ☒ | ☐ |
| b. Document Creation | ☒ | ☐ |
| c. Document Revision | ☒ | ☐ |
| d. Document Review and Approval | ☒ | ☐ |
| e. Implementation and Training | ☒ | ☐ |
| f. Control and Distribution | ☒ | ☐ |
| g. Periodic Review | ☒ | ☐ |
| h. Obsoleting | ☒ | ☐ |
| i. Retention, Archiving and Destruction | ☒ | ☐ |
| j. Monitoring | ☒ | ☐ |
| 9. Are records established and controlled to provide evidence of conformity to requirements and of effective operation of the QMS? | ☒ | ☐ |
| 10. Is there a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention, and disposition of records? | ☒ | ☐ |
| 11. Are procedures in place for making changes to specifications? | ☒ | ☐ |
| 12. Are there written specifications for incoming raw materials and finished products? | ☒ | ☐ |
| 13. Are batch records used to document critical production processes? | ☒ | ☐ |
| 14. Are production related records retained for a defined period of time? | ☒ | ☐ |
| 15. Are product dependent records retained as described in procedures? | ☒ | ☐ |
| 16. Does use of the lot number provide traceability back to the receipt of incoming raw materials? | ☒ | ☐ |

# VIII Operation

## VIII.1 Operational planning and control

| | Yes | No |
|---|---|---|
| 1. Does the organization plan and develop processes needed for product realization? | ☒ | ☐ |
| 2. In planning product realization, is the following determined, as appropriate? | | |
| a. Quality objectives and requirements for the processes, | ☒ | ☐ |
| b. the need to establish processes and documents, | ☒ | ☐ |
| c. the need to provide appropriate resources and facilities to ensure that product realization meets all requirements | ☒ | ☐ |
| d. required verification, validation[1)] monitoring, measurement, inspection and testing | ☒ | ☐ |
| e. activities specific to the product and the requirements for product acceptance (e.g. product specification) | ☒ | ☐ |
| f. aspects of activities related to product realization which influence (directly or indirectly) environment, | ☒ | ☐ |
| g. occupational health & safety hazards and risks related to the activities, regulatory requirements which have to be met for specific products and activities, | ☒ | ☐ |
| h. establishing operational and process controls and performance criteria where necessary, | ☒ | ☐ |
| i. records needed to provide evidence of conformity of the processes and resulting products and service | ☒ | ☐ |
| 3. Are appropriately documented records maintained in all phases of product realization as needed? | ☒ | ☐ |

## VII.2 Determination of requirements for products and services

| | Yes | No |
|---|---|---|
| 1. Are product and / or service specifications provided via e-commerce platforms or electronic catalogues to enable customers to review before placing an order? | ☒ | ☐ |
| 2. Are the following requirements determined? | | |
| a. Customer specified requirements, including delivery and post-delivery, | ☒ | ☐ |
| b. Requirements not customer specified but necessary for use, where known, | ☒ | ☐ |
| c. Statutory and regulatory requirements applicable for the product, | ☒ | ☐ |
| d. Additional requirements considered necessary | ☒ | ☐ |
| 3. Is there a determined and implemented effective arrangement for communication with customers in relation to the following? | | |
| a. Product information | ☒ | ☐ |
| b. Enquiries, contracts or order handling, including amendments | ☒ | ☐ |
| c. Customer feedback, including customer complaints | ☒ | ☐ |

| | | |
|---|---|---|
| 4. If product requirements change, are relevant documents amended and relevant personnel notified of changes? | ☒ | ☐ |
| 5. Is there a review of the requirements related to the product? | ☒ | ☐ |
| 6. Does the review ensure the following? | | |
| a. Product requirements are defined | ☒ | ☐ |
| b. Contract or order requirements differing form those previously expressed are resolved | ☒ | ☐ |
| c. Organization has ability to meet defined requirements | ☒ | ☐ |

## VIII.3 Design and development of products and services

| | Yes | No |
|---|---|---|
| 1. Is the design and development of products (product development process) controlled and does this process include the following main aspects? | | |
| a. Commercialization | ☒ | ☐ |
| b. Roll outs | ☒ | ☐ |
| c. Meeting safety and regulatory standards | ☒ | ☐ |
| 2. Are records maintained and evaluated before starting with product development process covering the following aspects? | | |
| a. Functional and performance requirements, | ☒ | ☐ |
| b. Applicable hazard, safety, environmental, statutory and regulatory requirements, or regulatory compliance for worldwide submission strategy, | ☒ | ☐ |
| c. Where applicable, information derived from previous similar designs and/or from risk management reviews, | ☒ | ☐ |
| d. Global commercialization plan identifying the marketing priority by country, | ☒ | ☐ |
| e. Standards and codes of practise which needed to be implemented, | ☒ | ☐ |
| f. Potential consequences of failure due to the nature of product, | ☒ | ☐ |
| g. Hazard plan identifying global labelling and safety requirements, and other requirements essential for design and development. | ☒ | ☐ |
| 3. Are the outputs of design and development in a form suitable for verification against the input and approved prior to release? | ☒ | ☐ |
| 4. Are controls to each design and development process or project implemented to ensure that the results to be achieved? | ☒ | ☐ |
| 5. Are verification, validation[1)] and review processes defined for design and development reviews if applicable? | ☒ | ☐ |
| 6. Is verification performed to assure that the design and development outputs meet the input requirements? | ☒ | ☐ |
| 7. Is an organization unit established which provide the following services for customers like | | |
| a. Answering quality and regulatory related product requests, | ☒ | ☐ |
| b. Establishing change notification commitments and negotiation of quality agreements, | ☒ | ☐ |
| c. Providing standardized documents, certificates and dossiers depending on product quality | ☒ | ☐ |
| 8. Is complaint, CAPA and internal change management based on a valid process? | ☒ | ☐ |
| 9. Are Customers notified about product specific changes based on product quality levels? | ☒ | ☐ |
| 10. Is there a definition of notifiable product changes? | ☒ | ☐ |

## VIII.4 Control of products and services

| | Yes | No |
|---|---|---|
| 1. Does the organization ensure that outsourced processes remain within the control of the QMS? | ☒ | ☐ |
| 2. Is a supplier qualification program in place? | ☒ | ☐ |
| 3. Are controls of external supplier implemented which include records based on defined requirement? | ☒ | ☐ |
| 4. Are there established and implemented inspections or other activities necessary for ensuring that purchased product meets specified purchase requirements? | ☒ | ☐ |

## VIII.5 Production and service provision

| | Yes | No |
|---|---|---|
| 1. Are production and service provisions planned and carried out under controlled conditions, including the following? | | |
| a. The availability of documented information that describes the characteristics of the product / service to be provided, | ☒ | ☐ |
| b. The availability of work instructions as necessary, | ☒ | ☐ |
| c. The results to be achieved, | ☒ | ☐ |
| d. The use of suitable infrastructure, | ☒ | ☐ |

| | | | |
|---|---|---|---|
| | e. The availability and use of monitoring and measuring equipment, | ☒ | ☐ |
| | f. The definition of monitoring and measuring activities to verify that criteria for control of processes and/ or acceptance criteria for products and services have been met, | ☒ | ☐ |
| | g. The definition of training requirements for employees, | ☒ | ☐ |
| | h. If needed (either by customer or regulatory requirements or because the resulting output cannot be verified by subsequent activities) , validation[1)] and periodic revalidation of processes, | ☒ | ☐ |
| | i. The implementation of required actions to prevent human error | ☒ | ☐ |
| | j. The implementation of product release, delivery, and post-delivery activities. | ☒ | ☐ |
| 2. | Are documents describing specific instructions or procedures, specific use of equipment, monitoring and measuring devices and delivery and post-delivery made available to all users? | ☒ | ☐ |
| 3. | Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence deficiencies become apparent only after the product is in use or the service has been delivered? | ☒ | ☐ |
| 4. | Is the status of a product always identifiable during production, filling and distribution? | ☒ | ☐ |
| 5. | Is the unique identification of the product controlled, where traceability is a requirement? | ☒ | ☐ |
| 6. | Are documents confirming the conformance of products to requirements made available to customers as appropriate? | ☒ | ☐ |
| 7. | Does the organization identify, verify, protect and safeguard customer property provided for use or incorporation into the product? | ☒ | ☐ |
| 8. | Are changes reviewed for an effect on product quality and performance, and further determine whether or not the changes affect customer requirements? | ☒ | ☐ |
| 9. | Are any changes in production or service provision reviewed, verified and validated, as appropriate, and approved before implementation? | ☒ | ☐ |

### VIII.6 Release of products and services

| | | Yes | No |
|---|---|---|---|
| 1. | Are release processes defined to verify that requirements have been met as appropriate for | | |
| | a. Raw materials, | ☒ | ☐ |
| | b. Intermediate products, | ☒ | ☐ |
| | c. Final products | ☒ | ☐ |
| 2. | Are there processes that ensure only tested and released material is used for production, filling and distribution? | ☒ | ☐ |
| 3. | Are products not released unless evidence of conformity to established criteria is verified? | ☒ | ☐ |
| 4. | Is the appropriate monitoring and measuring determined and is the monitoring and measuring equipment necessary to provide evidence of conformity determined? | ☒ | ☐ |
| 5. | Is the measurement equipment calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards? | ☒ | ☐ |
| 6. | Is the release of customer documents and services based on the principles described on chapter documented information? | ☒ | ☐ |

### VIII.7 Control of non-conforming outputs

| | | Yes | No |
|---|---|---|---|
| 1. | Does the organization ensure that process outputs, products, or services that do not conform to requirements are identified and controlled to prevent unintended use, delivery or impact on environment, health or safety? | ☒ | ☐ |
| 2. | If a nonconformity is observed are the following actions taken and documented? | | |
| | a. Investigation, root cause analysis | ☒ | ☐ |
| | b. Corrective and preventive actions | ☒ | ☐ |
| | c. Effectiveness check | ☒ | ☐ |

# IX Performance Evaluation

## IX.1 Monitoring, measurement, analysis and evaluation

| | | Yes | No |
|---|---|---|---|
| 1. | Has each responsible manager to determine for their area of responsibility? | | |
| | a. what needs to be monitored and measured (KPIs), | ☒ | ☐ |
| | b. the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results (e.g. process controls, audits, analysis of complaint data, statistical analyses, balanced scorecards) | ☒ | ☐ |

| | | | |
|---|---|---|---|
| | c. when and how often the monitoring and measuring will be performed and when the results from monitoring and measurement will be analysed and evaluated | ☒ | ☐ |
| 2. | Are quality complaints formally documented and investigated? | ☒ | ☐ |
| 3. | Is the information relating to customer perception as to whether the organization has met customer requirements monitored? | ☒ | ☐ |
| 4. | Is customer satisfaction data obtained from many sources, such as: | | |
| | a. customer surveys, complaints, and suggestions for improvements, | ☒ | ☐ |
| | b. customer audits, | ☒ | ☐ |
| | c. customer contacts with our customer-facing departments | ☒ | ☐ |
| | d. customer feedback obtained during sales and marketing visits and trade shows | ☒ | ☐ |
| 5. | Is the stability and effectiveness of the QMS ensured by: | | |
| | a. regular analyses of KPIs | ☒ | ☐ |
| | b. regular reviews of quality objectives, the context of the organization, the needs and expectations of relevant interested parties, audit results, corrective actions and of the Quality Mission Statement | ☒ | ☐ |

### IX.2 Internal audit

| | | Yes | No |
|---|---|---|---|
| 1. | Are internal audits planned on an annual basis based on complexity and criticality? | ☒ | ☐ |
| 2. | Does the internal audit program take into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits, customer feedback, previous management reviews and nonconformities? | ☒ | ☐ |
| 3. | Are records of the audits and their results maintained and corrective and preventive actions resulting from audits implemented in a timely manner? | ☒ | ☐ |

### IX.3 Management review

| | | Yes | No |
|---|---|---|---|
| 1. | Are management reviews planned on at an annual basis and are the results reviewed by the upper management? | ☒ | ☐ |
| 2. | Are records of the management review maintained and does the inputs include the following aspects? | | |
| | a. status of actions from previous management reviews | ☒ | ☐ |
| | b. changes relevant to the QMS | ☒ | ☐ |
| | c. data on the performance and effectiveness of the QMS, including trends | ☒ | ☐ |
| | d. resources required for maintaining the quality management system | ☒ | ☐ |
| | e. review of how well the QMS is addressing risks and opportunities | ☒ | ☐ |
| | f. any opportunities for improvement | ☒ | ☐ |

# X Improvement

## X.1 General

| | | Yes | No |
|---|---|---|---|
| 1. | Are improvement initiatives part of objectives? | ☒ | ☐ |
| 2. | Are there different starting points for improvements like | | |
| | a. investigations of nonconformities which lead to corrective actions | ☒ | ☐ |
| | b. opportunities for improvement observed at any level, either “spontaneously” or within the daily work or based on the review of KPIs, processes, documents etc | ☒ | ☐ |
| | c. opportunities for improvement observed during management reviews | ☒ | ☐ |
| | d. consideration of risks at any level can also show the need for risk mitigation | ☒ | ☐ |

## X.2 Non-conformity and corrective action

| | | Yes | No |
|---|---|---|---|
| 1. | Are corrective and preventive actions defined based on the roote cause investigation of non-conformities? | ☒ | ☐ |
| 2. | Is it ensured that product or a service which does not conform to product requirements be identified and controlled to prevent its unintended use or delivery? | ☒ | ☐ |
| 3. | Is there a documented procedure established to define the controls and related responsibilities and authorities for dealing with nonconforming product and service? | ☒ | ☐ |

| | | | |
|---|---|---|---|
| 4. | Is a non-conforming product subject to reverification to demonstrate conformity to the requirements? | ☒ | ☐ |
| 5. | Are suitable actions defined to eliminate the cause of non-conformities? | ☒ | ☐ |
| 6. | Are these actions monitored in appropriate system and is the result of the effectiveness check documented? | ☒ | ☐ |

### X.3 Continual improvement

| | | Yes | No |
|---|---|---|---|
| 1. | Is continual improvement supported by management as a key element of the QMS? | ☒ | ☐ |
| 2. | Are non-recurrent improvement activities (e.g. corrections and actions, innovation, breakthrough changes as well as re-organization) initiated individually? | ☒ | ☐ |
| 3. | Are the continual improvement activities based on methodologies such as Kaizen, and Lean-6-Sigma? | ☒ | ☐ |

## XI Survey contact information

For more information please contact your local sales representative.

Approved by:

Title: Head of Life Science Quality Management Systems & Audits

Date: April 2019

This document has been produced electronically and is valid without signature.

[Note 1): Definition of validation according to ISO 9000:2015, 3.8.13]