Role of ‘c’ in cGMP

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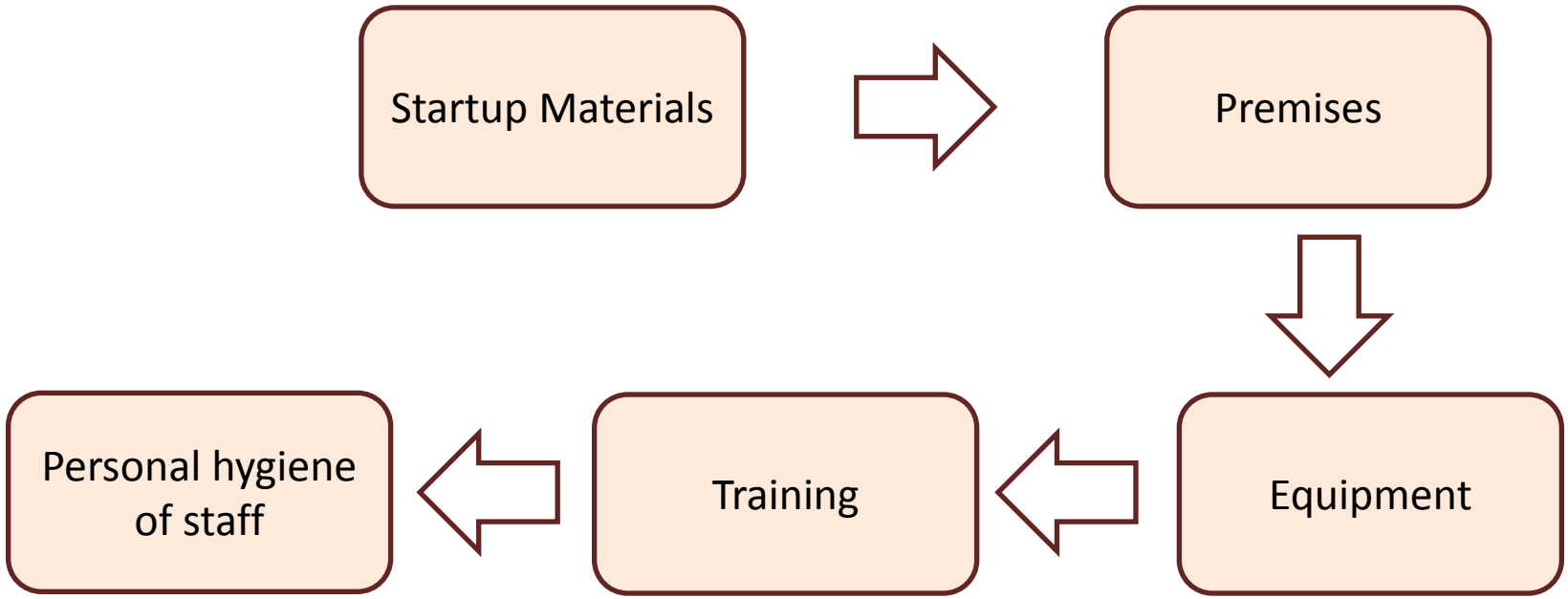
GMP

- GMP is a system for ensuring that products are consistently produced and controlled according to quality standards.

- It’s a magic key that opens the door to quality.

GMP

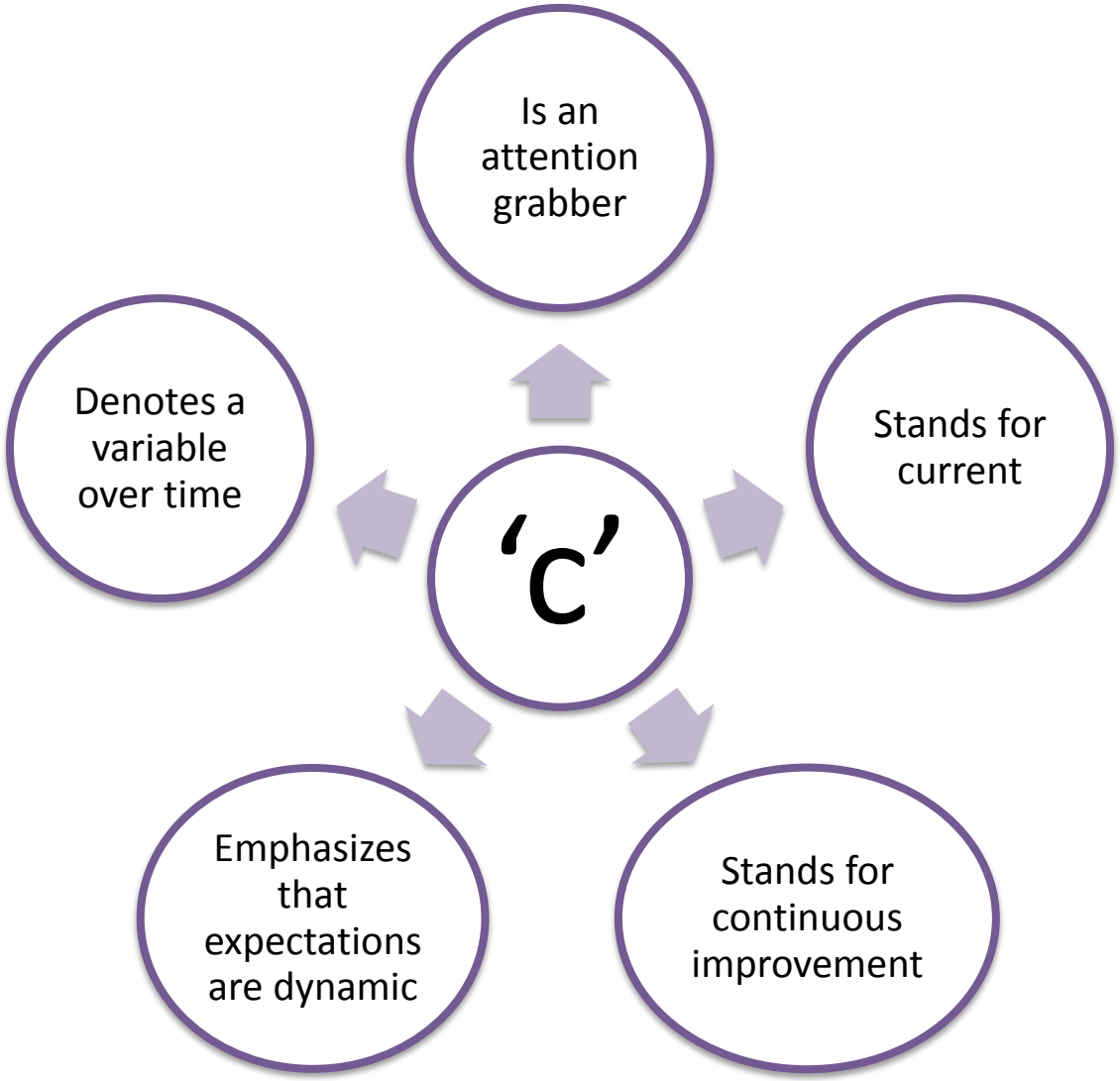
It covers all aspects of production from…



What is cGMP

- GMP is a common term and its full form is Good Manufacturing Practice.
- cGMP is a unique term to define most recent guidelines with improvement and additions.
- c is a variable in cGMP that's why it is written in small letter just like pH → p is variable potential in pH.

cGMP



cGMP

- cGMP reminds manufacturer that they must employ the technologies and systems which are up to date in order to comply with the current regulations.

- GMP has to be updated time to time in order to comply with the standard guidelines.

Examples

Quality Control

Previous Practice

- The equipments were not having audit trail function also the electronic archival of the data was not done.

Current Practice

- The equipments are having audit trails and the data is archived in the server for track and trace purpose.
- The backup of the HPLC and GC is taken and archived.
- The disaster recovery programs is in place.

HVAC

Previous Practice

- The DP limits was around 2 pascals in the areas, thus the improvement was done in the HVAC to avoid any chances of cross/gross contamination.

Current Practice

- The DP limits are currently around 10 pascals in the process areas and around 6 pascals between primary and secondary packing area.

DP=delta Pressure=△P= Pressure Differential

HVAC

Previous Practice

- Manometers were used in the areas for DP monitoring

Current Practice

- The magnehelic pressure gauges are now used in the areas for DP monitoring.

HVAC

Previous Practice

- Hygrometers were used for monitoring of temperature and RH.

Current Practice

- Digital hygrometers are now used for monitoring of temperature and RH, which are connected through Building Management System(BMS).

HVAC

Previous Practice

- The inlet air was not through HEPA.
- There was only 5µ filter along with a diffuser in the inlet air supply.

Current Practice

- The inlet air is through HEPA.
- In case of potent molecules, the HEPA is used at the exhaust also, to prevent any contamination going out of the rooms.

QA Systems

Previous Practice

- The QMS documents were all manual, therefore the time closure was the bottle neck.
- The archival of the paper documents was hard.
- Wear and tear of paper with time.

Current Practice

- The basic QMS systems like change controls deviations, CAPA, market complaints, investigation are all electronic online by using trackwise documentum compliance manager.
- The use of electronic systems ensures proper tracking and timely closure of the documents.

Production

Previous Practice

- Machines were not equipped with PLC.
- The entire process was person dependent and chances of mistake during process cannot be ruled out.

Current Practice

- The equipments are now equipped with PLCs (Programmable Logic Controller).
- PLC's are validated and product wise recipes can be feed into the system →the desired process is run automatically by the system.

Production

Previous Practice

- Data archival without PLC was not possible.

Current Practice

- The equipment PLCs can now be connected to the DAS (Data Acquisition System)for data archival and review.

Process Validation

Previous Practice

- Process Validation studies were conducted by collating the data of the batches from the batch production record.
- Even in case of prospective validation, BU/CU was not performed.

Current Practice

- Three batch validation is done i.e. prospective validation for all new products.
- This includes blend uniformity/ content uniformity analyses and stratified sampling and testing at different time point at compression or filling stage

Process Validation

Previous Practice

- The stratified sampling at either compression or coating stage was not done.

Current Practice

- The samples from multiple locations are drawn from coating pan in case of coated tablets.
- This gives assurance regarding the consistency and reproducibility of the results.

Water System

Previous Practice

- DM plant based systems were used for purified water generation

Current Practice

- RO/EDI Systems are used for purified water generation which provides good quality.

Stability

Previous Practice

- Normally the long term stability studies was being done at 25^0C/60% RH in the whole world with the concept that average temperature does not go beyond 30^0C except Brazil, where the stability was done at Zone IV B from the start i.e. 30^0C/75%RH.

Current Practice

- With the change in the climate conditions, most of the countries due to hotter and humid climates are asking for the stability data at Zone IV B i.e. 30^0 C/75%RH like India, Nepal, Kenya, Nigeria, UAE etc.

Adverse Drug Events (ADE)

Previous Practice

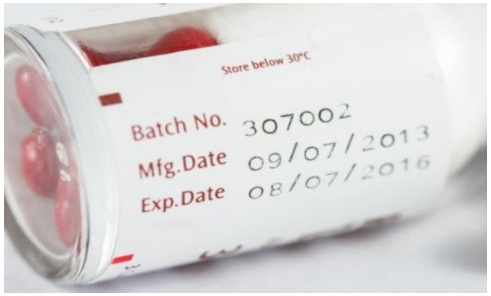
- Adverse Drug Events were logged, however, maintenance of a central data base and periodic updation of the same to the agency was not compulsory.

Current Practice

- Companies are now required to maintain a central database for the reported ADEs.
- These ADEs are to be submitted on the periodic basis to regulatory agencies to ensure the patients safety.
- ADEs need to be investigated and responded to the complainant as per SOPs.

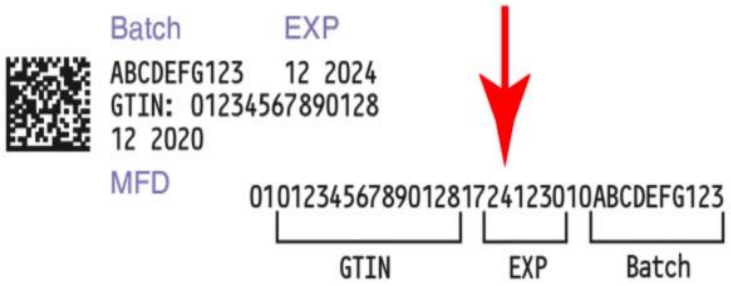
2D Coding

Previous Practice



- Only batch number, Mfg.Date and Exp.Date was printed on the cartons.
- In case of complaints or counterfeit, it is hard to say with conviction that the product does not originally belong to the company.

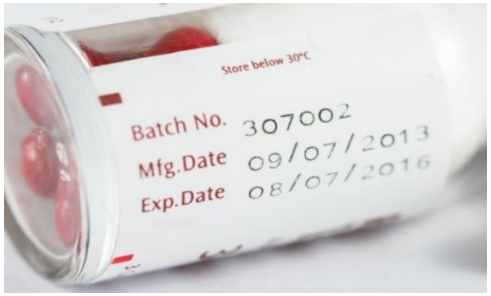
Current Practice



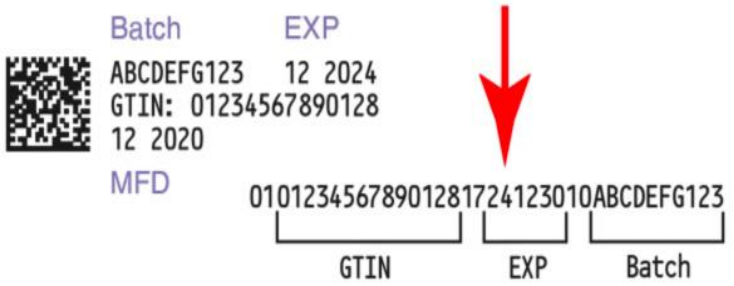
- As per the recent notification of DGFT (Director General of Foreign Trade), the 2D code is compulsory to be present in all the export products to prevent counterfeit drugs being exported from India.

2D Coding

Previous Practice



Current Practice



- The 2D code mainly consists of a 2 Dimensional coding which is printed on the carton along with:
  - GTIN (Global trade identification no)
  - Serial Number
  - Batch no. , MFD and EXP Date

Employee Trainings

Previous Practice

- Persons were undergoing training, however the certification process was not present.
- The rigorous monitoring was not done.

Current Practice

- The employee is allowed to work only when the person is fully trained after joining any organization.
- The employee certification is done to ensure the compliance.
- For routine trainings the location training coordinator is monitoring the training needs of the employee and is ensuring that the person is trained before doing any job.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