Effective Implementation of Quality Management System-Regulatory Compliance

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What is GMP

Good Manufacturing Practice is a system for ensuring that products are **consistently** produced and **controlled** according to Quality Standards.

It is designed to **minimize the risks** involved in any pharmaceutical production that cannot be eliminated through testing the final product.

GMP covers all aspects of production from the starting materials, premises, equipment, training, and personal hygiene of staff.

All Regulatory Authorities have published detailed guidelines to ensure compliance with the GMP.

Importance of GMP

- Aim is to produce medicine meeting the standard for **effective treatment of patients**.
- Poor quality medicine will lead to health hazards as it may contain toxic substances, enhancement of impurities beyond stated limits, failure to meet critical product quality parameters, etc.
- Medicines that contain little or none of the claimed ingredients will not have the intended therapeutic effect.

Why GMP is necessary although there is a QC Laboratory

- **Good Quality must be built in** during the manufacturing process, it cannot be tested into the product afterward.

- **GMP prevents errors** that cannot be eliminated through quality control of the finished product. It is one way, you cannot turn back to correct your errors.

- Without GMP it is impossible to be sure that every unit of medicine produced at the site is of the same quality.

Discussion points:

- To discuss the tricks and techniques to ensure GMP compliance in the facility all the time.
- How to inculcate the culture of compliance at the site.
- Ownership building at each level and its effective monitoring.
- How to achieve consistency in the middle of all variables.
- Importance of Risk Assessment and its effective implementation.
- How to forecast failures in advance and proactive steps to avoid them.
- How to handle failures and what it indicates.
- Techniques for successful get-through of any GMP inspection at the site.
- Investigation techniques of Market Complaints.
- Important factors to consider while writing a compliance report.

All time GMP compliance at site

- Focusing on the 3M: Man, Machine, and Method
- Why is the '**Culture of Compliance**' so important and how to develop?
- How to design a perfect JD and why it helps towards GMP compliance.
- What is ownership and how it is built?
- Effective training through visuals and mentoring. Challenging mechanism to understand and record competency.

Consistency in the middle of all variables

- What are the variables
- How to identify variables
- Risk assessment for impact assessment of all such variables.

Importance of Risk Assessment and its effective implementation

- Why is risk assessment important?
- Concept of risk assessment.
- Mitigation of risks.
- Elimination of risks.

How to forecast failures and avoid

- Focusing on the indications
- Uncontrolled variables
- Ineffective execution of change controls.
- Multiple minor deviations of the same nature.
- Random allotment of responsibilities to handle manpower crisis.
- Managing certain activities with less or incompetent manpower.
- Introduction or change of any formulation/pack with supportive study.
- Failure to adopt a timely change of regulatory requirements.

How to handle failures and what it indicates

- A failure indicates a partial crash of the laid-down QMS although it may not be a direct GMP failure.
- Investigation of failure on the ‘Why / How’ concept and not the ‘Who’ concept.
- The core focus of the investigation must be product quality relating to patient safety as the nucleus.

Successful get-through of GMP Inspections

- Preparation
- Presentation
- Participation
- Understanding the intention of the inspector when question asked.
- What to talk about and what not to talk.

Investigation of Market Complaints

- Acceptance
- Check for spurious.
- Thorough investigation with an open mind.
- Ask for more input from the complainant.
- Trend checks.
- Review of History sheets.
- Interviewing all personnel involved till the bottom line.
- Carry out all hypotheses.
- Submit meaningful conclusions after concluding the root cause with CAPA.

Writing a Compliance Report is an Art

- How to read and understand a deficiency report.
- In what context this observation was recorded and what opinion did the inspector share.
- Root cause: Wrong interpretation of the regulation, gap in execution or integrity issue.
- Expanding the arena to understand and address in a complete manner to mitigate hidden risks in and around the deficiency.
- Cost of compliance: Every commitment towards compliance is a cost to the company. Identify the best option to comply with minimal cost.


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