Role Of Current Good Manufacturing Practices In Current Scenario

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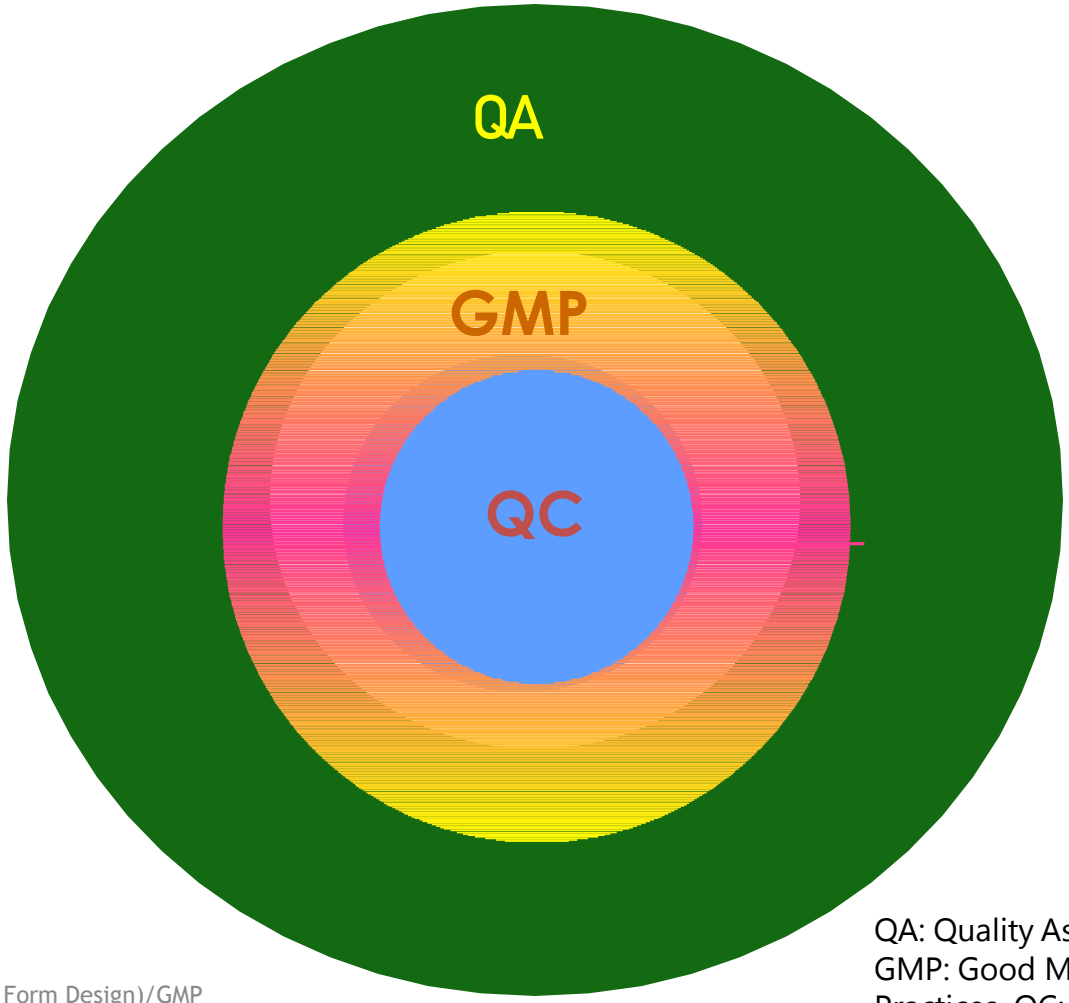
OBJECTIVES

1. TO AVOID CONTAMINATION AND CROSS CONTAMINATION
2. TO PRODUCE CONSISTENT QUALITY OF DRUG.
3. TO UNDERSTAND THE REGULATIONS OF GOOD MANUFACTURING PRACTICES
4. TO UNDERSTAND THE "FUNDAMENTALS", "BENEFITS" AND "KEY PARTS" OF CGMPS

Status of GMP in Pharmaceutical



QA: Quality Assurance
GMP: Good Manufacturing Practices QC: Quality Control

What are cGMPs?

- cGMP refers to the Current Good Manufacturing Practice regulations enforced by the US Food and Drug Administration (FDA).
- cGMP provide for systems that assure proper design, monitoring and control of manufacturing processes and facilities.
- Adherence to the cGMP regulations assures the identity, strength, quality and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations

Scope

- Formulation development
- Clinical Batches
- Manufacturing of Drugs and Cosmetics
- Repacking of Drugs and Pharmaceutical

Define GMP ?

- Good manufacturing practices (G.M.Ps)can be defined as Practices that have to be followed by pharmaceutical manufacturers to achieve a zero defect products
- **GMP is that part of Quality assurance which ensures that the products are consistently manufactured and controlled to the Quality standards appropriate to their intended use.**
- **A set of principles and procedures which, when followed by manufacturers for therapeutic goods, helps ensure that the products manufacture will have the required quality.**

Current Good Manufacturing Practice (CGMP) Regulations

- GMP as per Schedule "M"
- GMP as per WHO
- GMP as per MCA now known as MHRA
- GMP as per TGA
- GMP as per US FDA
- GMP as per ICH guidelines

WHO: World Health Organization
MHRA: Ministry of Health and Regulatory Affairs TGA: Therapeutic Goods Affairs
FDA: Food And Drug Administration
ICH: International Conference on Harmonization

A REVIEW ON HISTORY OF GMP

- The Medicine Inspector of the Department of Health and Social Security of England, in consultation with other interested bodies compiled the guide to GMP also known as the Orange Guide.
- The first edition of the guide was published in 1971, the manufacturing of drug carried out under the Medicines Act. It was a relatively light volume of 20 pages, and was reissue third impression in 1972, with the addition of a 2-page appendix on sterile medicinal products.

History contd..

- The color of its cover, it known as the Orange Guide. The second edition (52 pages, including five appendices) was published in 1977. The third edition (110 pages, five appendices) was published in 1983.
- The Medicines and Healthcare products Regulatory Agency (MHRA) has published new edition of the Orange Guide in 2007.
- In United States, the first GMP regulations were issued in 1963 and described the GMP to be followed in the manufacture, packaging, and storage of finished pharmaceutical products.

History contd..

- GMP regulations were developed by the US FDA and issued the United States CFR Chapter 21 in 1978. The regulation was similar in concept to the Orange Guide, but enforceable by law whereas the UK guide as an advisory.
- US congress passed the Federal Ani-tempering Act in 1983, making it a crime to tamper with packaged consumer products.

In the 1980, US FDA began publishing series of guidance documents that have a major effect on our interpretation of current GMP (cGMP).

History contd..

- A “Guide to Inspection of Computerized Systems in Drug Processing” was published in 1983 and “Guideline on General Principles of Process Validation” was published in 1987. March 1997, the US FDA issued 21 CFR Part 11 which dealt with the use of electronic records and signatures.
- In 2000, US FDA introduced a guidance document on the incorporation of risk management into device development.

Code of Federal Regulations (CFR)

- FDA's portion of the *CFR* is in Title 21, which interprets the *Federal Food, Drug and Cosmetic Act* and related statutes, including the Public Health Service Act. The pharmaceutical or drug quality-related regulations appear in several parts of Title 21, including sections in parts 1-99, 200-299, 300-499, 600-799, and 800-1299.
- The regulations enable a common understanding of the regulatory process by describing the requirements to be followed by drug manufacturers, applicants, and FDA.
- 21 CFR Part 314 and Part 600. Application and licensing submission requirements for new and generic drug applicants.
- 21 CFR Part 210. Current Good Manufacturing Practice in Manufacturing Processing, packing, or Holding of Drugs.
- 21 CFR Part 211. Current Good Manufacturing Practice for Finished Pharmaceuticals.

Interpretations of the Law

- The Code of Federal Regulations is a government publication where Federal Agencies post regulations
  - Contain regulations enforced by the DOT, DEA, FCC, FDA, and all other agencies
- Found in Code of Federal Regulations (CFR)
  - **Drug (cGMP): Title 21, Part 210 & 211**
  - Device (QSR): Title 21, Part 820
  - Combination Product: Title 21 CFR Part 3 Subpart A (section 3.2e)

c-GMP is an important tools?

- **Adulteration**
- **Safety**
- **Identity**
- **Strength**
- **Quality**
- **Purity**


1. Quality Management
2. Quality Assurance
3. Good Manufacturing Practice (GMP) for Medicinal Products
4. Quality Control
5. Sanitation and Hygiene
6. Qualification and Validation
7. Complaints and Product Recall
Good Manufacturing Practices (GMP) Components
8. Contract Production and Analysis
9. Self-Inspection, Quality Audits and Supplier's Audits and Approval
10. Personnel, Training and Personal Hygiene
11. Premises
12. Equipment
13. Materials
14. Documentation
15. Holding and Distribution

LOCATION:

One of the major source of contamination for pharmaceutical product is the environment in which the pharmaceutical industry is located. Hence, it becomes obvious that the pharmaceutical industry should be located in an area where the surroundings are clean. For this purpose it is ideal to locate the Pharmaceutical industry in the exclusive clean zones, if not there must be adequate greenery and area surrounding the manufacturing facilities which can protect from the probable contamination coming from the neighbouring industry.

DESIGN & LAYOUT

Design of the pharmaceutical industry depends upon the categories of formulations and the quantities of production expected to be manufactured. One of the basic principle is the entire production operation should be uniflow in direction. Adequate areas for all the operation including production, quality control, warehousing, in-process, quarantine, maintenance etc. have to be provided. The men and material entry should also be provided. For workers, change rooms,
canteens etc. should be segregated to maintain a good hygienic conditions. The material of construction should be capable of
being cleaned and sanitized.The design should also take care of service areas, proper pressure differentials and a centralized recording system for temperature, humidity and pressure differentials.

UNIFORMS TO THE WORKERS

- All the personnel's working should be provided clean uniforms as per the guidelines available for each of the operational areas. The workers should also be subjected to periodical medical examination to ensure that they are suitable to perform their jobs, as personnel are one of the major source of contamination.

TRAINING

- As personnel are considered as major source of contamination, it is essential that all personnel's be trained for their functional area as well as G.M.P. concepts. These training programmes need to address the requirements specific to the operations carried out.

MASTER FORMULA

- There must be a well-defined procedure specifying conditions under which the products has to be manufactured, the equipment required, the process controls that has to be monitored and the production processes that has to be adopted in a well-defined master formula.

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- Write in detail about GMP guidelines for testing of pharmaceutical products.
- Explain in detail about GMP requirements for manufacture of pharmaceutical products.
- Write about the following:
- a) GMP requirements for manufacture of tablets and capsules
- What are the aims and objectives of GMPs? Write about GMP requirements for manufacture of oral liquids.

THANK YOU