Good Manufacturing Practices for Pharmaceutical sector

March 3, 2021

The USFDA on Wednesday said that it had resumed physical inspections of some manufacturing sites in India deemed “mission critical” for the US market. the USFDA may grant approval without inspection for a pre-approval inspection (PAI) if a drug belongs to an already approved profile class and the manufacturer has a Good Manufacturing Practices (GMP) track record.

In news: USFDA begins inspections of Indian manufacturing sites deemed mission-critical
Placing it in syllabus: Economy
Dimensions

- What is GMP?
- Why is it important?
- Role of WHO
- India and GMP

Content:

What is GMP?

- Good manufacturing practice (GMP) 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 and equipment to the training and personal hygiene of staff.
- Detailed, written procedures are essential for each

process that could affect the quality of the finished product.
- There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process – every time a product is made.

Risks in Pharma Production

The main risks are:

- **unexpected contamination** of products, causing damage to health or even death;
- **incorrect labels** on containers, which could mean that patients receive the wrong medicine;

insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects.

Why is it important?

- A poor quality medicine may contain toxic substances that have been unintentionally added.
- A medicine that contains little or none of the claimed ingredients will not have the intended therapeutic effect.
- Poor quality medicines are not only a health hazard, but a waste of money for both governments and individual consumers.
- GMP is designed to ensure that such mistakes do not occur.
- Implementation of GMP is an investment in good quality medicines.
- This will improve the health of the individual patient and the community, as well as benefiting the pharmaceutical industry and health professionals.
- Most countries will only accept import and sale of medicines that have been manufactured to internationally

recognized GMP.
- Governments seeking to promote their countries' export of pharmaceuticals can do so by making GMP mandatory for all pharmaceutical production and by training their inspectors in GMP requirements.

Role of WHO

- The World Health Organisation (WHO) has established detailed guidelines for good manufacturing practice.
- Many countries have formulated their own requirements for GMP based on WHO GMP.
- Others have harmonized their requirements, for example in the Association of South-East Asian Nations (ASEAN), in the European Union and through the Pharmaceutical Inspection Convention.
- The World Health Organization (WHO) version of GMP is used by pharmaceutical regulators and the pharmaceutical industry in over 100 countries worldwide, primarily in the developing world.

India and GMP

- As per the norms laid down in the Drugs and Cosmetics Act, 1940 (DCA), all Indian manufacturers have to comply with the GMP guidelines as per Schedule M.
- In addition, those who wish to export have to comply with international GMP guidelines such as the WHO GMP or specific GMP requirements of the importing country (such as those of US FDA and MHRA).
- Generally, at the international level, WHO GMP guidelines are considered general and minimum technical requirements for quality assurance
- Schedule M gives the details about company premises, quality control system, quality control laboratories, GMP in production, cleaning of equipment, housekeeping, cross-contamination and other related topics.
- The Indian GMP guidelines as written in Schedule M of

the DCA were initially based upon the 1982 WHO GMP guidelines, and were subsequently renewed in 2001.

- However, its effective implementation remains an issue of concern till date. There remains some debate about fine gaps in the specific details of Schedule M vis-à-vis WHO-GMP guidelines, although the broad principles remain the same.
- Several recent cases of non-compliance on part of the Indian companies with international quality norms have arisen from breach of protocol and problems of record-keeping, which may or may not affect the quality of product.
- Such instances often result in casting doubt on the reliability and credibility of the Indian pharmaceutical industry.
- Between 2015 and 2017, there were 31 FDA warning letters to Indian pharmaceutical companies citing serious Data Integrity issues, including data deletion, manipulation or fabrication of test results.

Pharma Regulators in India

- The Central Drugs Standard Control Organisation (CDSCO) is India's national regulatory body for pharmaceuticals and medical devices.
- Drugs Controller General of India (DCGI) is the head of department of the Central Drugs Standard Control Organization
- Drugs Controller General of India, comes under the Ministry of Health & Family Welfare. DCGI also sets standards for manufacturing, sales, import, and distribution of drugs in India.

Mould your thought: What are Good Manufacturing Practices in pharmaceuticals? Discuss their importance.

Approach to the answer:

- Introduction
- Define GMP
- Discuss the risk in medicine production
- Discuss the benefits of GMP
- Conclusion