GMP

Good Manufacturing Practice

PHARMA™
KNOWLEDGE CENTRE
"My Learning Life"

CERTIFIED ISO 9001:2015 COMPANY

CERTIFICATION COURSE ON GOOD MANUFACTURING PRACTICE (GMP)

Good Manufacturing Practice

Good Manufacturing Practice (GMP) are systems created and mandated by the Government to regulate production, verification and validation of drugs, food and/or medical devices, ensuring that finished products are effective and safe for market distribution.

Importance of GMP

Today, GMP is more commonly known as cGMP, and have been established flexibly to permit every manufacturer to use their discretion in implementing the best controls for their own organization. This flexibility also allows manufacturers to make use of the latest and most innovative technologies to result in products of better quality.

The 'current' addition is also used to imply that the FDA expects companies to continuously stay up-to-date with regulations as they are altered to suit changing market and consumer needs. The reason for this is that systems, machines or equipment that were in use, say a few years ago, are not as efficient/effective today and are hence inadequate in ensuring maximum consumer protection.

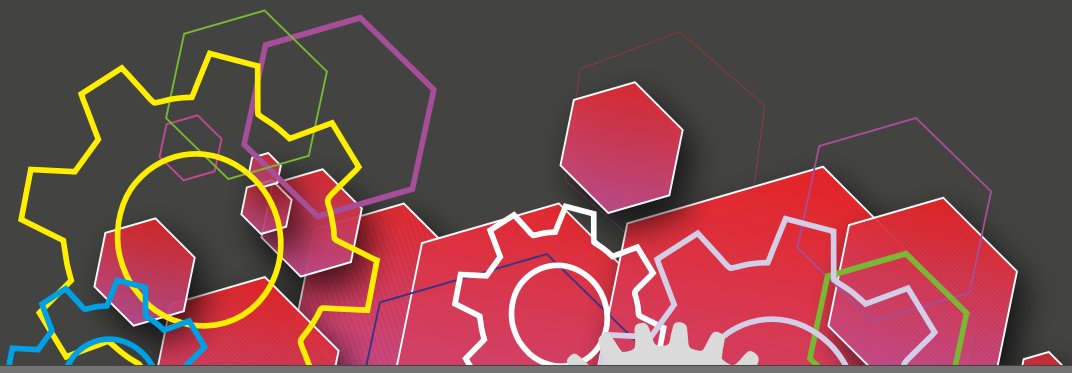
The cGMP requirements were established to be flexible in order to allow each manufacturer to decide individually how to best implement the necessary controls by using scientifically sound design, processing methods, and testing procedures. The flexibility in these regulations allows companies to use modern technologies and innovative approaches to achieve higher quality through continual improvement. Systems and equipment that may have been 'top-of-the-line' to prevent contamination, mix-ups, and errors 10 or 20 years ago may be less than adequate by today's standards.

cGMP Regulations

Current Good Manufacturing Practice (cGMP) regulations are guidelines which are set by the Food and Drug Administration (FDA), United States and regulators of each countries Food, Drug and Cosmetic product safety governing body. cGMP provide guidelines to develop systems which ensure that manufacturing facilities and processes are properly designed, monitored and controlled.

An industry that operates according to cGMP regulations offers the market products whose quality, identity, purity and strength has been tested and confirmed according to controlled manufacturing processes.

Part of cGMP for industries includes establishment of robust systems for quality control and management, using raw materials of proven quality, setting up strong operating procedures, identifying how quality deviations can be tested for products and maintaining consistent testing environments. Properly used, this scheme can be successful in curbing incidents of deviations, mix-ups, failures, contamination and other such errors.



Purpose of enacting cGMP

The average consumer cannot, either by sight, smell or touch, detect whether food, drug or cosmetic products are safe and/or effective. One part of determining this is testing products at various stages of production, but this alone cannot sufficiently ensure quality.

This is because testing is carried out on a rather small batch of products (such as 100 devices from a production line containing one million devices). This way, majority of the products can be sold on the market to maximize profit for the manufacturer, rather than sacrificing them to test procedures.

It is important to have guidelines/regulations governing every step, process, facility or equipment that will be used in the design and manufacture of consumer products. Facilities must be maintained in good condition, good manufacturing practice should be followed, employees should be properly trained and qualified, validation and verification of equipment should be done to maintain accurate, verified and calibrated measurements and processes should be consistent and reproducible.

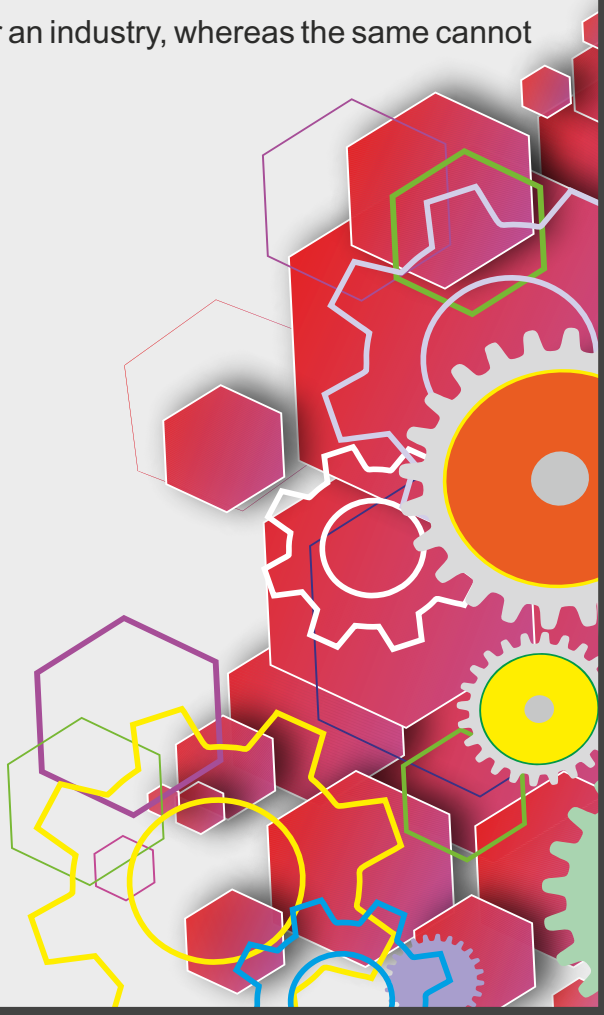
These are the main areas covered by cGMP regulations. By complying with the standards established in the regulations, a company has the best chance of always manufacturing products that are effective, efficient and safe for consumer use.

Comparison between cGMP and other Quality approaches

There are many quality assurance/control practices. cGMP distinguishes itself since it is mandatory for manufactures of products covered in the Food, Drug and Cosmetic Act.Others, such as ISO quality certification are not mandatory, which means manufacturers are encouraged but not required to comply with them.

However, many of the aspects covered in the various quality standards are the same, differing slightly only on allowable thresholds. cGMP include all guidelines relating to process validation, Comprehensive Corrective and Prevent Action (CAPA), vendor qualification, good laboratory practice as well as design and management reviews.

Failure to comply with cGMP may attract immediate sanctions for an industry, whereas the same cannot be said for other QC standards like ISO.



cGMP Compliance

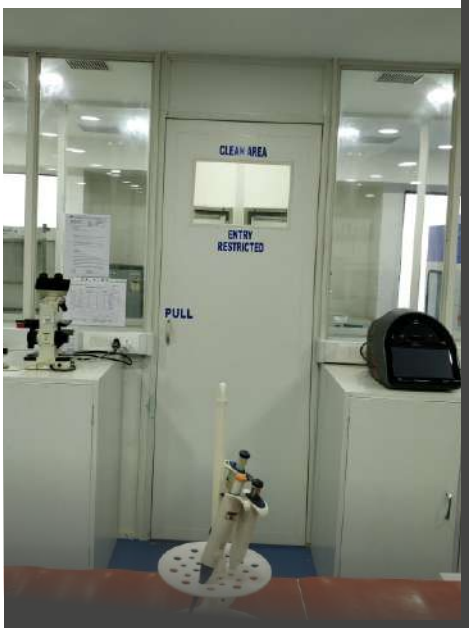
There are many aspects on compliance with Good Manufacturing Practice, and cGMP as required by the FDA. Usually, the FDA conducts an inspection of a manufacturer's facilities and processes, issuing warning letters and reports detailing areas of non-compliance. Subsequently, these areas highlighted must be corrected within a suitable timeframe, or a company's products will not be approved for sale into the American market.

The following is full list of cGMP regulations:

- Improving Documentation of GMP Procedures
- Better Compliance through Master Manufacturing Records
- Improving Batch Production Records
- Specifications that Improve Compliance
- Improving Quality through In-Process Control
- Documenting Deviations for Improved Compliance
- Supplier and Vendor Qualification
- Complaints and Recalls
- Packaging and Labelling
- Equipment for Manufacturing
- Facility Design for Manufacturing
- Facility Areas for Manufacturing
- Testing in Manufacturing
- Training Documentation

Regulators Perspective for cGMP Regulations

Regulators inspect pharma manufacturing facilities worldwide, including facilities that manufacture active ingredients and the finished product. Inspections follow a standard approach and are conducted by highly trained staff. Regulator also relies upon reports of potentially defective drug products from the public and the industry. Regulators will often use these reports to identify sites for which an inspection or investigation is needed. Most companies that are inspected are found to be fully compliant with the cGMP regulations.



Course Description

This programme is targeted towards imparting theoretical as well as practical knowledge of Good Manufacturing Practice to its candidate. After completion of the course participant is expected to have in-depth knowledge and better understanding of industry guidelines, regulations, regulatory bodies,compliance and future prospects. The modules have been compiled to introduce the attendee to various aspects and basics of GMP, its need and benefits in assuring quality production. Several specialized modules have been added to guide the candidate through GMP regulations, compliance needs, comparative GMP, rules of India and other countries, etc.

The curriculum is an admixture of components like Theory of the Subject, Hands on Practical Training, Self-development by way of Presentations, Group Discussions, Case Studies, Q&A sessions & Soft Skills required for the industry like handling difficult situations and people, trustworthiness and sustainability.

MODULE 1

- Brief about Pharma Companies
- Good Manufacturing Practice
- History of GMP
- Flow Process in Pharma Company
- Glossary / Terminology in Pharma Companies

MODULE 2

Various GMP Requirements on:

Premises, Buildings, Facilities, Equipment, Utilities, Personnel & their responsibilities, Research & Development, Warehouse, Materials,Production & Process, Quality Control, Quality Assurance, Distribution control Engineering and Maintenance, etc.

Stability

- Training on ICH Q1A- Q1F Guideline
- Documentation on Stability

MODULE 3

Workflow of Warehouse Management

- Receipt and Handling of Raw Materials and Good Distribution Practices
- Packing Materials, Solvents, Hazardous Material, Miscellaneous Materials, Intermediates and Finished Products

MODULE 4 : WORKFLOW OF PRODUCTION MANAGEMENT

For Small Molecule

- Types of Dosage Forms
- Solid Dosage Forms
- Liquid Oral Dosage Forms
- Parentrals and Injectables
- Filling of various Dosage Forms
- Packing and Dispatch of Finished Product

OR

For Biologics

- Dispensing
- Upstream for Bacterial manufacturing
- Upstream for Mammalian manufacturing
- Downstream for Bacterial manufacturing
- Downstream for Mammalian manufacturing
- Filling of various dosage forms
- Packing and Dispatch of Finished Product

MODULE 5

- Workflow in HR
- Workflow in Engineering
- Utility: Air, Water, Compressed Gas and Chiller

MODULE 6

- Demonstration of HPLC & LCMS
- Hands on Practical

Add ons

Analytical Hands on Training

1

HPLC Theory Training
- Demonstration of HPLC
- Hands on Practical

Gas Chromatography with Head Space
- Demonstration of GC
- Hands On Practical

KF Titration Theory
- Demonstration and Hands On Training

IR Theory
- Demonstration and Hands On Training

U.V Spectrophotometer Theory
- Demonstration and Hands On Training

Wet Chemistry
- Heavy Metal Analysis

Physicochemical and Biochemical Testing

2

- Gel Electrophoresis (Agarose and SDS) and Gel Documentation
- Blotting Techniques
- ELISA
- Protein Purification (RP and SEC)
- Enzymatic Assays

Molecular Biology

3

- DNA Isolation
- PCR and thermocycler
- Plasmid Isolation and Copy Number
- Cloning
- Qualification in Micropipetting (Single Channel and Multi Channel)

Cell Culture

4

- Mammalian Cell Culture and Cell Lines
- Revival, Subculturing, Cell Counting, Cryo preservation
- Proliferation of cell line NSF60,Hella
- Statistical Analysis of Biological Assays

Microbiology

Theory on Microbiological Techniques for Pharma Industry

5

- Media Preparation, Plate Preparation and Sterilization Basic Microbiology Techniques and Culture Handling (Subculturing and Preservation)
- Microbiology Limit Test and Bio Burden
- Water Sample Analysis
- Environmental Monitoring
- Sterility Testing
- Antibiotic Assays
- Bacterial Endotoxin (LAL Test)
- Utility Testing (Compressed Gases)
- Growth Promotion Test
- Growth Curve
- Handling of Positive Culture
- Trend Analysis
- Setting Action and Alert Limits

Programme Deliverables

- A comprehensive study material for all the modules in hard/soft copies ensuring the needs of the candidate. The accompanying training material is appropriately aligned with the current Industry's expectations
- Assignments for all the programme modules for continuous evaluation and guidance
- Interactive or recorded lectures on all key areas of the programme giving all flexibility to the participants
- Assessment and evaluation for all the programme modules, in order to enhance the levels of competencies and skills of the participants leading towards the objective of application on the job
- At the end of each programme modules, the trainers shall obtain feedback from the participants using specially designed questionnaires
- Training on Soft Skills

Certification

Pharma Knowledge Centre is exclusively providing the **Specialization Certification** to the students, to get highly paid placement on priority basis.

Placement Assistance & Corporate Relations

The Institute has partnered with many organizations for providing with placement assistance to its participants. Besides, it has a robust placement cell comprised of senior level Human Resources professionals and Talent Acquisition experts which maintains close links with business and industry. This cell is continuously engaged in promoting the employability of our participants and encouraging the concerned Human Resources department and Hiring Managers to recruit/hire our candidates for their vacant positions. The efforts of our placement cell also include helping with professional resume writing & interview skills.

Learning Objective

1) General principles and approach to GMP
2) Regulatory requirements for application of GMP
3) Key steps and activities for a GMP programme
4) How compliance and GMP are strategically used
5) Principles and requirements of GMP
6) How to classify cGMP non-conformances
7) Application of GMP in production and process control
8) How to apply GMP principles in process design
9) How to use GMP to maintain process control of production lines
10) The different tools applicable to GMP
11) GMP for an example of pharmaceutical product
12) How to apply GMP to validation

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