



GMP AND cGMP CONSIDERATIONS

What is GMP ?

- ◆ 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
- ◆ "GMP" - A set of principles and procedures which, when followed by manufacturers for therapeutic goods, helps ensure that the products manufactured will have the required quality.

What is cGMP ?

- ◆ Usually see “cGMP” – where c = current, to emphasize that the expectations are dynamic

Quality Definition

- ◆ Quality of a medicinal product is measured by its fitness for purpose . Safety and efficacy are not separable from Quality but part of it
- ◆

Quality	Safety	Efficacy	X
	Quality		
Safety	Efficacy		

GOOD MANUFACTURING PRACTICE

Standards of Performance

AUDIT

Personal

Internal

External

COMMITMENT

TRAIN

Top Management

Managers/Supervisors

Operators/Technicians

Support Staff

REINFORCE

Top Management

Operators/Technicians

Managers/Supervisors

Support Staff

Good Manufacturing Practices

- ◆ A basic tenet of GMP is that quality cannot be tested into a batch of product but must be built into each batch of product during all stages of the manufacturing process.
- ◆ It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

Some of 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 GMP is important

- A poor quality medicine may contain toxic substances that have been unintentionally added.
- A medicine that contains little or none of the claimed ingredient will not have the intended therapeutic effect.

GMP helps boost pharmaceutical export opportunities

- ◆ 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.

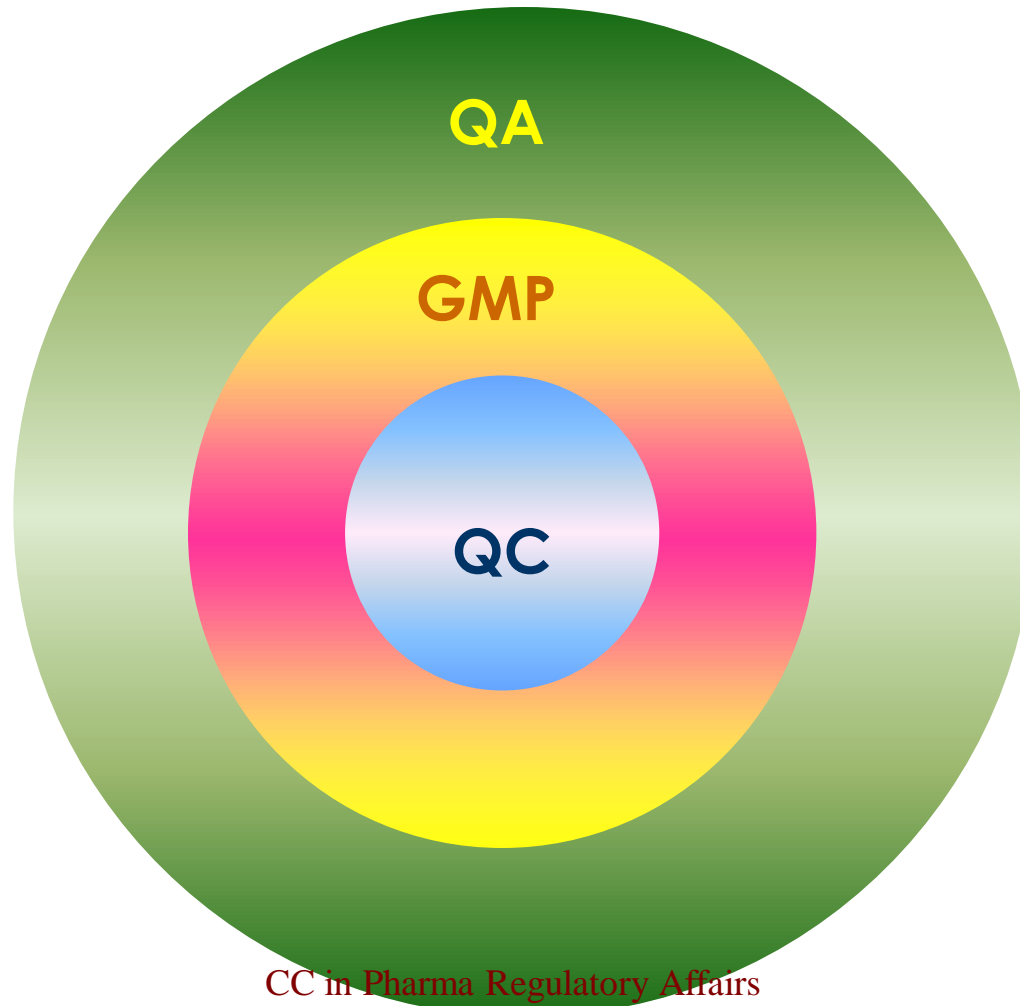
GMP Covers...

- ◆ **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.

GMP

- ◆ The Quality of a formulation or a bulk drug depends on the Quality of those producing it
- ◆ GMP is the magic key that opens the door of the Quality
- ◆ In matter of GMP, swim with the current and in matter of Quality stand like a rock!

QA, GMP & QC inter-relationship



QA, GMP & QC inter-relationship

QA: It is the sum total of the organized arrangements with the objective of ensuring that products will be of the quality required for their intended use

QA, GMP & QC inter-relationship

GMP

Is that part of Quality Assurance aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use

QA, GMP & QC inter-relationship

QC

Is that part of GMP concerned with sampling, specification & testing, documentation & release procedures which ensure that the necessary & relevant tests are performed & the product is released for use only after ascertaining it's quality

QC and QA

- ◆ QC is that part of GMP which is concerned with sampling, specifications, testing and with in the organization, documentation, and release procedures which ensure that the necessary and relevant tests are carried out
- ◆ QA is the sum total of organized arrangements made with the object of ensuring that product will be of the Quality required by their intended use.

QC and QA

- ◆ Operational laboratory techniques and activities used to fulfill the requirement of Quality
- ◆ All those planned or systematic actions necessary to provide adequate confidence that a product will satisfy the requirements for quality



QC and QA



- ◆ QC is lab based
- ◆ QA is company based

GMP guidelines

- ◆ GMP as per Schedule M
www.cdsc.nic.in
- ◆ GMP as per WHO
www.who.int
- ◆ GMP as per MCA now known as MHRA
www.mca.gov.uk
- ◆ GMP as per TGA
www.tga.gov.au
- ◆ GMP as per US FDA
www.fda.gov
- ◆ GMP as per ICH guidelines
www.ich.org

GMP

- ◆ GMP in solid dosage forms
- ◆ GMP in semisolid dosage forms
- ◆ GMP in Liquid orals
- ◆ GMP in Parenterals Production
- ◆ GMP in Ayurvedic medicines
- ◆ GMP in Bio technological products
- ◆ GMP in Nutraceuticals and cosmeceuticals
- ◆ GMP in Homeopathic medicines

GMP

- ◆ Good Manufacturing Practice
- ◆ Good Management Practice
- ◆ Get More Profit
- ◆ Give more Production
- ◆ GMP Training with out tears

GMP

- ◆ All past GMPs are history....It is looking like in rear view mirror and driving

Ten Principles of GMP

1. Design and construct the facilities and equipments properly
2. Follow written procedures and Instructions
3. Document work
4. Validate work
5. Monitor facilities and equipment
6. Write step by step operating procedures and work on instructions
7. Design ,develop and demonstrate job competence
8. Protect against contamination
9. Control components and product related processes
10. Conduct planned and periodic audits

Beyond GMP

- ◆ Reduce pollution -→ Zero discharge
- ◆ Adaptation of environment friendly methods
- ◆ Consideration for better and healthier life tomorrow
- ◆ Consideration of ethics in life
- ◆ One should begin with end in mind otherwise it will be the beginning of the end

Cost of effective GMP

- ◆ In fact Cost benefits – positive cost benefits of GMP/QA
- ◆ Good plant lay out, Smooth work flows, Efficient documentation systems, well controlled process, good stores lay outs and stores records- These are Good manufacturing practices
- ◆ Reduction in work in process and inventory holding costs
- ◆ Avoidance of cost of Quality failure (cost of waste, of rework, of recall, of consumer compensation and of loss of company reputation)

List of important documents in GMP

- ◆ **Policies**
- ◆ **SOP**
- ◆ **Specifications**
- ◆ **MFR (Master Formula Record)**
- ◆ **BMR**
- ◆ **Manuals**
- ◆ **Master plans/ files**
- ◆ **Validation protocols**
- ◆ **Forms and Formats**
- ◆ **Records**

10 attributes of a good document

1. **Accurate**
2. **Clear**
3. **Complete**
4. **Consistent**
5. **Indelible**
6. **Legible**
7. **Timely**
8. **Direct**
9. **Authentic**
10. **Authorized**

Certifying agencies

- ◆ **ICH.** www.ich.org
- ◆ **WHO.** www.who.int
- ◆ **US FDA.** www.fda.gov
- ◆ **EU/EMA.** www.emea.europa.eu

How do GMPs of different countries compare?

At a high level, GMPs of various nations are very similar; most require things like:

- Equipment and facilities being properly designed, maintained, and cleaned
- Standard Operating Procedures (SOPs) be written and approved
- An independent Quality unit (like Quality Control and/or Quality Assurance)
- Well trained personnel and management

cGMP For Finished Pharmaceuticals

1. General Provision
2. Organization & Personnel
3. Building & Facilities
4. Equipment
5. Control of Components & Drug Product Containers & Closures
6. Production & Process Control
7. Packaging & Labeling Control
8. Handling & Distribution
9. Laboratory Control
10. Records & Reports
11. Returned & Salvaged Drugs



General Provision



1. Scope
2. Definitions

Organization & Personnel

1. Responsibilities of quality control unit.
2. Personnel qualifications.
3. Personnel responsibilities.
4. Consultants.

Building & Facilities

1. Design and construction features.
2. Lighting.
3. Ventilation, air filtration, air heating and cooling.
4. Plumbing.
5. Sewage and refuse.
6. Washing and toilet facilities.
7. Sanitation.
8. Maintenance.

Equipment

1. Equipment design, size, and location.
2. Equipment construction.
3. Equipment cleaning and maintenance.
4. Automatic, mechanical, and electronic equipment.
5. Filters.

Control of Components & Drug Product Containers & Closures

1. General requirements.
2. Receipt & storage of untested components, drug product containers, and closures.
3. Testing and approval or rejection of components, drug product containers, and closures.
4. Use of approved components, drug product containers, and closures.
5. Retesting of approved components, drug product containers, and closures.
6. Rejected components, drug product containers, and closures.
7. Drug product containers and closures.

Production & Process Control

1. Written procedures; deviations.
2. Charge-in of components.
3. Calculation of yield.
4. Equipment identification.
5. Sampling and testing of in-process materials and drug products.
6. Time limitations on production.
7. Control of microbiological contamination.
8. Reprocessing.

Packaging & Labeling Control

1. Materials examination and usage criteria.
2. Labeling issuance.
3. Packaging and labeling operations.
4. Tamper-evident packaging requirements for over-the-counter (OTC) human drug products.
5. Drug product inspection.
6. Expiration dating.

Handling & Distribution

1. Warehousing procedures.
2. Distribution procedures.

Laboratory Control

1. General requirements.
2. Testing and release for distribution.
3. Stability testing.
4. Special testing requirements.
5. Reserve samples.
6. Laboratory animals.
7. Penicillin contamination.

Records & Reports

1. General requirements.
2. Equipment cleaning and use log.
3. Component, drug product container, closure, and labeling records.
4. Master production and control records.
5. Batch production and control records.
6. Production record review.
7. Laboratory records.
8. Distribution records.
9. Complaint files.

Returned & Salvaged Drug Products

1. Returned drug products.
2. Drug product salvaging.



THANK YOU