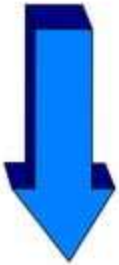
What is GMP?

- Good Manufacturing Practice is a set of regulations, codes, and guidelines for the manufacture of drug substances and drug products, medical devices, in vivo and in vitro diagnostic products, and foods.

GMP handbooks for every industry

OBJECTIVE

Guarantee high quality products to the consumer.



Delivering products free of all possible contamination

GENERAL REQUIREMENTS

- Avoid risks and possibilities of mix-up at all stages of Mfg, labeling Pkg and testing
- AHUs, comfort of the personnel working and regular monitoring of temp & humidity, Particle Count, DOP testing etc.
- Proper drainage system which prevents backflow. Avoid open channels and if provided must be able to clean and disinfect.

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.

Good Manufacturing Practices

- A basic principle 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.

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

GMP Categories

- Sale
- Premises
- Equipment
- Personnel
- Sanitation
- Raw Material Testing
- Manufacturing Control
- Packaging Material Testing
- Finished Product Testing
- Quality Control Department
- Records
- Samples
- Stability
- Sterile Products

Sale

- No distributor ... and no importer shall sell a drug unless it has been fabricated, packaged/labeled, tested, and stored .

Premises & Equipment

- Permits effective cleaning
- Prevents contamination
- Orderly conditions
- Good state of repair

Personnel

- Appropriate education, training and experience
- Sufficient number of people
- Receive GMP training

sanitation

- Sanitation Program to prevent contamination
  - Limit the ***sources*** and ***types*** of contamination
    - Cleaning procedures for facilities & equipment
    - Pest control
    - Environmental monitoring

Raw Material, Packaging Material and Finished Product Testing

- each lot or batch of raw material is tested
  - confirm the identity of the raw materials
  - provide assurance that quality of the drug in dosage
- Samples of incoming materials are collected and tested before use
- Approved test methods and specifications are used
- Results must conform to specifications for release for use or sale
- Transportation and storage records

Manufacturing Control

- Written procedures are established and followed
  - Master formulae, manufacturing order and packaging order
- Critical processes are validated
- 2nd person verification of activities
- Self-Inspection Programmed

Quality Control Department

- Quality Control Responsibilities
  - Testing of bulk components prior to use by production
  - Testing of finished product prior to release for sale
  - Stability program
  - Review batch records, labels
  - Release product, based on QC test results
  - Training, auditing
  - Customer complaints

Records

- Document all GMP activities
- Use Good Documentation Practices (GDP)
- Records must be readily available

Good Documentation Practices

- Documentation must be:
  - permanent (black or blue ink)
  - legible, clear, concise
  - accurate
  - Timely, complete

Samples

- Retain samples of each lot of raw material and finished product for specified period of time

Stability

- Establish the length of time in which the product meets all specifications
- Monitor the drug for this period of time

Sterile Products

- Packaged in separate enclosed area by trained personnel using method to ensure sterility

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 IN.....

- 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

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.

Conclusion

From the above discussion we can conclude that -

- Pharmaceutical Industry is regulated by GMPs
- Good Manufacturing Practices must be followed
- GMPs ensure drug products are safe, pure and effective.

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THANK YOU