Libyan International Medical University

Faculty of Pharmacy

Good Manufacturing Practice (GMP)

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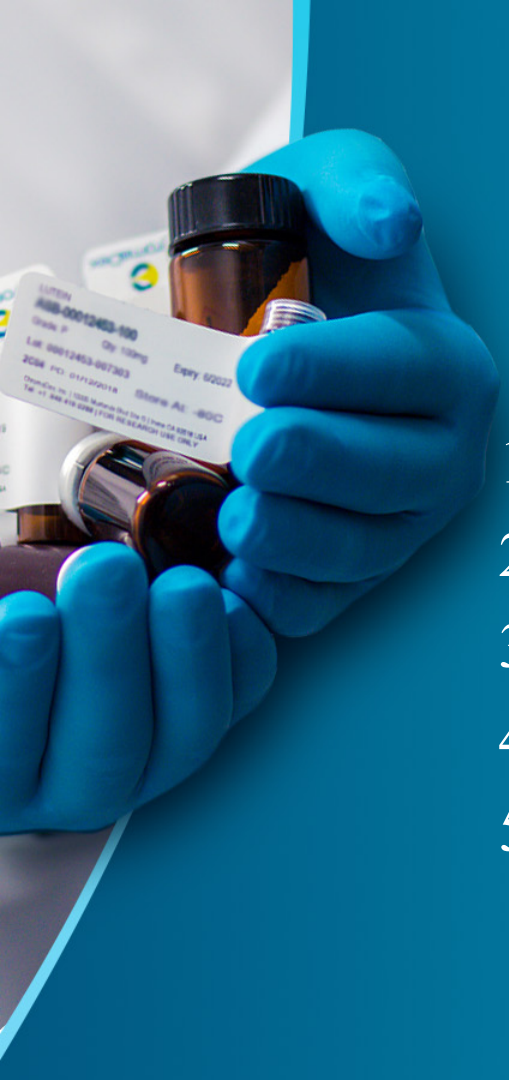

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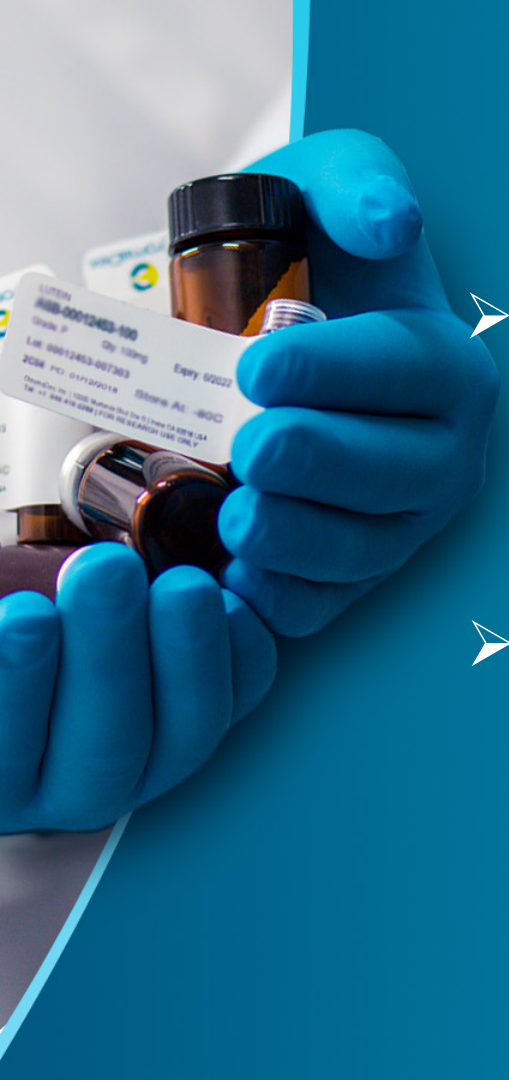
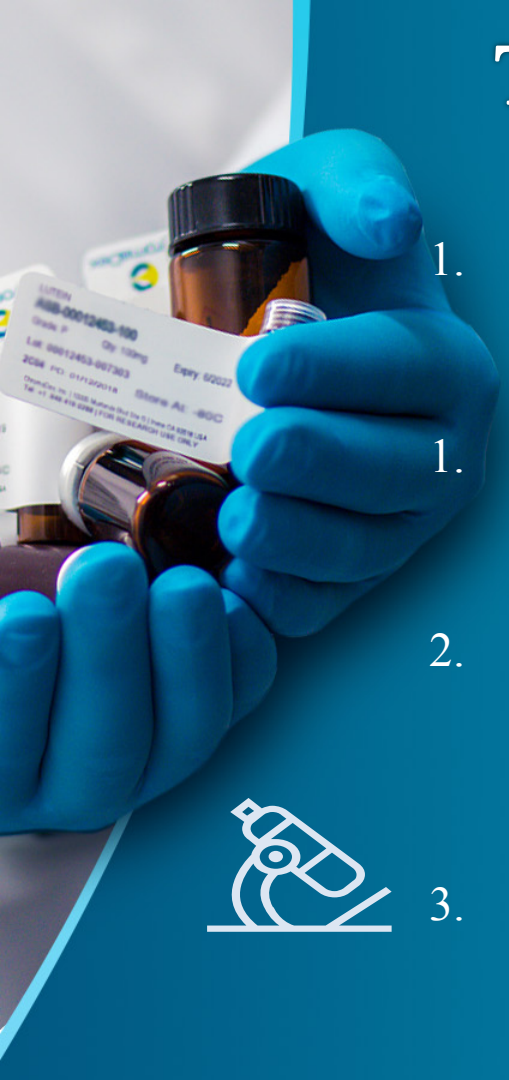
1) Define Good Manufacturing Practices.
2) Discuss some of the main risks
3) Explain why GMP is important.
4) Illustrate GMP Guidelines.
5) Explain the areas of good manufacturing practice (GMP)

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..
- 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



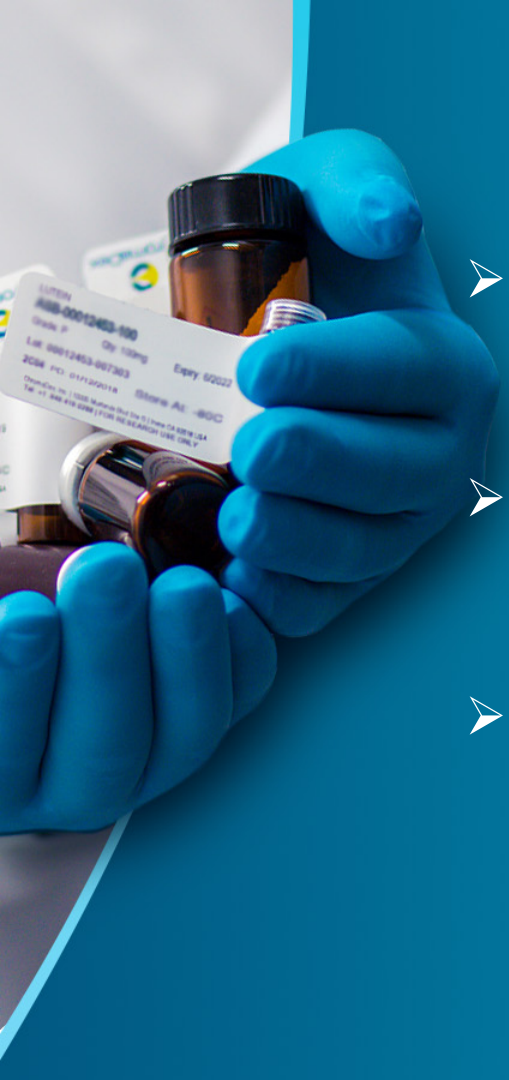
The four most important principles of GPM

1. Every process and every task is described in detail in specification documents (e.g. work instructions, SOPs, checklists).

1. Every employee (including managers) carries out the work exactly as defined and reports any deviation immediately

2. The employee records everything in detail while carrying out the tasks so that it is possible at a later stage to identify the who, what, and when of something that happened or was observed.

3. If this is the case, the work processes and specifications must be improved before a quality error occurs (continual improvement process, CIP).



Some of the main risks

- Unexpected contamination of product, 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.

What are GMP Guidelines ?

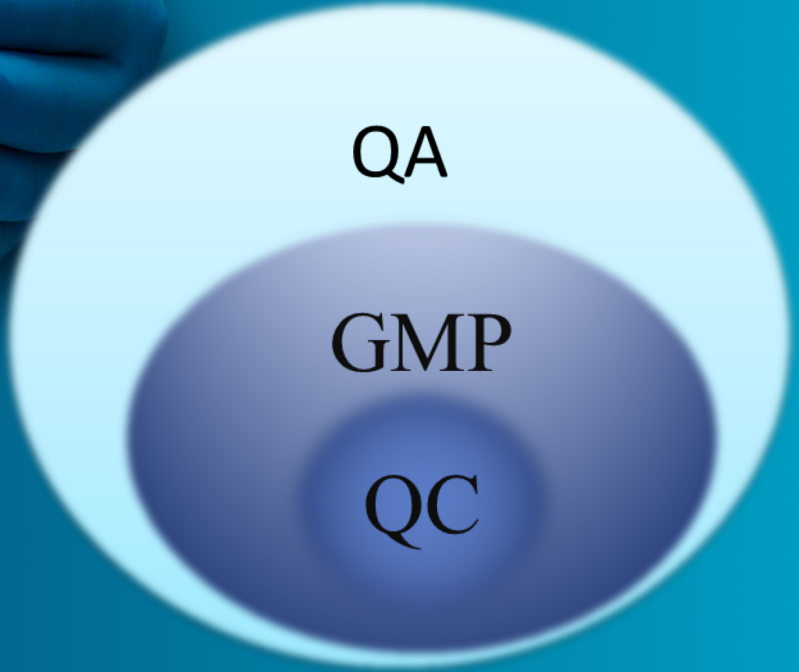
Quality management

Building and facilities/ Premises

Sanitation And hygiene

Equipment

QA, GMP and QC inter-relationship

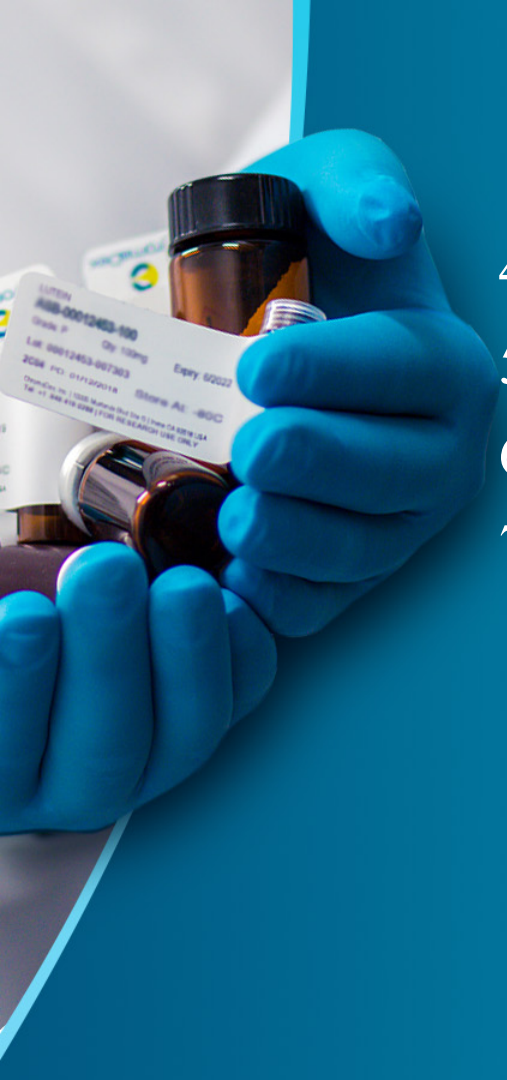


Quality Control	Quality Assurance
Focused on Product	Focused on Process
Reactive	Pro-active
Line Function	Staff Function
Finds Defects	Prevent Defects
Testing	Quality Audits
QC is lab based	QA is company based

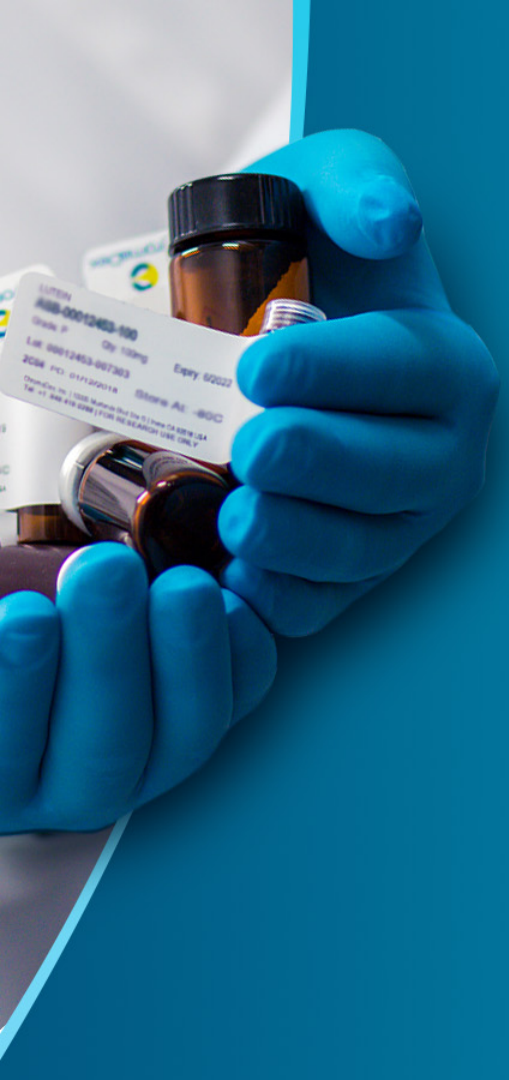
TO COMPLY WITH GMP

1. All manufacturing processes are clearly defined
2. Appropriately qualified and trained personnel.
3. Adequate premises and space.

TO COMPLY WITH GMP



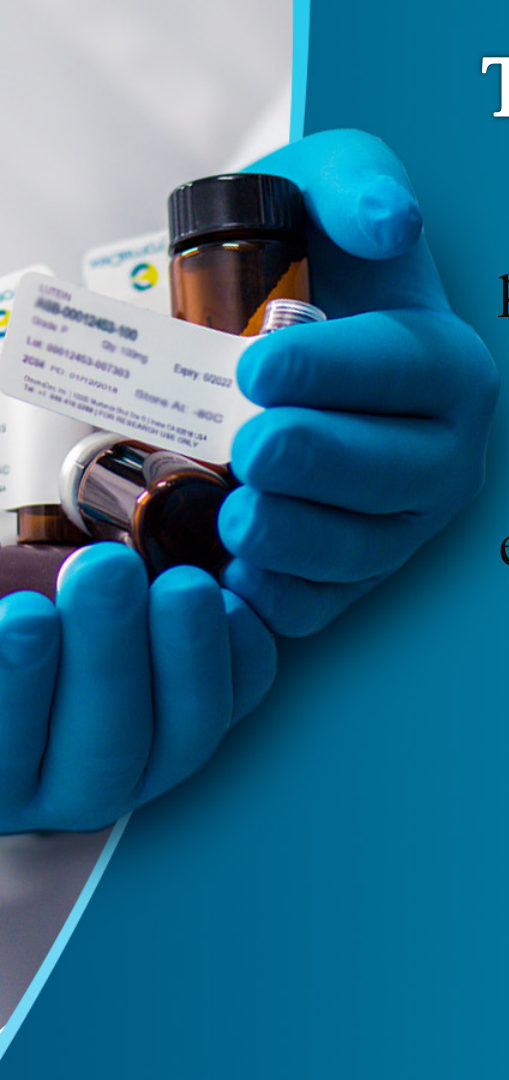
4. Suitable equipment and services.
5. Correct materials, containers and labels.
6. approved procedures and instructions.
7. Suitable storage and transport



TO COMPLY WITH GMP

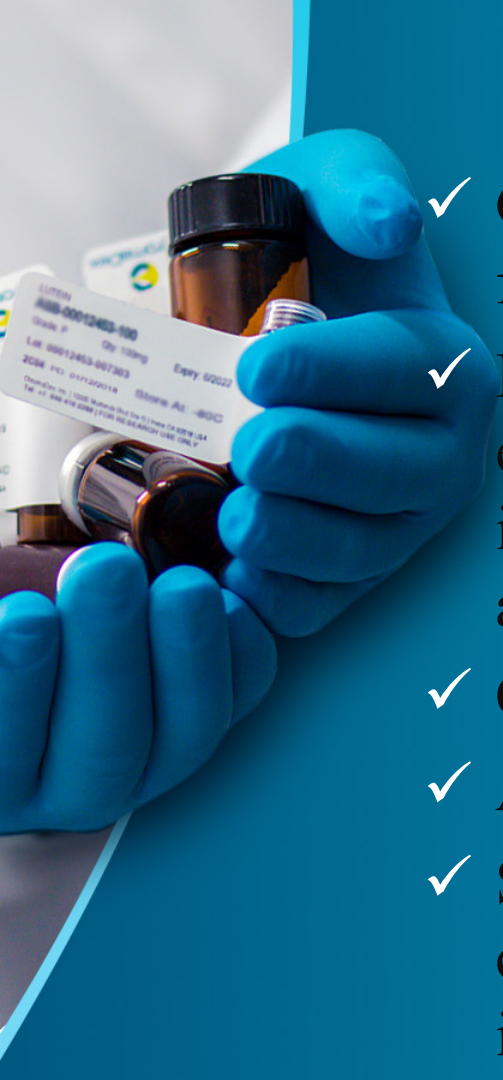
8. Instructions and procedures are written in an instructional form in clear and unambiguous language
9. Records are made, manually and/or by recording instruments
10. The distribution (wholesaling) of the products minimizes any risk to their quality.

TO COMPLY WITH GMP



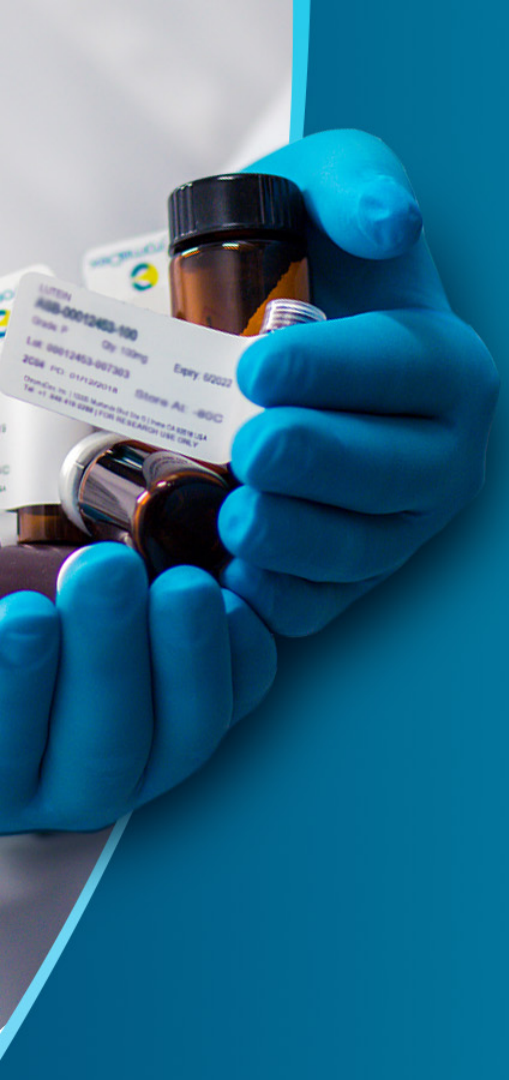
11. A system is available to recall any batch of product.

12.Complaints about marketed products are examined



Summary

- ✓ GMP is principles and procedures which, when followed by manufacturers for therapeutic goods
- ✓ Important principles of GPM The employee records everything in detail while carrying out the tasks so that it is possible at a later stage to identify the who, what, and when of something that happened or was observed.
- ✓ QA,GMP and QC inter-relationship.
- ✓ Areas of good manufacturing practice.
- ✓ Suitable equipment and services/Correct materials, containers and labels./approved procedures and instructions / Suitable storage and transport.



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Thanks.. !