



GMP

Good Manufacturing Practices





- **18 years experience in pharmaceutical field**
- **Certified lead auditor ISO 9001:2015 From IRCA**
- **CQE Certified Quality Engineer from The Egyptian Society of Quality Engineers**
- **Certified trainer from AAST Arab academy for science and technology**
- **Certified trainer from Cairo Governorate General Office**
- **Certified Management consultant from Cairo Governorate General Office**
- **I have trained hundreds of students from various universities , including Alexandria, Cairo, Tanta, Elmenia, Pharos, arab academy, and Japanese EJUST**
- **I have trained hundreds of trainees from various Arab nationalities, such as Saudi Arabia, the United Arab Emirates, Iraq, Syria, Sudan, Kuwait, and Jordan, Lebanon Additionally,**
- **I have provided consulting services in the field of quality and ISO.**





GMP Outlines

1. Introduction to quality
2. Introduction to GMP
3. Recognize the GMP concept
4. Recognize the risk concept
5. Differentiate between types of risk
6. Apply 10 principles of GMP



Introduction to Quality

- What is quality
- What are the specifications
- What are customer requirements



Introduction to GMP

- History of GMP
- Definition of GMP
- Concept of GMP
- Aim of GMP



Identify risks

- Definition of risks
- Types of risks
- Differentiate between risks
- Action to eliminate the risks



Principal 1 Validation

- Definition and concept of validation
- Types of validation
- Qualification
- Calibration
- Verification



Principal 2 Premises

- URS
- Design
- Cleaning
- Maintenance
- Types of premises



Principal 3 Personal

- Qualification

- Training

- hygiene



Principal 4 Validation

- Resources

- Tasks

- Scope



Principal 5 Production

- receiving & recording of starting materials
- Inspection of starting materials
- preparation of production documents, weighing activities
- cleaning & sanitization of equipment



Principal 6 Material

- Types of materials
- Supplier of the material



Principal 7 Documentation

- Data integrity
- GDP
- Document control
- Document life cycle



Principal 8 complaints

- Manage complaints
- Investigation
- CAPA



Principal 9 Recall

- Types of recall
- Difference between recall and withdraw
- Recall classification



Principal 10 Self Inspection

- Self inspection in QRM
- Self inspection classification
- Acceptance criteria
- Report of Self inspection



Thank

you