

Basic GMP requirements for MSME

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Pharmaceuticals

- Highly regulated
- Safeguards health
- Need to comply to Pharmacopoeial standards
- Comply with Audits
- Overcome Intellectual property barriers
- Must Comply with c GMP guidelines



Issues

- Product recalls
- Mix-ups
- Wrong labelling
- Foreign matter
- Contamination
- Productivity loss
- Wastage
- Loss of image
- Impact on profit



Reasons

- Improper GMP at Manufacturing
- Improper GMP at Material manufacturer
- Improper handling in Transportation
- Inadequacy in Specification
- Packaging design



Attitude in the past

- Subjectivity
- Focus on output than GMP
- Multi tasking
- It is costly
- No reward or returns in price



Manufacturing site

- Non polluted
- Good ventilation
- Clean surroundings
- Free from dust, cobwebs
- Controlled environmental conditions
- Insect-o-cutors
- Prevent from Rodents/Insects
- House keeping/Cleaning procedures
- Proper material movement



Personal hygiene

- Proper gowning including head gear
- Hand wash-Disinfectant
- Safety shoes
- Lockers/storage
- Health
- Separate eating area



Equipment and material

- Each machine shall be labelled
- Sufficient space between walls and equipment
- Operating instructions
- Preventive maintenance
- Safety precautions
- Separate storage of change parts, plates, cylinders, tools with proper labelling
- Machine log



Storage

- Well protected
- Segregation
 - Quarantine
 - Approved
 - Rejected
- Receipt, storage and Issuance procedures
- FIFO/ LIFO
- Avoid mix-up
- Waste / rejects disposal procedure



Manufacturing process

- Line clearance
- Operating instructions
- Batch manufacturing procedure
- Bill of materials
- Process controls
- Process Validation
- Defects display
- Reporting any kind of issue



Testing

- Incoming materials
- In-process samples
- Finished goods
- Equipments
- Calibration
- Standards
- Test procedures



Documentation

- Written procedures
 - SOPs, STPs, Specifications
- Job cards/Batch record
- Job description
- Deviations
- Change controls
- Review procedure



Training

- Skill development
- On job training
- Skill enhancement
- SOPs and STPs
- Safety
- First aid
- Assessment and Record



Complaint handling

- Record
- Investigation
- Senior management intervention
- CAPA
- Process/ system improvement
- Review



Internal audits

- Competent personnel
- Schedule
- Reports
- Action plan
- Review



End result

- No Subjectivity
- Systematic approach
- Consistency
- Minimum rejects
- Overall quality
- Improves health of the enterprise and health of the patients



Thanks