

GMP Audit Checklist

Check if all the points under each component are compliant.
Apply corrective actions in case of non-compliance.

Quality Management System (QMS)

- Is the QMS documented and up to date?
- Are procedures followed to maintain the QMS?
- Is there a system in place to handle and document non-conformances?

Facilities and Equipment

- Are facilities and equipment clean and well-maintained?
- Are equipment calibration and validation records up to date?
- Are facilities and equipment designed to prevent contamination and cross-contamination?

Production Operations

- Are production processes documented and followed consistently?
- Is there a system in place to track production batches and materials used?
- Are there procedures to prevent contamination and cross-contamination during production?

Quality Control

- Is there a system in place to test finished products for quality and safety?
- Are testing procedures documented and followed consistently?
- Are test results recorded accurately and completely?

Personnel

- Are personnel trained and qualified for their roles?
- Are personnel following hygiene and safety procedures?
- Are personnel records up to date and accurate?

Materials Control

- Is there a system in place to ensure the quality of incoming materials?
- Are materials stored in appropriate conditions?
- Are materials tracked and labeled accurately?

Packaging and Labeling

- Are packaging and labeling procedures documented and followed consistently?
- Are labels accurate and complete?
- Is there a system in place to track and control packaging materials?

Documentation

- Is all GMP-related documentation complete, accurate, and up to date?
- Is there a system in place to control and maintain GMP-related documentation?
- Is all documentation accessible and properly stored?

Fda Gmp Gap Analysis Checklist

Ensheng Dong



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