



Quality System :: GMP :: Validation

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teamwork

teamwork

full suite service

Quality System :: GMP :: Validation

- INSPECTION AND AUDIT
 - Identify deficiencies and implement corrective actions and follow up tracking

- CHANGE CONTROL
 - Implementation and integration with document systems

- DEVIATION MANAGEMENT
 - Implementation of corrective action and preventive action (CAPA)
 - Root cause analysis

- DOCUMENT CONTROL
 - Document Formats and Numbering
 - Issuance and Change Control

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- LABORATORY CONTROL
 - Product stability testing program
 - Lab compliance
 - Sampling plan

- MATERIALS MANAGEMENT
 - Supplier qualification programs
 - Material specifications
 - Packaging and labeling control
 - Warehousing control - quarantine through release with traceability

- PRODUCTION CONTROL
 - Master batch records and procedures
 - Product changeovers
 - Cleaning validation

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■ QUALIFICATION AND VALIDATION

- Validation Master Plan
- Risk Assessment
- Production equipment
- Utilities and warehouse
- Laboratory equipment
- Method validation
- Computer system validation (CSV)
- Process validation
 - Integration with process development and stability testing

■ CONTAMINATION CONTROL

- Facility, equipment and procedure review
- Microbial alert and action limits
- Cleanroom strategy

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■ QUALITY ASSURANCE

- Quality manual and quality policy
- Batch release procedure
- Complaint handling procedure
- Recall
- Reprocessing and rework

■ TRAINING

- Implementation of training plan
- Provide customized training sessions on-site by experienced GMP trainers

■ PROJECT MANAGEMENT

- Deploy internal and external resources to meet business and compliance objectives, with emphasis on timeliness and cost efficiency