

# **Standard Controls of Quality**

**Research/Organization: GLP**

**Manufacturing: GMP**

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# GLP (Good Laboratory Practice)

## Fundamentals of GLP

- Standard Operating Procedures
- Raw Data and Data Collection
- Records and Recording
- Archives and Archiving

## Quality Assurance

- SOP Review
- QA Schedule & Inspection Plan
- Inspections of Suppliers and Contractors
- Archiving of QA files and reports

# GLP (Good Laboratory Practice)

## Implementation

- Appoint Implementation Project Team
- Establish Project Tasks
- Project and Progress Review
- Task Implementation
- Formal Audit & Reports Filed

# GMP (Good Manufacture Practice)

## Fundamentals of GMP

- Standard Operating Procedures
- Raw Data and Data Collection
- Records and Recording
- Archives and Archiving

## Quality Control

- Specifications and Tests
- Standard Material
- External Quality Audit

# GMP (Good Manufacture Practice)

## Quality Assurance

- Material Sampling/Validation
- Inspection
- Risk Analysis
- Product/Process Stability Validation

## Implementation

- Appoint Implementation Project Team
- Establish Project Tasks
- Project and Progress Review
- Task Implementation
- Formal Audit & Reports Filed