

Procedures, Templates and Checklists for FDA Compliant Process Validation

Proven procedures, templates and checklists for Manufacturing Process Validation!

This comprehensive package will provide sample procedures and templates to address FDA and ISO process validation requirements including protocols for:

- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

Why purchase these quality documents?

- Save time in validation effort
- Achieve increased confidence in compliance
- Ensure consistency in process validation efforts

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Procedures

- Validation Plan
- Validation Procedure

Samples

- Installation Qualification Sample
- Operational Qualification Sample
- Performance Qualification Sample

Templates

- Validation Report
- Safety Risk Analysis

Checklists

- Checklist for Device Software Validation Required
- Checklist for Drugs Software Validation Required

Reference Materials

- 21 CFR Part 11 Electronic Records; Electronic Signatures
- 21 CFR Part 820 Quality System Regulation
- FDA General Principles of Process Validation
- GHTF General Principles of Process Validation

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