IT Procedures, Templates and Checklists for FDA Compliance

Proven procedures, templates and checklists for validation of non-product software and 21 CFR Part 11 compliance!

The FDA Quality System Regulation requires validation of software used in manufacturing or the quality system (820.70(i)) and ISO 13485:2016 has three requirements for the validation of software used in the quality system and in manufacturing processes (4.16, 7.5.6, 7.6).

This package will provide proven documents that address FDA and ISO requirements including the following:

- **Identifying software systems that require validation**
- **Compliance with 21 CFR Part 11 electronic records and electronic signatures**
- **Procedures for development and validation of non-product software**

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Procedures
- Backup Procedure
- Electronic Record Procedure
- Risk Analysis Procedure
- Security Procedure
- Software Change Control Procedure
- Software Development Procedure
- Test Procedure

Guidelines
- Coding
- Design Description
- Requirements Specification
- Test Procedure

Checklists
- Design Description
- 21 CFR Part 11 Required Activities
- Requirements
- Software Subcontractor Selection
- Software Validation Required (21 CFR Part 211)
- Software Validation Required (21 CFR Part 820)

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