INTLAND SOFTWARE

Why use this Validation Kit?

A one-stop-shop to fully validate your development platform against regulatory requirements

Cut the time and effort costs of tool qualification for use in targeted regulated areas

Intended use limits the scope of your validation efforts to the features & use cases relevant for you

Need help?

This Validation Kit comes packaged with domain-oriented consulting in order to help you understand and implement its application for your use case or defined SOP.

Customization is also available to help fit the use cases, environment, and other specific requirements to the audited process.

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FDA Title 21 CFR Part 11 Validation Kit

Intland Software's FDA Title 21 Code of Federal Regulations Part 11 Validation Kit was designed to help medical and pharma users of our products comply with regulations on electronic record keeping and e-signatures. Use this template to greatly reduce the costs of tool validation for regulatory compliance.

This template helps accelerate and simplify the tool qualification process, enabling you to easily validate Intland's products for use in targeted regulated areas as per FDA 21CFR11.

This Kit contains the following elements populated with predefined content:

Qualification Plan of ALM software

- Purpose and strategy of qualification
- Procedure
- Personal aspects and schedule
- Deliverables

User Requirements Specifications of ALM software

- ALM-specific requirements
- FDA 21CFR11-related requirements

Functional Design Specifications of ALM software

- Functional Design ALM software
- Functional Design FDA 21 CFR Part 11

Test Protocols ALM software

- CT Configuration Tests
- FT Functional Tests
- UAT User Acceptance Test