Intelex Validation Fact Sheet

A crucial aspect of QMS implementation is the validation of the system. Whether it is a pre-validated or externally validated system, validation serves as a critical checkpoint to guarantee that the system meets organizational objectives and regulatory requirements. This document highlights the benefits of opting for an externally validated system, while also demonstrating the inherent risks associated with a pre-validated system. It also delves into the importance of validation and demonstrates how it integrates into the implementation process.

BENEFITS OF EXTERNALLY VALIDATED SYSTEM

- Provides the client with the opportunity to tailor the system to best fit the organization's needs
- Increases familiarity with the system and validation process, which enhances quality oversight and validation options
- Establishes a trusted relationship with a validation partner for sustained audit defense and system enhancements support
- Creates the ability for streamlined subsequent validation if the system experiences enhancements, patches, etc.

AUDIT DEFENSE RATE

100%

Glemser is Intelex's only validation partner and has been validating Intelex systems for 7+ years. All clients have reported no audit findings or CAPAs based upon the validation documents.

RISKS OF PRE-VALIDATED SYSTEM

- Configuration capabilities are restricted
- Out-of-the-box system often requires additional configuration, resulting in the need for external validation
- Any configuration changes will put the organization at risk of non-compliance and CAPAs
- Not having access to a trusted validation partner for audit support and future enhancements

VALIDATION TRIGGERS

Updates to Configuration

- Addition of new Applications
- Changes to workflows
- Changes to core behavior
- Field changes hardly ever impact validation

Updates to Platform Version

- Updates are applied as requested
- Periodically (6, 12 months, etc.)
- New Functionality or Features
- Patch to address an encountered issue

FDA REGULATORY ENFORCEMENT

The FDA can exercise a range of enforcement actions to compel industry compliance, including:

- FDA 483
- Warning Letter
- Injunction
- Recall
- Seizure
- Arrest
- Debarment
- Withholding approval of new products
- Import from foreign countries
- Consent Decree

HOW DOES VALIDATION FIT INTO THE PROCESS?

DESIGN > CONFIGURATION > TESTING > VALIDATION ★ > GO-LIVE

Need validation support? Contact Glemser to get started today.
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