TEKLYNX Validation Accelerator Pack (VAP)

Expedite your alignment with industry standards in life sciences, meet FDA and EU compliance requirements, comply with 21 CFR Part 11, and save time and resources by accelerating your validation of labeling processes with TEKLYNX VAP.

Validation and Documentation Are Required in Highly-Regulated Companies – TEKLYNX Can Help

As a component of quality assurance, validation is critical. Regulatory authorities like the United States Food & Drug Administration (FDA) and the European Union (EU) have guidelines related to process validation to confirm a company's labeling processes will result in reliable outputs while meeting the determined quality standards.

The TEKLYNX Validation Accelerator Pack (VAP) is available for purchase with CODESOFT + LABEL ARCHIVE or TEKLYNX CENTRAL labeling applications. It is comprised of valuable templates that outline the comprehensive list of necessary acceptance criteria, testing instructions, expected results, and worksheets for documentation of actual results of testing from the validation team.

TEKLYNX VAP includes the required testing procedures for validation and quality protocols: Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ); providing medical device manufacturers and life science companies with a tool to simplify and accelerate validation documentation and management.

The TEKLYNX Validation Accelerator Pack Includes:

- **Installation Qualification (IQ) Protocols:** Test protocol worksheets to guide and validate the computing prerequisites for correct installation of TEKLYNX software
- **Operational Qualification (OQ) Protocols:** Test protocol worksheets to guide and validate that TEKLYNX software performance is consistent with the user requirement specification
- **Performance Qualification (PQ) Protocols:** Test protocol worksheets to guide and validate TEKLYNX performance and alignment with customer requirements
- **References and Associated documents:** A comprehensive list of references including user guides, regulatory guidelines, and training materials
- **Validation Plan/Report:** Templates to ensure validation activities are properly planned, reported, and completed in one primary document

The TEKLYNX VAP templates are in accordance with verification and validation strategies, are easily adaptable to specific project requirements, and helps save time for your validation team.

TEKLYNX recommends you work with our professional services team for label management deployment to help satisfy the documentation needs of IQ, OQ, and PQ validation packages, and to ensure your labeling system aligns with best practices. **Contact TEKLYNX in your region for pricing and to learn more.**

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