LOFTWARE SPECTRUM® VALIDATION ACCELERATOR PACK

SAVE TIME, REDUCE COST OF IMPLEMENTING A VALIDATED AND COMPLIANT LABELING SOLUTION

Now you can streamline the validation workload for a standardized Enterprise Labeling Solution while meeting evolving FDA and EU regulatory requirements.

USDM Life Sciences and Loftware have partnered to develop a Validation Accelerator Pack (VAP) to simplify compliance, increase productivity and minimize costs. The Loftware Spectrum VAP—leveraging the industry's most powerful labeling solution—enables medical device companies to quickly and cost-effectively implement and maintain a validated, compliant labeling solution.

As USDM's only VAP for an Enterprise Labeling Solution, the Loftware Spectrum VAP is a set of content-rich validation templates that are ready to be configured to reflect your implementation decisions:

- Validation Plan
- System Requirement Specifications
- Functional Risk Assessment
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Traceability Matrix
- Validation Summary Report
- 21 CFR 11 Assessment

The VAP templates are in MS Word and can be easily updated to include your specific information and project details.

"The Loftware Spectrum VAP helps medical device companies meet regulatory challenges, while reducing validation time and costs up to 50%."

—Jay Crowley, Vice President
UDI Services and Solutions
USDM Life Sciences

Value-Added Benefits of Loftware Enterprise Labeling

- Sustain regulatory compliance across your extended supply chain with dynamic, data-driven labeling
- Adapt more easily to customer, 3PL and CMO label requirements
- Respect and leverage "sources of record" to ensure label accuracy
- Reduce label template maintenance with integrated, automated solution
- Configure and scale labels to expand into new markets
- Help facilitate 21 CFR Part 11 compliance with configurable framework and eSignature capabilities

LOFTWARE™ ENTERPRISE LABELING SOLUTIONS

USDM Life Sciences

WHY VAPS FOR UDI COMPLIANCE?

Today's medical device companies are challenged to manage global compliance standards and accelerate performance to maintain a competitive edge. It's vital to continue to pursue new ways to decrease costs, shorten time to market, and increase productivity—all while achieving, simplifying and maintaining compliance.

USDM VAPs are proven to help companies meet these challenges. In some cases, they have reduced validation time and costs by up to 50%. With medical device companies working toward UDI compliance, the Loftware Spectrum VAP can save significant effort and ensure a sustainable labeling solution across your extended supply chain.

Here are more details on the specific documents you'll find in the Loftware Spectrum VAP:

VALIDATION PLAN AND VALIDATION SUMMARY REPORT

The Validation Plan contains standard sections and wording which you can leverage to conduct a validation project. Use the instructions included to add project-specific information. The Validation Summary Report summarizes the project and specifies the Standard Operating Procedures (SOPs) you can use to maintain the validated system.

SYSTEM REQUIREMENTS SPECIFICATION (SRS)

The SRS lists business-level requirements and was used to develop the qualification test scripts for Loftware's Enterprise Labeling Solution. You should review the SRS and modify it as needed to match your company-specific business requirements. Changes to the SRS would require corresponding changes to the qualification test scripts.

INSTALLATION/OPERATIONAL/PERFORMANCE QUALIFICATION TEST SCRIPTS (IQ/OQ/PQ)

The IQ verifies and documents that system components are combined and installed in accordance with specifications, supplier documentation, and local and global requirements. The IQ does not address the installation of other required infrastructure such as server hardware, operating system software, etc. or other products. The OQ tests the system against specifications to demonstrate correct operation of functionality that supports the specific business processes throughout all specified operating ranges. The PQ tests the system to demonstrate fitness for intended use and to allow acceptance of the system against specified requirements.

Testing will be executed manually by using the system and completing the corresponding script documents. Data will need to be provided by the company performing the validation; instructions about the type of data required are included in the script.

TRACEABILITY MATRIX

The Traceability Matrix traces the requirements and specifications defined in the SRS to where they are tested or verified.

FUNCTIONAL RISK ASSESSMENT

The Functional Risk Assessment will facilitate the identification and analysis of potential risks involved in the validation of the Loftware Enterprise Labeling Solution. Once completed it provides documentation of the potential risks, potential effects, probability of occurrence and detection, and any mitigation activities.

21 CFR 11 ASSESSMENT

Title 21 Code of Federal Regulations (CFR) Part 11 compliance allows the FDA to accept electronic records and signatures in place of paper records and handwritten signatures. This assessment looks at how you can add workflow and eSignature capabilities for managing labels to meet compliance and gain operational efficiencies.

GET STARTED WITH THE LOFTWARE SPECTRUM VAP TODAY!

For more information, contact us at SalesInfo@loftware.com.