

FULLSCOPE FDA VALIDATION TOOLKIT

for PROCESS INDUSTRIES FOR MICROSOFT DYNAMICS AX

Software validation within highly regulated life sciences systems environments can be a daunting task—especially for transaction-oriented systems such as enterprise resource planning (ERP). Fullscope understands the unique challenges facing life sciences companies and offers a comprehensive solution to facilitate the development of mandatory software validation deliverables in an easy-to-use toolkit.

The U.S. Food and Drug Administration (FDA) Validation Toolkit for Process Industries for Microsoft Dynamics AX 2009 delivers best practices at your fingertips. It offers unprecedented services, coupled with validation starter templates, protocols and scripts, to let pharmaceutical manufacturers or other life sciences companies quickly and cost-effectively navigate the complicated validation process.

Complete Validation Processes Quickly

Companies that manufacture medical devices, pharmaceuticals or other regulated substances must demonstrate that they can meet the consistent manufacturing, safety and tracking standards required by law. Fullscope's FDA Validation Toolkit includes a "how to guide" for project management, risk assessment, tracking and managing validation activities, templates for completing the documentation required by the U.S. FDA, documentation for a vendor audit of Process Industries for Microsoft Dynamics AX, and consulting services to assist the manufacturer in completing the validation process.

Capture Standard Information to Reduce Time and Effort

The U.S. FDA and other similar regulatory agencies worldwide validate a manufacturer's implementation and intended use of a vendor's software rather than the software itself, forcing each life sciences company to conduct a complete validation process based on risk. The software, documentation and services provided in the Fullscope FDA

Validation Toolkit can help reduce the time and effort required by capturing as much of the standard information as possible from common validation practices and templates.

Manage the Validation Process with Ease

Additional software provides you with tools to manage the validation process, track company-specific changes made to Microsoft Dynamics AX, and monitor on-going compliance status. The consulting services include on-site assistance from experienced validation consultants to conduct the risk assessment, implement the software, plan the validation project and complete the templates.

Key Enhancements for 2009

- Support for Latest Good Automated Manufacturing Practice (GAMP) 5 methodology
- Updated Validation Master Plan (VMP) including risk assessment
- Support for a hosted or virtual systems environment, or installation directly on your servers
- Support for medical devices (discrete processes)
- Includes test protocols for 20 new business processes
- Virtualization scripts
- Estimated \$50K+ in consulting cost savings
- Enhanced *Introduction To FDA Validation* video delivered on DVD
- Includes validation verification videos that show recorded session running test scripts
- Toolkit delivered in convenient DVD format

<p>Validation document templates</p>	<p>The validation toolkit includes a comprehensive set of starter templates to accelerate validation initiatives. These templates are pre-populated and formatted for ease of use and editing. The starter templates include:</p> <ul style="list-style-type: none"> • Validation Master Plan (with risk assessment) • User Requirement • Software Plan • Requirements Disaster Recovery • Software Traceability • Validation Test Plan • Supplier Audit Check List • Internal Procedures • Signature Matrix • Validation Standard Operating Procedures • Installation Qualification (IQ) • Operational Qualification (OQ) • Performance Qualification (PQ) • Validation Summary Report <p>plus many others.</p>
<p>Validation test scripts</p>	<p>Fullscope offers IQ, OQ and PQ test scripts to help accelerate the validation process. These scripts provide an excellent starting point to help reduce the overall time and effort required for validation.</p>
<p>Validation project management</p>	<p>Our validation consultants come from the ranks of leading global life sciences companies. Their experience and proven validation methodologies deliver valuable assistance to ensure your project is on time and within budget.</p>
<p>Test script execution services</p>	<p>Our flexible test script execution services are designed to be delivered either with assistance from members of your team or we can execute the scripts for you, saving you time and money.</p>

For more information on the FDA Validation toolkit, please contact Fullscope at info@fullscope.com or visit www.fullscope.com.

