

TECTURA VALIDATION TOOLKIT FOR LIFE SCIENCES COMPANIES

VALIDATE YOUR MICROSOFT DYNAMICS ERP IMPLEMENTATION

- REDUCE YOUR RISK
- STREAMLINE THE ERP VALIDATION PROCESS
- REDUCE VALIDATION TIME AND COSTS
- ACHIEVE CLARITY, ACCOUNTABILITY, AND CONTINUITY FOR YOUR ERP SOFTWARE VALIDATION



Validate Your Microsoft Dynamics ERP Implementation

LIFE SCIENCES COMPANIES WIN WITH REDUCED RISK AND GREATER CONFIDENCE

Software validation is not an option for today's highly regulated life sciences organisations. Validation and verification is required by the FDA to ensure that Enterprise Resource Planning (ERP) systems have clear user requirements that define the intended use of the system; and that these are strictly upheld over time.

VALIDATION IS A PROCESS, NOT AN EVENT

Tectura's experienced ERP implementation team understands this. Today we are assisting clients worldwide to implement life sciences ERP solutions utilising our Microsoft Dynamics ERP implementation methodology that lays the groundwork for successful future system validation.

CHALLENGES OF VALIDATION

As life sciences organisations increasingly automate highly regulated processes, labor-intensive and costly system validations pose a significant challenge. As technology adoption increases to meet the needs of cutting-edge organisations, a single company can find itself validating multiple systems - and the costs quickly add up.

The validation of an ERP system, given its process and transactional nature, takes time; and with rigid requirements relating to document preparation and testing – labor costs associated with validation are high. In addition, some life sciences organisations attempt to minimise risk by validating every command within a Commercially-Off-The-Shelf (COTS) solution. This is not only expensive but is also unnecessary. Risk-based validation has been accepted for many FDA regulated environments over the last decade. Taking full advantage of the Commercially-Off-The-Shelf (COTS) solution and validation framework allows organisations to focus on commercially effective business processes as well as maintain high levels of compliance.

ONE TOOLKIT – MANY BENEFITS

Tectura has focused efforts on solving the challenges of software validation

and assisting life sciences organisations to streamline the process, cut associated costs and reduce risk. The Tectura Validation Toolkit incorporates key software validation document templates with best practice guides and educational videos that provide your organisation with the tools to rapidly validate your ERP solution.

End-to-end validation can be achieved by utilising the resources contained in the toolkit – from establishing scope and developing user requirement specifications, to devising a validation master plan and running test scripts. The Tectura Validation Toolkit walks you through every step of the validation process with flexible templates and testing protocols based on GMP functionality and our methodology can ensure your systems remain in a validated state over time.

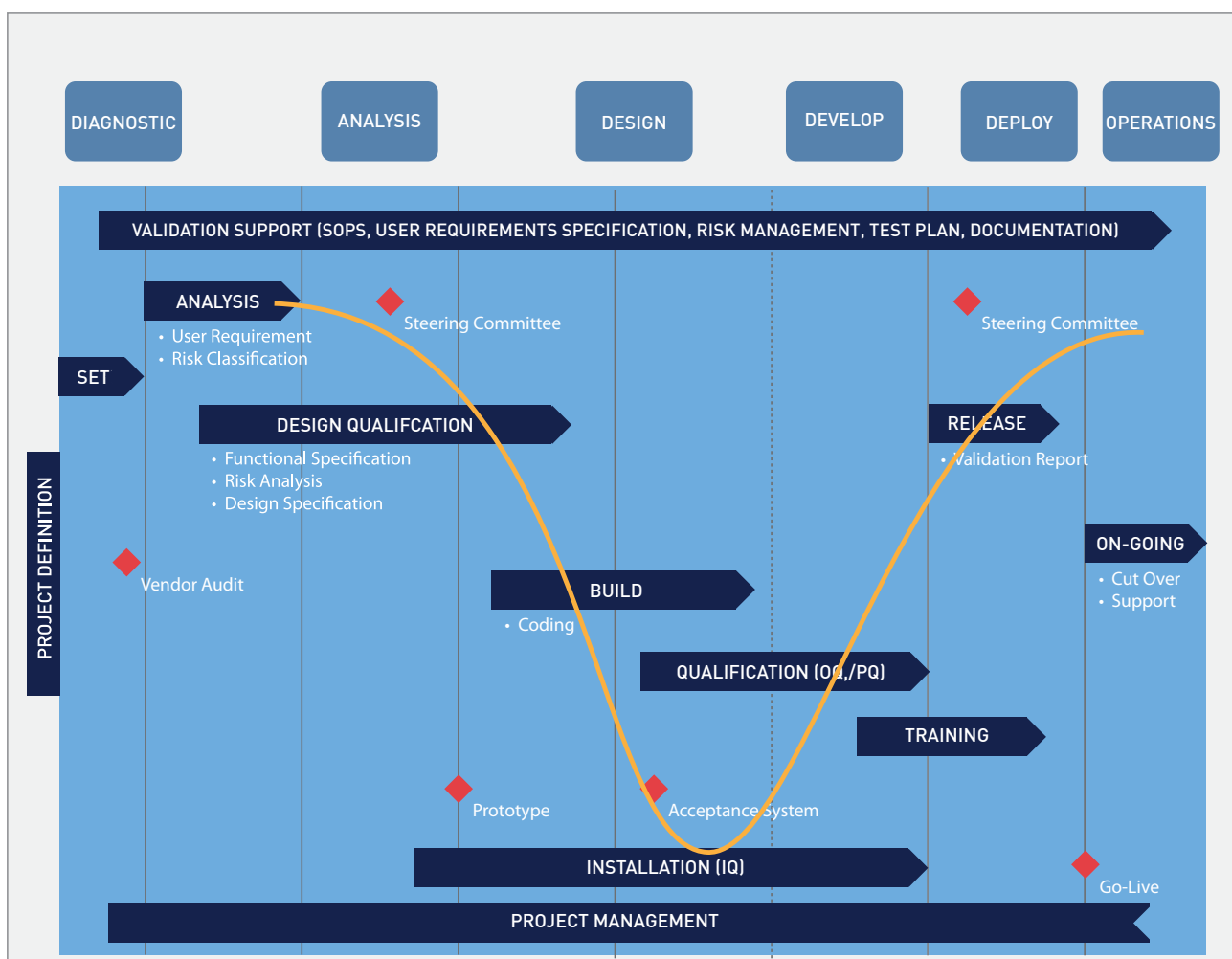
COMPLIANCE TEMPLATES	RISK DOCUMENTS	CHECKLISTS AND PROCEDURES
<ul style="list-style-type: none">• Validation Master Plan• Validation SOP• Validation Summary Report	<ul style="list-style-type: none">• Disaster Recovery Plan• Software Traceability• Risk Assessment	<ul style="list-style-type: none">• Internal Procedures• Signature Matrix• Supplier Audit

VALUABLE COMPONENTS WITHIN THE VALIDATION TOOLKIT



DETERMINING YOUR ORGANISATION'S RISK

The Toolkit helps you establish how much validation your organisation requires. With expert guidance you can identify critical control points to help determine the degree of testing required, the focus for your testing efforts, and development of a risk mitigation plan – all resulting in better, smarter testing. The toolkit assists you in determining the full spectrum of your associated risk from legal to regulatory, technical to external. Whether you use internal quality management resources, validation experts, or FDA specific consultants to assist in your effort, the Tectura Validation Toolkit can provide Microsoft Dynamics specific templates and guidelines. The Toolkit allows life science companies to get a head start on standard industry best practices.



V-MODEL FOR TECTURA'S VALIDATION METHODOLOGY - THE CHART ABOVE SHOWS A STANDARD V-MODEL SOFTWARE DEVELOPMENT PROCESS. THIS STANDS AS THE BASIS FOR OUR VALIDATION METHOLODOLOGY.



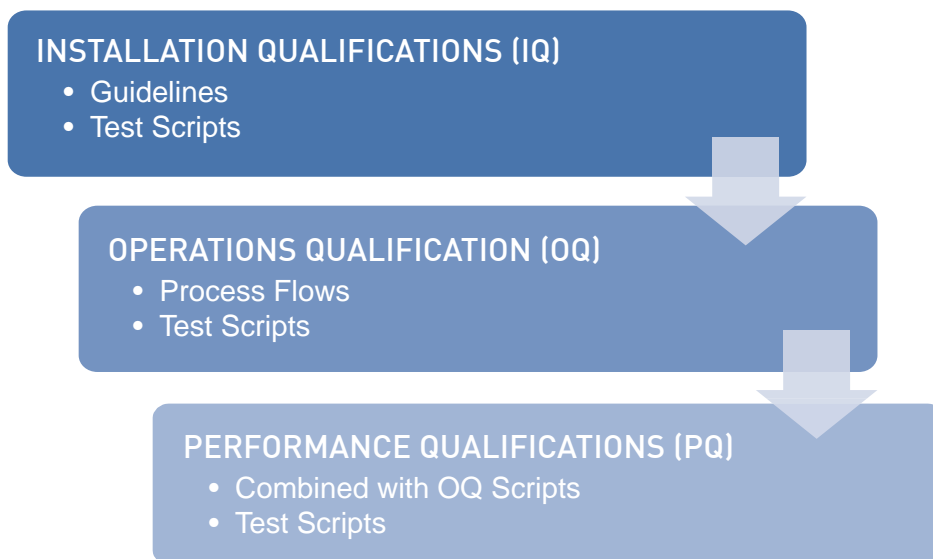
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TESTING PROTOCOLS

Within the Tectura Validation Toolkit, IQ/OQ/PQ Test Protocols are provided to accelerate your validation efforts:

- Installation Qualification – the IQ confirms the software has been installed correctly
- Operations Qualification – the OQ tests the functional elements within the system and insures the system will meet all defined user requirements (intended use)
- Performance Qualification – the PQ demonstrated the computerised process will consistently produce acceptable product/output under normal operating conditions. The demonstration is achieved using the appropriate methods and tools for process validation.

The OQ/PQ are combined within the validation toolkit.



CRITICAL TEST PROTOCOLS DELIVERED IN THE VALIDATION TOOLKIT

WHY TECTURA

Tectura delivers unmatched, in-depth experience in the complex requirements of the Life Sciences industry. We deliver industry-specific solutions to clients around the world that help them run highly regulated, validated businesses competitively. Whether you need an end-to-end business solution for improved quality, cost efficiency and profitability; a robust CRM solution to easily access critical information and manage complex industry relationships; or a Validation Toolkit to streamline and reduce the time and costs associated with an ERP validation, Tectura is your go-to partner.

YOU CAN HAVE IT ALL WITH TECTURA AS YOUR SOLUTIONS PARTNER

- Reduced risk
- Accelerating project completion
- Clarity, accountability, and continuity

FOR MORE INFORMATION

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