CQRM XD Validation Management

Compliance & Validation Solutions

Xybion CQRM® XD Validation Management Services provides superior service and expertise required to meet all of your Computer System Validation and Software Testing needs. As a leading global enterprise solutions and services organization for over 40 years, Xybion proves the foundation of our business is in our dedication to established quality processes, personalized support, and the success of your projects. In the past ten years, our firm has successfully completed over 500 projects in several highly regulated industries including Life Sciences, Energy, Transportation, and Finance.

Xybion can help you define and complete your validation projects on time and within budget through our services and enterprise solutions. With global experience including projects in the USA, Canada, EMEA, and Asia-Pac, Xybion leverages its extensive experience to cover all of your GxP and other compliance standard needs.

Key Benefits:

Reduce Long Term Costs. We have the capability to deliver projects from our HQ in Princeton, NJ or off-shore in our Global Delivery Center in Chennai, India.

Experience Efficient Business Processes. As project scope increases/decreases, Xybion turns around quickly with a smooth scaling up or scaling down response. Collaborate with Highly Experienced Consultants. Our employees are renowned for their domain experi-ence, practical understanding and implementation of reg-ulatory requirements. Xybion consultants have an average of 10+ years of expertise in validation.

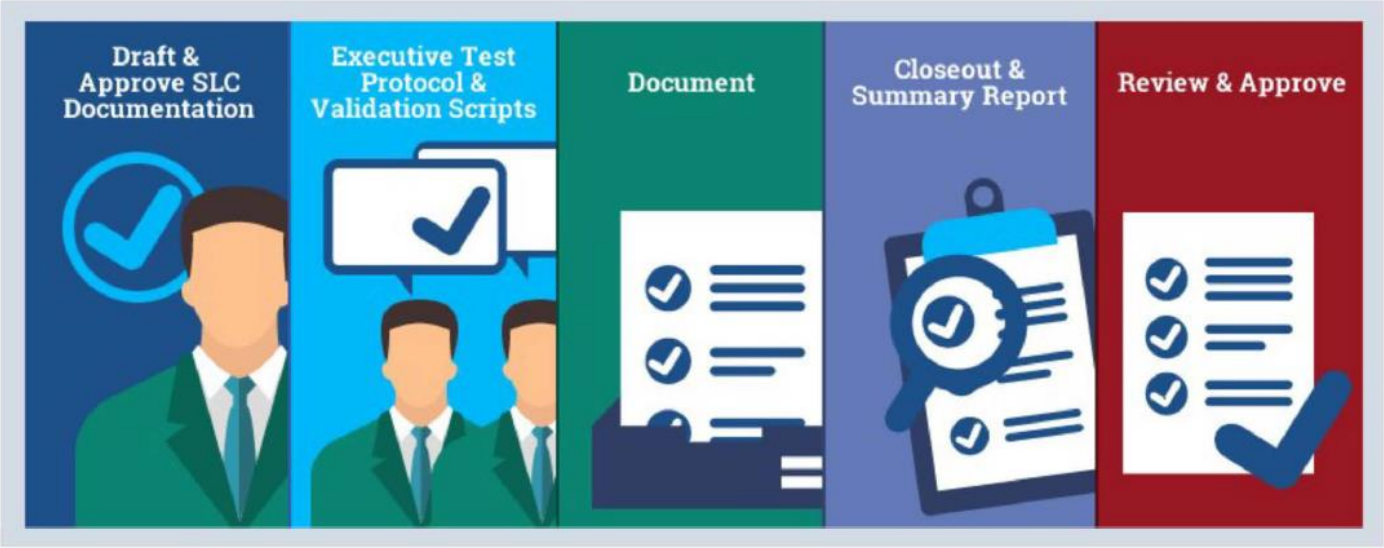

Figure 1. Validation business process begins with a full review or creation of SOLC documentation and ends with detailed summary report and formal project close out.

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Xybion

CQRM XD
Validation Management

Our support begins with assigning a group of highly qualified and experienced consultants to your project. We staff projects based on required expertise and scope, providing the most efficient and cost effective Computer System Validation services.

Our core competencies include:

Project Initiation and Planning

- Project Management
- Software Development Life Cycle
- Gap Assessments
- Risk Assessments
- Validation Master Planning (VMP)

System Requirements and Design:

- User Requirements Specifications (URS)
- Functional Specifications (FS)
- Design Specifications (DS)
- Design Review
- Supplier/Vendor Audits

System Development and Verification:

- Leveraging of Vendor Documentation
- Unit Testing
- Integration Testing
- System Testing
- Site Acceptance Testing (SAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Requirements Traceability

System Operation:

- Data Archiving
- Continuity Planning
- Change & Configuration Management
- Incident and Problem Management
- Periodic System Reviews
- Best Practices Training

System Type Expertise:

- Enterprise Systems including CRM, ERP, EAM, and SFA
- Laboratory Systems including Laboratory Operations (R&D, QA/QC)
- Quality Systems including CAPA Data Management, Clinical Trial Applications, and SharePoint
- Pharmacovigilance and Medical Information Systems

Did You Know?

- **Validation and qualification services have been core competencies of Xybion since the company's inception in 1977.**
- **Our validation specialists have completed over 500 validation projects.**
- **Our consultants have extensive global experience with FDA regulations and the mitigation of risk for companies all of sizes.**
- **Xybion features on shore and off-shore capability with its Global Compliance Center, located in Chennai, India.**
- **Clients include Merck, Novartis, Johnson & Johnson, and many more.**

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