

Reduce long-term costs and experience efficient business processes

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, Europe, and Asia, Xybion leverages its extensive experience to cover all of your GxP and other compliance standard needs.

## Key Benefits:

- **Reduce long-term costs:** We can 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 or 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 experience, practical understanding, and implementation of regulatory requirements. Xybion consultants have an average of 10+ years of expertise in validation.

## Computer System Validation Services



Xybion CQRM XD Validation Management Services provides superior service and expertise required to meet all 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. 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.

### Did You Know?

- Validation and qualification services have been core competencies of Xybion since the company's inception.
- 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 the sizes.
- Xybion features on-shore and off-shore capability with a Global Compliance Center providing global services.
- Clients include Merck, Novartis, Johnson & Johnson, and many more.

## Our Core Competencies Include:

### Project Initiation and Planning

- Project management
- Software development life cycle
- Gap assessments
- Risk assessments
- Validation Master Planning (VMP)

### 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

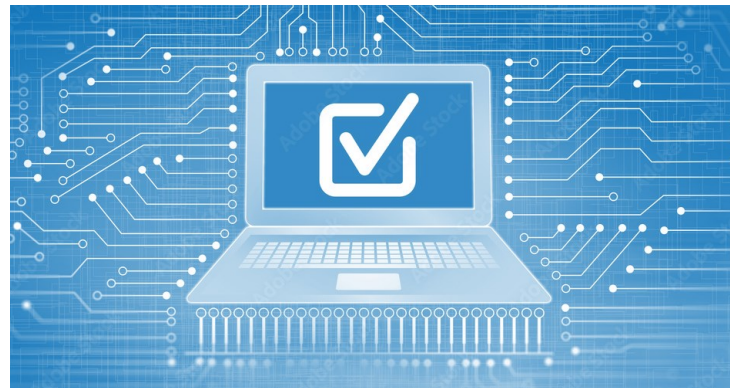
- Data archiving
- Continuity planning
- Change and configuration management
- Incident and problem management
- Periodic system reviews
- Best practices training

### System Type Expertise

- Enterprise systems including CRM, ERP, EAM, and SFA
- Laboratory Systems including laboratory operations (R&D, QA, and QC)
- Quality Systems including CAPA data management, clinical trial applications, and SharePoint
- Pharmacovigilance and medical information systems
- Validation Master Planning (VMP)

### System Requirements and Design

- User Requirements Specifications (URS)
- Functional Specifications (FS)
- Design Specifications (DS)
- Design review
- Supplier and vendor audits



## Unified Solution for Predictive Compliance, Quality and Risk management

### About Xybion

Xybion is a leading SaaS company dedicated to providing life sciences and health systems companies with innovative software solutions to accelerate the transformation of today's inventions into tomorrow's approved medicines, devices, and diagnostic tests designed to save lives and keep employees safe. Our intelligent cloud platform and software solutions help companies accelerate digital transformation of processes, speed up innovation, optimize operations, reduce compliance risks, and achieve significant cost savings.

Xybion is serving over 160 customers in 29 countries including all the top 20 global biopharmaceutical

companies. Xybion's global scale and expertise brings employees around the world to help companies in life sciences, health systems, research institutions, and governments. We help companies digitally transform their regulated business operations. Our unique solutions focus on employee health and safety, integrated preclinical lab management, early-stage drug discovery, digital lab solutions, regulatory compliance, GRC, quality management, predictive compliance, content management, and systems validation.

