



The consultants and technicians of GxP Partners provide start-to-finish client care, ranging from product surveys to determine suitable software solutions to the support required after roll-out.

**We give you direct access to our years of experience implementing and validating a range of systems for Compliance, Quality, and Project Management.** GxP Partners understands that each organization has unique business processes, regulatory requirements, and technology needs. Our goal is to help you identify and implement the most effective solution based on your needs – on time, on budget.

GxP Partners specializes in technology for compliance and operational excellence. We offer implementation, validation, and training services plus feature-rich software and Web-based applications for:

Document Management

Learning Management

Product Life Cycle Management

Project Management & Execution

Quality & Compliance Management

Scanning, Automated Data Capture & PDF Rendition

Validation Management & Execution

GxP Partners is a trusted technology partner to organizations that are heavily regulated and that rely on intricate business and workflow processes to meet their goals. Our software selection and implementation services are ideally suited to pharmaceutical (bulk and finished), biotechnology, medical device and diagnostics, consumer products, cosmetics, and veterinary industries.

We have extensive knowledge of software products, business processes, and industry standards and regulations, including ISO, GAMP, GLPs, GMPs, QSR, 21 CFR Part 11, FDA/CBER Blood Regulations, OSHA, and HIPAA.

To every client, we bring our vast education and training plus years of hands-on experience within Life Sciences companies. Our on-staff project leaders and network of technical and

industry specialists work with your organization to ensure that you achieve compliance and operational excellence.

GxP Partners' services are ideal for software deployments of any size, from single-site / single units to multi-site / thousands of units. We provide:

- User requirements and business process analysis
- Implementation workshops
- Learning plans
- Comprehensive classroom training
- Development of user manuals, procedures, and quick reference guides
- System validation
- Comprehensive compliance consulting

*When you need more than just software, we're your compliance partner.*

## Software Selection

GxP Partners leads your team through a proven process to identify the right software solution:

- Define a plan, develop a charter and scope statement, organize the team, initiate the process
- Establish a budget and return on investment (ROI) for the selection process and solution
- Lead the business process analysis and re-engineering
- Identify business requirements based on improved processes, regulatory requirements, and business needs
- Identify and shortlist the vendors by compiling and issuing a Request for Information (RFI) to qualified candidates
- Screen potential vendors with the team and issue a Request for Proposal (RFP)
- Arrange for software demonstrations, manage the evaluation process, and ensure all key business requirements are addressed
- Manage the final selection process, define the final budget recommendation and ROI, define the project charter, present to executive team, and rollout the solution

## Solution Implementation

To implement software solutions efficiently and cost effectively, GxP Partners offers services to:

- Develop a centralized data filing system, data retention plan, and archiving process for historical records
- Conduct configuration workshops and develop configuration specifications
- Oversee system installation, configuration, and setup of maintenance tables
- Manage data conversion and migrations
- Establish data entry processes and oversee data entry personnel
- Develop and deliver SOP and software training and materials
- Analyze, recommend, and deliver other initiatives required for compliance, such as: project definitions and plans, user requirements, risk assessments on proposed solutions, customized training and documentation, testing required to validate a product, validation documentation and scripts, and integration with other products or processes
- Ensure a successful software rollout through customized activities such as: site training plans, module and curriculum development

for learning management systems, streamlined CAPA and product complaints processes, management of internal and external audits, assessing and addressing requirements for CAD or 3-D drawings

## Project Management

Your GxP Partners team works closely with representatives from your organization to deliver on a mutually developed project plan, which typically comprises: *Project Initiation, Project Planning, Project Execution, Project Control, and Project Closing*. Following the Project Management Institute (PMI) methodology, our Project Managers:

- Issue project charter and scope documents
- Create project plans, work breakdown structures, Gantt and PERT charts
- Manage deliverables, implement change requests, and address risk
- Maintain project scope documents and project management plans plus provide performance reports and forecasts
- Report on lessons learned and project closure

## Validation

Backed by our history with Good Automated Manufacturing Practice (GAMP) and experience with global validation projects, the GxP Partners team is available to:

- Define user, functional, system, or design requirements
- Configure specification documents
- Develop validation plans
- Develop and execute validation documentation and scripts
- Prepare requirements traceability documents, validation summary reports, and system release reports
- Prepare periodic review plans
- Develop comprehensive system retirement plans, validation documentation and scripts, and summary reports
- Provide guidance on 21 CFR Part 11
- Conduct training on computer validation

GxP Partners also offers a start-to-finish solution for validating a computer system following GAMP. The policies and easy-to-use templates guide you through the process from planning to "go live," guaranteeing compliance and optimal system performance.



With GxP Partners, you can:

- Improve the quality of your project planning and tracking
- Quickly capture the complexity of your projects
- Provide higher visibility of your critical tasks
- Resolve project issues quickly
- Reduce your project risk

...all from our proven approach to project management

GxP Partners, LLC  
www.gxppartners.com

41 University Drive  
Suite 400  
Newtown, PA 18940  
215.752.8699 tel  
888.606.6280 toll free  
info@gxppartners.com