that's our job

The project managers, consultants, and technicians of GxP Partners provide start-to-finish **auditing and validation** services. We have extensive experience qualifying network infrastructure as well as validating automation, computer, and laboratory systems in FDA-regulated environments. We also perform internal and supplier audits plus training in the areas of computer validation, change management, and Part 11. **You have direct access to our years of experience implementing feature-rich systems that meet the requirements of ISO, GAMP, GMPs, QSR, 21 CFR Part 11, FDA/CBER Blood Regulations, OSHA, and HIPAA.**

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

Clinical Trial and Submission Management

Laboratory Notebook

Project and portfolio Management

Quality & Compliance Management

Scanning, Automated Data Capture & PDF Rendition

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. We provide innovative, systematic approaches to Business Process Management, Compliance Management, and Quality Management.

GxP Partners audits and validates systems in FDA-regulated environments. Our services are ideally suited to pharmaceutical (bulk and finished), biotechnology, medical device and diagnostics, consumer products, cosmetics, and veterinary industries.

Because our knowledge and hands-on experience span business processes and systems, we offer a range of services unmatched by other validation or consulting companies. The result: you guarantee both regulatory compliance and optimal system performance.

GxP Partners has the credentials and expertise you require to:

- Perform GMP, quality systems, and supplier audits as well as periodic reviews
- Conduct gap analyses of your quality systems and validation processes, including your policies, procedures, templates, documentation, and Validation Master Plan (VMP)
- Develop validation plans for specific projects
- Develop and execute validation scripts following approved protocols
- Provide guidance on interpreting government regulations
- Conduct training on auditing, GxPs, validation, change control, and Part 11

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

GxP Partners

Auditing Services

GxP – Our team of auditors will perform audits of your company's clinical, laboratory, quality, manufacturing, and packaging divisions, as well as contract research, laboratories, manufacturing, and packaging organizations to ensure GxP and regulatory compliance.

Quality Systems – We will review your quality systems, policies, and procedures to ensure compliance with industry best practices and government regulations. Your auditor will report exceptions and recommend solutions, offer staff training, and review findings with management.

Suppliers – Using your company's audit documents or those that we've developed, we perform supplier audits. With a complete report of findings, you can ensure initial and ongoing adherence to your company's quality program and their software development lifecycle.

Periodic Review of Computer Systems – Our consultants will lead your team through the process of verifying your computer system's state of validation. Services range from developing your periodic review procedure to conducting the actual review.

Validation Services

Automation Systems – GxP Partners follows the ISPE Validation of Process Control Systems and Automated Systems guidelines. We qualify and validate a range of control systems including: Programmable Logic Controllers (PLCs), Supervisory Control and Data Acquisition (SCADA) Systems, and Manufacturing Execution Systems (MES).

Computer Systems – We have extensive experience validating prospectively or retrospectively computerized systems in manufacturing, warehouse, quality assurance, R&D, and clinical. Our consultants adhere either to your validation policies or ISPE GAMP 5 based validation methodology.

Network (Infrastructure) – Our team of consultants can qualify your enterprise-wide IT installations, including servers, mainframes, network hardware, and applications. We develop the necessary plan, protocols, and test scripts to ensure your network infrastructure is qualified based on your company policies and procedures and industry standards (ISPE Guide to IT Infrastructure Control and Compliance).

Commissioning and Facility Qualification – Adhering to the ISPE Baseline Guide for Commissioning and Qualification, GxP Partners' consultants will work with your engineers to ensure your facilities and equipment are designed and qualified to meet the rigorous standards required of any facility manufacturing products regulated by FDA.

Documentation and Training Services

Validation Methodology – GxP Partners develops, reviews, and maintains both site master plans and project-specific validation plans. Following the Project Management Institute (PMI) methodology, we guide the project team toward defined goals related to the validation project. The result: Your validation projects are completed on time and on budget while you ensure compliance with applicable regulations.

Compliance Training – GxP Partners provides training in the areas of GMPs, QSR, computer validation, change management, and Part 11. Through our mentoring services, we work directly with IT organizations, engineers, quality assurance specialists, and validation technicians to ensure compliance with regulations and company policies.

Documentation Development – We develop policies, SOPs, work instructions, and training material for software, validation, quality systems, and GMP operations. GxP Partners oversees a full range of documentation development to ensure compliance with company quality policies, manufacturing processes, and government regulations.

GxP Partners specializes in the processes and software for:

Business Process Automation – project management and execution; product life cycle management, enterprise content management, routing and approval, dynamic workflows; scanning, automated data capture, and PDF rendition

Compliance & Quality Management – collaborative tools for managing audits, calibration, CAPA, complaints, and SOPs; compliance and quality dashboards; regulatory document control and management; submission management; and laboratory notebook

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GxP Partners, LLC
www.gxppartners.com

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

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