that's our job

Today's life sciences organizations are increasingly challenged to "do more with less," balancing their need to innovate with the structure imposed by regulatory requirements. GxP Partners enables you to meet the challenge by combining integrated software solutions with a full range of implementation and validation services for: **quality management and control, clinical trial management and eCTD submissions, and labeling and product information management**. Do you currently manage your quality, clinical trial, or submissions processes manually? Is your typical validation process taking six to nine months? Must you comply with regulations for audit trails and electronic signatures? Do you find that your multiple software vendors know their products but not your business? Are you sending boxes of documents to offsite storage? If yes to any or all, it's time to become **connected, compliant, and cost effective.**

GxP Partners can help you specify and implement the ideal clinical, regulatory, or quality system solution if you need to:

- Submit information to the FDA and EMEA
- Manage your quality system to comply with GxP regulations
- Upgrade a cumbersome, paper-based validation process
- Exchange information with constituents, customers, partners, and vendors in a broad range of formats
- Enable stakeholders to easily interact with your organizational processes to provide and receive correct, complete information
- Increase document processing capacity without increasing headcount
- Address your clinical, laboratory, regulatory and quality systems requirements

The Situation: The push for cost containment and efficiency in implementing today's software solutions has accelerated along with increasing regulations. The life sciences industry must comply with GLPs, GCPs, GMPs, QSR, 21 CFR Part 11, FDA/CBER Blood and Tissue Regulations, OSHA, and HIPAA. Companies in the food industry must meet SQF, HACCP, and ISO 22000 standards and regulations. Simultaneously, The Government Paperwork Elimination Act (GPEA), which provides for electronic submission of forms, also requires that systems protect confidentiality, ensure that information in not altered in an unauthorized way, and make it available when needed. In this stringent regulatory environment, organizations face the daunting tasks of managing documentation, processing forms, and tracking equipment calibration, training, and quality processes. You need solutions to operate effectively, achieve competitive advantage, and pass inspections and audits.

The Solution Benefits: Through your Quality & Compliance Management solution implemented by GxP Partners, you can...

- Apply industry best practices in addressing your unique needs and business challenges
- Facilitate compliance with FDA, EMEA and other global regulations, including quality and labeling standards
- Improve efficiency and productivity throughout your enterprise
- Support multi-user collaboration in creating, reviewing, and sharing content, documents, and records of all types
- Increase efficiency in the exchange of information for managing clinical trials
- Streamline validation execution and costs
- Ensure quality by design throughout laboratory, clinical, and manufacturing processes
- Reduce time to market

GxP Partners

GxP Partners: Enabling Our Customers to "Do More with Less"

GxP Partners offers a portfolio of proven solutions that have already passed audit in organizations with stringent process and compliance requirements. We represent the best in **Quality, Compliance, and Business Process Management**. Then we add the elements that make your solution *your* solution. We're a software systems reseller specializing in compliance auditing, systems integration, validation, and implementation services.

Through Quality & Compliance Management solutions from GxP Partners:

- **A small biomarker-based genetic testing laboratory** secured a flexible solution to manage both clinical and non-clinical workflows and forms within a dynamic quality system. The one-year rollout included training on modules for managing incidents, deviations, and corrective and preventive action (CAPA).
- **A leading global medical device company** implemented a standardized approach to validation and a global quality system. The solution eliminated multiple databases and dysfunctional processes, resulting in a reduced cost of quality and improvement measurable on the corporate P/L. The validation required for regulatory compliance was completed in weeks versus months.
- **Five of the top ten pharmaceutical companies** implemented a global learning management system to address compliance requirements and reduce the cost of training.

Your Partner in Process Improvement and Compliance

A GxP Partners solution enables you to meet your regulatory requirements while automating and streamlining processes and communication for:

Quality

- Manage document control, CAPA, complaint handling/material returns, incident/deviation reporting, audits/ surveys, change management, employee training, instrument calibration/ maintenance, and project management
- Manage all controlled documents – from creation through approval, distribution, and archiving – for GLP, GCP, and GMP
- Ensure compliance with ISO and the regulatory requirements of agencies such as FDA, EMEA, EPA and OSHA
- Automate the execution and periodic review processes of all validation efforts
- Automatically generate required employee training assignments
- Unify your quality process throughout the enterprise by passing information to and from LIMS, ERP, MES, and other external systems
- Reduce inefficiencies and costs due to re-routing documents and expensive customizations to link to enterprise systems while maintaining each division's independent workflow
- Easily and rapidly retrieve documents and generate reports on the state of your quality operations
- Automatically manage supplier statuses and quality information (such as nonconforming material reports) and approved vendor lists (AVLs)
- Identify, mitigate, and prevent high-risk events

Clinical Trials & Submissions

- Manage multiple clinical trial studies and sites with greater efficiency and knowledge interchange
- Base decisions on real-time information
- Track clinical trial progress
- Create, review, and manage electronic common technical document (eCTD) submissions

Labeling & Product Information

- Meet the FDA's structured product labeling (SPL) and physicians labeling rule (PLR) standards
- Author, publish, review, and save industry-compliant labels
- Collaborate in authoring and reviewing content according to marketing authorization requirements set forth in the product information management (PIM) standard
- Categorize and re-use common content for labels globally

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

GxP Partners

that's our job

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:

Compliance & Quality Systems Management

Document & Content Management

Validation Execution

Learning Management

Clinical Trials & Submissions Management

Scanning, Automated Data Capture & Forms Processing

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