GxP Partners Solution Showcase

PGx:HEALTH™
A DIVISION OF CLINICAL DATA

PGxHealth, a division of Clinical Data, Inc., provides biomarker-based genetic and pharmacogenetic tests and targeted therapeutics in the areas of CNS, cardiovascular diseases, and oncology. Through a recent implementation of EtQ, GxP Partners and PGxHealth unified the quality process throughout the organization by automating the management of incidents, deviations, and corrective / preventive actions (CAPAs). With this compelling software solution, PGxHealth not only introduced a more efficient, collaborative approach to tracking and sharing information, it also enabled compliance with components of GCP (FDA/ICH), GLP (FDA/OECD), GMP, and CLIA regulations. The benefits of EtQ extend to biotechnology organizations working in energy, agriculture, food science, and medicine – all of which require a quality system to ensure that *no time is lost and no problem overlooked.*

The Situation:

PGxHealth initiated a search for an integrated system to manage documents, incidents and deviations, and CAPAs and to track employee training. The existing incidents and deviations process was entirely manual. The organization needed a solution that would ensure the efficient capture, exchange, and storage of accurate information on the quality process throughout the workflow – from initial contact with the physician, to receipt of the sample, pre-lab preparation, sample processing, analysis, reporting, and ultimately communicating results to the physician.

The motivating factors behind the implementation were: the automation of business processes, time savings, and a minimal level of manual intervention. PGxHealth also wanted a system that it could grow with to automate future business processes, such as scheduling and recording the results of instrument and equipment calibration. Paper-based systems would be phased out over time.

The Solution:

The solution combined the best of EtQ Reliance 5.2 software, a configurable commercial off-the-shelf (COTS) system, and GxP Partners implementation services to enable:

- a smooth transition from an established, albeit manual, incidents and deviations process to one managed electronically
- the recording of incidents and collecting of required information to conduct investigations, including a risk analysis
- the identification and tracking of deviations through planning, approval, and completion
- the initiation of CAPA requests from multiple points in the workflow, with routing through the review, root cause, corrective action taken, and verification stages
- the management of all controlled documents – from creation through approval, distribution, and archiving
- the ability to track certification requirements and to easily schedule and record employee training

The EtQ Reliance solution implemented by GxP Partners and PGxHealth began with a requirements definition followed by a project plan and timeline for the one-year rollout and training on Incidents, Deviations, and CAPA. GxP Partners led the design phase, completed the software installation, and oversaw the Installation Qualification (IQ).
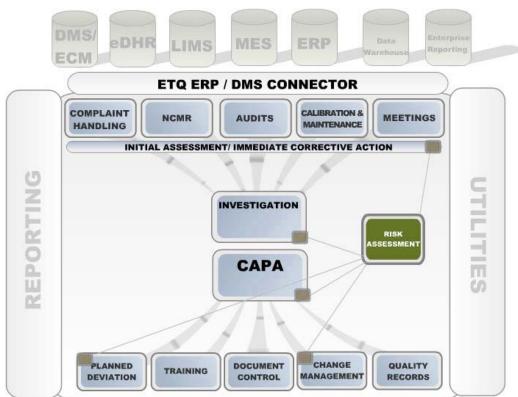
During implementation meetings, the team had discovered that PGxHealth requirements could be met through designing a Deviations form and workflow within the Incidents module. A separate Deviations module was deemed unnecessary. Forms for both Incidents and Deviation were integrated with the CAPA module, enabling users to initiate CAPAs from the Incidents and Deviation workflows based on defined conditions. Both clinical and non-clinical workflows were incorporated.

PGxHealth engaged GxP Partners to define the project and then provide a specified level of support throughout the implementation. GxP Partners executed the configuration and assisted during the Operational Qualification (OQ). PGxHealth handled the Performance Qualification (PQ). The base of 30 clinical users will be doubled over the next year with the rollout of Document Control, Employee Training, and Calibration Management modules across the broader organization.

EtQ Reliance Features and Benefits :

EtQ is the leading Enterprise Quality and Compliance Management Software for identifying, mitigating, and preventing high-risk events through integration, automation, and collaboration. The solution offers:

- Best-in-class integrated modules to manage and measure quality and compliance processes and execute organizational change
- Integrated FDA compliance as a system pre-configured to exceed 21 CFR Part 11 requirements, including audit trails; no additional programming required
- Step-by-step root cause analysis and built-in risk assessment
- Closed-loop CAPA, including electronic distribution of results
- The ability to easily attach supporting documentation such as error files, log files, manuals, and drawings to incident reports
- Connectors to production systems, which can be automatically updated throughout the event resolution process (for instance, a complaint status can be updated based on CAPA investigation results)
- The ability to minimize the number of CAPAs using an advanced filtering model, including automatic segregation and categorization of events

Contact
GxP Partners
if you need:

A single solution for capturing, organizing, and sharing information to
– Manage quality and compliance
– Reduce costs
– Create business advantage

A standardized system for data
– Capture
– Management
– Processing
– Delivery
– Storage
– Access
– Preservation

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ETQ ERP / DMS CONNECTOR

DMS/ECM eDHR LIMS MES ERP Data Warehouse Enterprise Reporting

REPORTING | UTILITIES

COMPLAINT HANDLING | NCMR | AUDITS | CALIBRATION & MAINTENANCE | MEETINGS

INITIAL ASSESSMENT/ IMMEDIATE CORRECTIVE ACTION

INVESTIGATION

RISK ASSESSMENT

CAPA

PLANNED DEVIATION | TRAINING | DOCUMENT CONTROL | CHANGE MANAGEMENT | QUALITY RECORDS

GxP Partners — Excellence Through Quality | EtQ