

TrackWise Success Story

ImmucorGamma: Implementation of TrackWise for Calibrations and Preventive Maintenance (Cal-PM)

Business Overview

ImmucorGamma may not be the first name that comes to mind when one gives or receives blood. However, over 50% of the nation's blood supply and approximately 25% of the world blood supply is tested using ImmucorGamma's products.

ImmucorGamma is a global in-vitro diagnostics company specializing in the area of pre-transfusion diagnostics. It develops, manufactures and sells products used by hospital blood banks, clinical laboratories and blood donor centers to detect and identify certain properties of human blood prior to patient transfusion. The company has been experiencing rapid growth and has nine locations worldwide, including its corporate headquarters in Norcross, GA and sites in North America, Europe, South America and Asia.

The Cal-PM System at ImmucorGamma

The Cal-PM system at ImmucorGamma is used for processing, tracking, monitoring and reporting on Equipment Records, Work Orders, Preventive Maintenance, Calibration, and Validation events. Primary users of the system include Calibration/Validation, Maintenance and Quality, and users from all departments who can create equipment and facility work orders.

Challenges Prior to TrackWise

Prior to implementing TrackWise, Cal-PM was handled by a combination of decentralized systems including Lotus Notes, Microsoft Excel and paper. The systems served as repositories for data, and offered very little functionality in terms of workflow, notification and automation. As a result, Cal-PM processes were manual and time consuming, which led to inefficiencies and additional work.

For example, Calibrations and Preventive Maintenance orders were sometimes missed, resulting in deviations. The deviation process then required extra work, in addition to corrective actions, which resulted in additional work and documentation. An internal 21 CFR Part 11 gap analysis also identified numerous issues inherent in the design of the Lotus Notes tool and Excel spreadsheets. Lotus Notes and Excel did not provide the security requirements or audit trail capabilities required by the regulation.

A Time for Change

ImmucorGamma has been embarking upon a "Paperless Project" to increase efficiencies in its business processes and improve quality in the organization. This initiative, driven by the IS organization, began by identifying key systems in the organization that would serve as strategic tools to replace legacy systems and manual paper processes. Already successfully deployed for product complaint handling, TrackWise was selected as ImmucorGamma's enterprise quality workflow management tool.

Understanding the challenges faced with the legacy Cal-PM systems, as well as the desired system functionality of the "to-be" system, it was obvious that TrackWise was the clear solution. TrackWise could support a 100% electronic process that would provide security, ensure 21 CFR Part 11 compliance and automate workflow and business rules, eliminating the errorprone manual processes that were in place.

"Sparta provides more than a product, they provide solutions. They take an interest in our business and understand what we're doing."

David McCampbell
Vice President,
World Wide Information Services
ImmucorGamma



Implementation of TrackWise for Cal-PM

ImmucorGamma assembled a project team consisting of IS, Maintenance and Validation/Calibration, with adjunct team members from Quality and Regulatory. Sparta also provided a dedicated Product Specialist on a part-time basis (15 days overall) to assist with configuration design and development. The implementation consisted of configuring nine “Projects” in TrackWise, which automated and handled the following processes:

1. New Equipment Requests
2. Validation Action Items
3. Calibration Schedules
4. Preventive Maintenance Schedules
5. Approved Equipment Records
6. Scheduled Preventive Maintenance Work Orders
7. Scheduled Calibrations
8. Unscheduled Work Orders
9. Facility Work Orders

Today, any user can enter a “New Equipment” request directly into the TrackWise system. This notifies the Validation group, which then creates Validation, Calibration and Maintenance plans online. Validation Actions (e.g., IQ/OQ) are recorded and tracked online using Parent-Child relationships.

TrackWise workflows are used to route new Equipment Records and their linked Calibration (Cal) and Preventive Maintenance (PM) plans through an approval process. Once approved, the TrackWise Coordinator 24/7 business rules engine monitors, schedules, and automatically creates PM and Cal Work Orders based on the approved frequency. When work orders are performed, they are recorded and approved directly via TrackWise workflow. Additionally, the system updates equipment status when each piece of equipment is taken out of service, retired or put back in service.

A key aspect of the Cal-PM system is the reporting functionality, which in addition to providing informative trending and status reports, is also used to print bar code labels that are affixed to each piece of equipment. This enables Immucor-Gamma to utilize barcode scanning devices to retrieve records directly from the TrackWise system.

Migration of legacy data was another key stage in the transition to TrackWise. ImmucorGamma utilized the off-the-shelf PR Import Utility (standard with the TrackWise Integration Manager package) to map data fields and migrate data into the new system.

The TrackWise Cal-PM system resulted in the elimination of eight standard operating procedures (SOPs) ImmucorGamma has replaced these with ‘Job Aides’ that describe the steps to complete tasks within the system.

Key Benefits

Numerous benefits were achieved with implementation of TrackWise for Cal-PM. The system replaced a hybrid combination of paper and non-compliant data collection methods with a 21 CFR Part 11 compliant electronic system.

ImmucorGamma standardized multiple systems onto a single platform and process in both of its major manufacturing sites, resulting in efficiencies and improved compliance. The entry of data is now easier, and due to a uniform selection of terminology, users can be assured that equipment lists, status and work orders are up to date. The automated scheduling of PMs and Calibrations facilitates a more tightly controlled calendar of events, enabling the departments to plan and manage resources effectively. More accurate metrics are reported due to the quality of data captured in the system, and the power of integrated Crystal Reports has resulted in more informed, faster decision-making.



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About Sparta Systems: Founded in 1994, Sparta Systems, Inc. is the industry leader for Enterprise Quality Management Solutions. Its product, TrackWise®, is used by Global 500 companies around the world to ensure compliance, improve control, reduce risk, and lower costs by consolidating issues and actions, automating workflow, and facilitating trending and reporting. Additional information about Sparta Systems and TrackWise can be found at www.spartasystems.com