

IMMUCOR IMPLEMENTS TRACKWISE[®] FOR CAL-PM

Automates Key Processes
to Improve Efficiency

Case Study

QUICK FACTS

Immucor

- Industry: Medical Device
- Distribution: Global
- Employees: 725+
- Solution: TrackWise

Honeywell

AUTOMATING TO IMPROVE EFFICIENCY

Understanding the challenges faced with the legacy Cal-PM systems, as well as the desired system functionality of the “tobe” system, it was obvious that TrackWise was the clear solution.

BACKGROUND

Immucor 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 Immucor’s products. Immucor is a global in-vitro diagnostics company specializing in the area of pretransfusion 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.

CAL-PM AT IMMUCOR

The Cal-PM system at Immucor 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.

OPPORTUNITY

Increasing Efficiency with Paperless Processes

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. These systems did not provide the security requirements or audit trail capabilities required by the regulation.

SOLUTION

Automating Key Processes with TrackWise

Immucor embarked 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 Immucor’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 “tobe” system, it was obvious that TrackWise was the clear solution.

RESULT

Greater Efficiencies and Improved Compliance

Immucor assembled a project team consisting of IS, maintenance and validation/calibration, with adjunct team members from quality and regulatory. A dedicated product specialist was provided on a part-time basis to assist with configuration design and development. The implementation consisted of configuring nine “projects” in TrackWise, which automated and handled the following processes:

- New Equipment Requests
- Validation Action Items
- Calibration Schedules
- Preventive Maintenance Schedules
- Approved Equipment Records
- Scheduled Preventive Maintenance Work Orders
- Scheduled Calibrations
- Unscheduled Work Orders
- Facility Work Orders

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 error prone manual processes that were in place.



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 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.

Immucor 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) Immucor 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 noncompliant data collection methods with a 21 CFR Part 11 compliant electronic system. Immucor 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.

For more information

To learn more, visit
www.spartasystems.com

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