

ACIST Manges Compliance with TrackWise



Business Overview

ACIST Medical Systems manufactures state-of-the-art contrast injection systems used by operating rooms, radiology and cardiac labs for both diagnostic and interventional procedures. ACIST was founded in 1991 by Dr. Robert F. Wilson, M.D., who envisioned an easier way to deliver contrast media during angiography. Originally incorporated as Invasatec, the company rebranded itself as ACIST Medical, to stand for "Automated Contrast Injection System Technology." In 2001, ACIST was acquired by the Bracco Group, a world leader in global solutions for the imaging field. Today, over 1,000 ACIST systems are used in over 30 countries worldwide. The company has approximately 120 employees.

Growing Pains

ACIST's quality systems were comprised of Microsoft Access databases, Excel spreadsheets and paper forms. These homegrown systems, used to manage complaints, material review board dispositions (MRBs), corrective and preventive actions (CAPAs) and Incoming Inspections, became unmanageable due to ACIST's rapid worldwide growth.

The lack of centralization and transparency in its disparate systems led to growing difficulties in obtaining accurate and reliable information on a timely basis, particularly for complaint management. An additional pain resulted from the lack of real-time communication of issues between the U.S. headquarters and the sites in Europe and Japan. As a result, international sites were required to send updates to ACIST Corporate on a monthly basis. This data was then integrated into the main Access database. The process caused delays in information delivery, as well as significant administrative overhead to process the data. Above all, data integrity was a concern, as any person with database access could change field values, saved queries, and even source code. In summary, the existing systems were inefficient, insecure, and non-compliant with 21 CFR Part 11.

A Robust Solution for a Medium-Sized Business

By 2002, ACIST's complaint system needed an overhaul. ACIST began searching for a new system that would allow the organization to promote a harmonized process. ACIST required the new solution to enable accurate, secure, compliant and timely exchange of information. The system was required to be user-friendly and capable of expanding with the company's growth as future needs for additional quality applications emerged. While its initial goal was to improve the complaint handling and investigation process, ACIST aspired to streamline its entire Quality Management System (QMS). As a mid-sized, yet growing company, its key concerns were finding a robust system that would be easy to implement, require little maintenance effort, and be nimble enough to meet additional quality initiatives.

"TrackWise has enabled us to automate your key quality processes with agility and consistency. We have reduced complaint response and closure time, while realizing significant support savings."

Plarent Ymeri,
Project Manager
ACIST™ Medical Systems

ACIST evaluated various QMS applications as well as the option of building an internally developed system. Its parent company, Bracco Diagnostics, had recently implemented TrackWise and recommended it as a viable solution based upon its success. After a thorough evaluation of the system, ACIST found TrackWise to be highly configurable, easy to implement, and scalable to incrementally meet future needs. It solidified its decision to implement TrackWise for complaint management with the long-term vision of utilizing it for other applications upon successful deployment of its initial project.

Initial Implementation

The ACIST and Bracco quality teams collaborated on the initial TrackWise rollout at ACIST's U.S. headquarters in Minnesota. An interdepartmental approach was taken for the TrackWise configuration design to ensure harmonization. User requirements were established for all functions of the organization that had input into the complaint management process. These areas included customer support, service, quality assurance, manufacturing, regulatory affairs and engineering.

While designing the initial workflow, the ACIST project team identified bottlenecks in its existing business process and designed the TrackWise solution to streamline its workflow. ACIST completed its implementation, including validation and training activities, in a total of four months. The system rollout was an immediate success, resulting in consistent and fluid information flow as well as increased efficiency.

Global Deployment for Complaint Handling

ACIST moved rapidly to deploy TrackWise on a worldwide scale. To ensure security between ACIST's U.S. operations and its global service and distribution sites, ACIST established a demilitarized zone (DMZ) between 'trusted' and 'untrusted' networks, and utilized Secure Socket Layer (SSL) encryption. Today, service centers in Japan and Holland, along with distribution sites in Hong Kong, South Korea, Australia, Brazil, China and Taiwan utilize the complaint management system. Critical information is processed and managed accurately, securely, and timely in compliance with regulatory mandates.

Rollout of Additional Applications

The success of ACIST's complaint handling implementation prompted its quality organization to utilize TrackWise to manage other quality processes. TrackWise was subsequently deployed for managing failure investigations, material review board (MRB) issues and corrective and preventive actions (CAPA). The system provides an effective mechanism to manage root cause analysis and provides senior staff and functional managers clear visibility into which CAPAs are assigned to their areas.

The TrackWise Parallel StateMachine™ has drastically improved workflow, allowing appropriate MRB members to disposition products more efficiently via a parallel review and approval process. Quality assurance and human resources track training requirements and documentation, and are able to easily produce comprehensive reports. ACIST has also implemented TrackWise to manage device installations and contract management. These tracking areas allow customer service and customer support to keep track of accounts that have expiring warranties and service contracts. TrackWise proactively notifies customer service when a contract is expiring by issuing e-mail notifications. These automated alerts augment powerful forecasting reports that provide valuable information to management months in advance.

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