

Case Study of Corporate Account

Efficiency Keeps ARUP Laboratories Industry Leader

ARUP Laboratories owned by the University of Utah (UU) is a leader in the laboratory testing market space. Serving clients in all 50 states, ARUP offers an extensive menu of over 2,000 diverse medical laboratory tests and test combinations, with a particular expertise in the more exotic analyses. Operating 24 hours a day, the company processes over 20,000 specimens of blood, body fluid, and tissue biopsies each day. Although ARUP maintains super human testing efficiency and turn around time, their success hasn't happened overnight.

Challenges

ARUP has experienced phenomenal growth over the past few years. Today, ARUP employs more than 1,600 people in numerous departments ranging from immunology, pathology and blood services to clinical trials testing and beyond. Each department relies heavily on Standard Operating Procedures (SOP') to specify employee tasks in a manner compliant with FDA and CLIA regulations.

As the number of employees and new services were added to ARUP's overall business, the number of SOPs skyrocketed. Their ability to keep pace using manual processes became a serious challenge enterprise-wide. According to Joli Passey, the quality and compliance specialist responsible for managing all of ARUP's corporate SOPs, the job became extremely difficult due to sheer document volumes. "Manually routing all the necessary policies, procedures, processes and forms for collaboration, approval, distribution and training was awfully time-consuming, causing tracking difficulties and process delays. Anytime a document changed, it had to be routed from person-to-person and department-to-department to collaborate and then approve the changes. All signatures were maintained on a separate signature sheet that accompanied the documentation." Upon approval the SOP was printed, dated and filed in 4-inch, 3-ring binders. Anyone needing the proper SOP, form or work instruction had to dig through the barrage of 3-ring binders. Although ARUP's turnaround remained acceptable for customers, the time required checking and re-checking documentation for proper data, dates and signatures created a heavy workload for each department, hindering testing turnaround.



Finding a Solution

In mid 2001, ARUP's quality and compliance department set out to find a viable solution that would help the company automate their paper processes while maintaining accuracy and fast turnaround times without the added workload. To meet regulatory compliance, ARUP required that the software solution had to comply with FDA GxP regulatory requirements, especially 21 CFR Part 11. After much due diligence and evaluation of vendors, ARUP selected the MASTERControl Quality Management Suite from MasterControl Inc. in November 2001. "When searching for a solution, the MasterControl suite of quality management products met all our needs including the necessary elements to comply with 21 CFR Part 11 for electronic records and signatures," explained Passey.

Implementation

In January 2002, MasterControl was installed at ARUP under the control of the Quality and Compliance department. Soon thereafter, validation commenced to fulfill corporate and regulatory requirements. Each validation phase including Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ) was completed by ARUP with the help of the validation protocols provided through DCS. The implementation, configuration, and validation went smoothly, despite encountering a few hiccups typically related with any large system installation. "Technical support was excellent. Any issues during installation and validation were resolved quickly and in a professional manner," concurred Passey.

Training was provided to individuals responsible for system administration that in turn were responsible for training other users as the system was implemented. While surveying employees about MasterControl's ease-of-use, Passey garnered positive feedback. "Most users find MasterControl easy to use once they have been given some basic training on the system. The biggest hurdle for most users is the addition of dual passwords. But since this is one of the 21 CFR Part 11 requirements, they've adapted well."

MasterControl at Work

Since the implementation of MasterControl, ARUP has experienced remarkable efficiency, better process management and faster turnaround times. "Tracking documents, revisions and approvals is much more efficient and turnaround times have dramatically improved with MasterControl," noted Passey. Now ARUP can handle more paperwork with less work due to a variety of tangible benefits:



- **Automating Routing, Collaboration, Approvals and Electronic Signatures** - ARUP's controlled documents are managed and maintained with ease. All routing, collaborations, approval and change management of SOPs, processes and forms are automated. ARUP's document approval cycle times are greatly improved and can be monitored while in process, each step of the way. Upon approvals, electronic signature attributes are captured including first and last name, date, time and meaning of the signatures to guarantee ARUP complies with 21 CFR Part 11 requirements.
- **Ensuring Enterprise Security, Audit Trail Management and Compliance** - MasterControl's built-in features required for GxP requirements and 21 CFR Part 11 compliance have provided ARUP with impeccable system security. Role-based security for all personnel handling polices and procedures ensure that only the right users and departments have access to the appropriate document. With MasterControl's audit trail capabilities, ARUP departmental managers can quickly access and view the entire history of a document, including any related notes and changes.
- **Facilitating Notification and Training** - When corrective actions initiate change management and document approval cycles, everyone affected by the change is automatically notified of the changes. ARUP managers have peace-of-mind knowing that workers are using current document versions.
- **Improving Turnaround Times with Less Work** - Most importantly, ARUP has continued to sustain and improve their service turnaround times with greater efficiency, not having to divert so much attention to manually routing and management. According to Gusto Colonna, a document manager within the Transfusion Medicine Department, ARUP's ability to automate paper processes has made her job much easier. "Prior to coming to ARUP, I worked for a small company where managing paperwork manually proved to be extremely difficult, time-consuming and inefficient. When I started working here at ARUP, managing the same processes was like a night and day difference. Controlled documents are all stored electronically and are easy to locate and access. Our department members can find procedures, work instructions and the forms they need all while being reassured they are using the most up-to-date versions."



Enterprise-wide Roll-out

After the implementation within ARUP's quality and compliance departments, the enterprise implementation of MasterControl commenced on July 2002 on a departmental basis. MasterControl has become a key product for ARUP. "It is the central solution in the development and roll out of our company-wide quality plan," said Passey. Since then, ARUP has implemented MasterControl within a variety of departments including Immunology, Transfusion Medicine, Infectious Disease and UU Clinical Laboratories. ARUP continues to methodically roll out their quality strategy with plans of adding new document types and quality processes as they go. With over 50 technical departments and several non-technical departments within the company, the roll out methodically moves forward.

Tested and Proven

It's been a couple of years since ARUP started automating their quality systems, an endeavor that continues still today at their own set pace. With each new department implementation, the journey proves to be a success. More importantly, ARUP continues to improve all their service offerings with Robotic-like efficiency each step of the way.

About MasterControl

MasterControl produces software solutions that enable regulated companies to get their products to market faster, while reducing overall costs and increasing internal efficiency. MasterControl securely manages a company's critical information throughout the entire product lifecycle. Our software is known for being easy to implement, easy to validate and easy to use. MasterControl QMS and QEM solutions include quality management, document management/document control, product lifecycle management, audit management, training management, bill of materials, supplier management, submissions management, and more. Supported by a comprehensive array of services based on industry best practices, MasterControl provides our customers with a complete information management solution across the entire enterprise. For more information about MasterControl, visit www.mastercontrol.com, or call: 1.800.825.9117 (U.S.); +44 (0) 1256 325 949 (Europe); or +81 (03) 6801 6147 (Japan).