CASE STUDY

CLIENT PROFILE:

A global provider of infection prevention and other procedural products and services to healthcare, pharmaceutical and medical device customers.

With thousands of associates operating in more than 100 countries, the company generally maintains decentralized operations. Each unit is responsible for its own computer software and systems, and their validation and verification. In 2007 its corporate IT selected Compliance Associates Validator to automate the validation lifecycle of its software and computer systems to comply with strict regulations set out by the Food and Drug Administration (FDA) and other governing bodies. Use of the solution has continued to grow across the organization.

"We don't have a lot of internal resources to throw at validation. Validator streamlines what we do. It improves documentation through electronic signatures. And it gives us a defined roadmap to follow," says Project Manager, Validating Systems, "Prior to Validator, we had paper-based processes, manual signatures and large binders put in drawers never to be looked at again. It was a case of, 'do it yourself and kill a lot of trees.'"

Originally the company turned to Compliance Associates in 2007 for consultative help on its Product Lifecycle Management (PLM) system. After that, Validator was deployed for another system, which led to use on further systems. Today, it is used to validate corporate systems, such as HR, enterprise-wide training and campus systems. It was also recently implemented for the company's contract sterilization business. The group

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currently has more than 50 facilities across the globe, three-quarters of which acquired within the last year. Validator is helping them as they move to a single operational model and to avoid delays caused by global operations.

"None of the newly acquired companies have been on the system before, and every day one of them is going to be audited by the FDA, or ISO, or the European Commission or various national auditors," notes the Validating Systems Project Manager. "They need to be able to quickly pull the same documents and information, because they are all on the same system. But they are across multiple time zones and don't have the luxury of waiting or calling around. Validator eliminates all that possible delay."

Several of the company's R&D and manufacturing facilities worldwide have also adopted the software on an individual case-by-case basis. "We don't go in and dictate the software used for quality systems, but as computer system validation becomes more important to various groups — as it has now that it is specified in ISO 13485 (the design and manufacture of medical devices) — we introduce them to Validator". The solution has gained even traction over the last year, coinciding with the company's rapid pace of acquisition.

With new groups and businesses becoming part of the company, Validator is also helping ensure knowledge transfer. "It allows us to update documents quickly when needed and understand which documents need updating.

"Even if a system only has a lifecycle of four or five years, there might be three or four different administrators

managing it in that time. Validator gives us a repository and framework for validation that makes that transition run more smoothly."

As validation becomes more important across the organization, the validation team is on a quest to educate. "We want everyone to understand what their job is when it comes to computer system validation, and their responsibilities."

Validator assists with this task by giving non-experts all the tools they need in a single location. A smaller scale team can then manage the overall validation project, "It allows us to get more people involved, get them in and out quickly to do what they need to, and we don't have to train them in the process."

In fact, Validator has given them the opportunity to expand the team. When the group recently sought a new member, finding one with computer system validation experience was a challenge. They instead hired a top prospect with a Master's in Library Science and process expertise.

"Validator helps someone without a complete knowledge of computer system validation get up to speed and become a contributing team member faster, because they have all the tools and templates available, and know where to find everything they need." Internal validation training for new hires is a lot more efficient as a consequence of using the product.

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