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A New Vision of Quality Assurance

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Rick Smith sees quality efforts at Alcon Manufacturing Ltd. in a whole new light.

As quality assurance engineering manager, products and processes, Smith is starting to witness the fruits of a recent rollout of a new corrective action tracking system. For the first time since the Houston plant opened in 1989, Smith and his quality team have complete visibility and reach into its corrective and preventive action (CAPA) activities.

Corrective actions no longer take several weeks to close, and plant managers can more easily view departmental activities and problems. Anyone with the proper login information can now access quality reports via the company intranet. There's no longer a need for chasing binders.

"For Alcon, this is going to be a global solution and very important for the future," Smith says.

A Closer Look

Alcon Laboratories Inc. manufactures ophthalmic pharmaceuticals, ophthalmic surgical equipment and devices, contact lens care products and other consumer products that treat diseases and conditions of the eye. With its principal U.S. operations in Fort Worth, Texas, Alcon operates facilities in 75 countries and employs a work force of more than 11,000. In 2002, the company posted sales of \$3 billion.

Like any manufacturer of its size, Alcon operates many manufacturing facilities that contain a large hodgepodge of information systems used to control, chronicle and correct plant floor processes. The systems are a mix of off-the-shelf and homegrown solutions, all functionally adequate but not really suitable for today's information-hungry management and regulatory personnel.

Alcon's Houston facility was one such facility from a quality perspective. It boasted 12 different CAPA systems, most of which were created within Microsoft Excel or Access applications. But the facility also had a work force clamoring for change. Such initiative has helped the facility nab Alcon's Plant Productivity Award for 10 consecutive years.

Simultaneously, Alcon needed a tool to help it meet the FDA's requirements for electronic signatures, electronic records and full audit trails. The disparate quality applications in Alcon's many facilities around the world weren't going to live up to the new electronic standards demanded by 21 CFR Part 11.

"One of the reasons we wanted to go with a new CAPA system was 21 CFR Part 11, but also the FDA's emphasis through the QSIT [quality system inspection technique] inspection tool used within CAPA [activities,]" Smith says. "Effective corrective and preventive action is a big thing for the FDA."

Caught in the Web

After nearly a nine-month search, Alcon found its answer in late 2001. The manufacturer selected CATSWeb, the Web-based enterprise quality tracking system from Morgan Hill, Calif.-based AssurX Inc.

The Alcon research team involved in the software selection felt CATSWeb met all the requirements to be compliant with 21 CFR Part 11. In particular, the new CAPA offering had electronic signature components and controls, controls for identification codes and passwords, and time-stamped audit trails.

Additionally, the software was Web-based, which meant the databases could be set up at Alcon's corporate headquarters in Fort Worth, and Alcon wouldn't have to worry about re-implementation of the software at all of its facilities. To access the system, users need only the proper log-in information and a Web browser that connects to the company intranet.

AssurX calls its software "true" zero-client software. Because CATSWeb is based on HTML Version 3.0 standards, most browsers should not have compatibility issues; other CAPA software based on technology such as JavaScript or ActiveX Controls might require the latest browser technology or might only be compatible with one type of operating system. AssurX believes users can reasonably assume that any Internet-capable client system meets the minimum requirements for accessing the CATSWeb software, which means users need not place these systems under any validation controls. Alcon has no plans to validate client terminals--in Houston or its other facilities--used to access its intranet and ultimately CATSWeb.

Smith says AssurX's understanding of the pressures that come with validation of individual client terminals

and entire software systems was appreciated. "They had a validation package that was available off the shelf to help in the validation activities. That was a tremendous help," he says.

Alcon's Houston facility went live with their first CATSWeb applications in August 2002. Smith says only about four months were needed after the software installation to train the 50 or system 60 users in Houston, to set up its CAPA processes and to validate those same processes.

Instead of simply duplicating the dozen existing CAPA systems in the new software environment, Smith and the Alcon team reengineered the processes that had come under scrutiny. In doing so, they cut the number of manufacturing processes that fell under its CAPA umbrella to five.

"We basically built them up from scratch and put them into CATSWeb," Smith says.

To set up the processes, Alcon's quality personnel relied on CATSWeb's customized forms, each with their own sets of fields, validation rules, default values, workflow rules and access restrictions. If so desired, users also can attach files, notes, electronic signatures or links to the forms for further explanatory needs.

The Results Trickle In

By the end of 2002, Smith had yet to put together any return on investment numbers, but the anecdotal evidence coming from the plant floor was encouraging. Early benefits include:

- **Time for closure on corrective action has gotten a lot faster. Quality personnel used to spend four to six weeks closing corrective actions. "We have had them closed in under a week and that's not uncommon," Smith says.**
- **Speed and access to information is much greater. One of the key aspects of an effective CAPA process is management review, and now Alcon's executives have much greater visibility into correction actions directly from their desktop PCs.**
- **Quality engineers are able to concentrate on larger issues. A complaint trend used to be the sole responsibility of quality engineers, but with CATSWeb clearly delineating the complaints, the quality department confidently can assign a manufacturing representative to investigate problems.**
- **Administrative requirements for CATSWeb are minimal. Because the software is hosted centrally, "we don't have to worry about testing on all the PCs that we have around the world," Smith says.**

Based on the early success in Houston, CATSWeb is being rolled out to other facilities in the Alcon family.

"A number of facilities are in the process of implementation and validation," says Jeff Mazik, Alcon's senior information specialist for global information technologies. "The ones that will probably soon be done with certain applications in CATSWeb will be our Fort Worth, Irvine, Calif., and Cork, Ireland, plants."

The transfer of knowledge should occur quickly. Mazik says the other facilities are using the CATSWeb applications first built in Houston either verbatim or as a guide in the creation of other applications.

From a technical perspective, the rollout to the other facilities, both domestically and internationally, should go smoothly as well, according to Mazik.

"We see the administration and implementation as being much easier," he says. "A great example of that occurred during a conference call recently with one of our facilities in Kaysersberg, France. They knew little about CATSWeb, but they had sent one person to do some of the training. So they had all of these questions about how do they get the software installed and what do they have to do.

"Basically, the answer was that you don't have to do anything but develop your applications in CATSWeb. It's all there for you and all ready to go."

Sidebar 1:

The Tip Sheet

After searching for a new corrective and preventive action (CAPA) software solution, Alcon's Rick Smith offered some advice for other manufacturers following the same path.

1. **Involve CAPA system users in the design and implementation of the software. This ensures the software will answer real-world concerns.**
2. **Look for a CAPA solution that's scalable and secure. With 21 CFR Part 11, it's a good bet that pharmaceutical manufacturers are looking for an enterprise solution, not just a single facility answer. That means any CAPA solution must demonstrate the ability to be used in an intranet or Internet environment and to be distributed over multiple servers to accommodate hundreds of concurrent users. The solution should also feature the latest encryption technology to protect information as it moves across broadband connections.**
3. **Keep integration needs in mind. Information systems rarely work in isolation for too long. In the case of Alcon, CATSWeb is not yet linked to its J.D. Edwards enterprise resource planning system,**

but those plans may change depending on company needs in the coming years.

4. Conduct regular meetings with users once the CAPA software is installed. A monthly face-to-face meeting or conference call of users can lead to better communication and more efficient knowledge transfer.