

BAUSCH & LOMB



CUSTOMER CASE STUDY

IMPLEMENTING A GLOBAL
21 CFR PART 11 COMPLIANT
CAPA SYSTEM



BAUSCH & LOMB: IMPLEMENTING A GLOBAL 21 CFR PART 11 COMPLIANT CAPA SYSTEM

When Peter J. Mueller, Manager of Global Quality Information Systems selected a global CAPA (Corrective and Preventive Action) system for his company, he knew exactly what he was looking for. Bausch & Lomb, founded in 1853 and headquartered in Rochester, New York, is a leading global vision care company. Today, the company has over \$1.5 billion in annual revenues, over 10,000 employees in 35 countries, with products distributed in over 100 countries.

Bausch & Lomb is divided into (5) business units comprised of:

- Contact Lenses
- Lens Care
- Cataract and Vitreoretinal Surgery
(surgical products)
- Refractive Surgical Products
(lasers)
- Pharmaceutical Products
(including generic and proprietary prescription pharmaceuticals, mostly in the ophthalmic field, over-the-counter eye drops and other medications.)

Mueller's planning process identified three key criteria that had to be met:

- The ability to manage all CAPAs on both a local and global level—local facilities would log site-specific issues, but site managers needed to share knowledge among multiple facilities.
- The system must provide a central repository of all CAPAs for all facilities so that Global Quality Assurance could manage and track all issues throughout the organization.
- 21 CFR Part 11 compliance—CAPA system had to provide electronic signatures, time-stamped audit trails, security controls, etc.

Mueller chose CATSWeb, from AssurX Inc. By the end of 2002, CATSWeb will be rolled out to all 40 global facilities, replacing paper-based systems, home grown applications, as well as two competitive software products. 21 CFR Part 11 compliance was a key factor in Mueller's decision. Bausch & Lomb had already created a position paper on 21 CFR Part 11 requirements. In addition to developing policies, procedures and remediation plans to bring all existing systems into compliance, Bausch & Lomb performed gap analyses on various commercial offerings. According to Mr. Mueller, "We felt CATSWeb was above and beyond in compliance with 21 CFR Part 11 requirements. And we have a very strict interpretation of those requirements."

AssurX, Inc., is a leading global CAPA system provider for FDA-regulated companies throughout the world. In 1998, AssurX decided to re-engineer its popular idsCATS client/server product and replace it with a compatible product based on pure Internet architecture. After two years of development, CATSWeb was launched in early 2000, making it the first Web-based corrective action tracking system on the market. AssurX built a myriad of functionality into CATSWeb including universal e-mail integration (i.e., use of any existing e-mail system), strict security controls, the ability to attach any type(s) of files including documents, drawings, images, spreadsheets, etc. CATSWeb was designed from the ground up to easily integrate with

**BAUSCH & LOMB
SELECTED CATSWEB
OVER ALL OTHER
VENDORS FOR:**

SUPERIOR
ARCHITECTURE

NO CLIENT-SIDE
SOFTWARE AND
EASY VALIDATION

WORKFLOW
FLEXIBILITY

100% HTML
RELIABILITY,
SCALABILITY
AND SECURITY



other information systems including ERP, Manufacturing Execution Systems (MES), Supply Chain Management, Customer Relationship Management and custom corporate systems.

Companies could now leverage the power of browser-based systems, reduce IT costs, lower the learning curve for users, and redirect valuable IT resources to more important projects within the organization. Proprietary client-side software became a thing of the past: all that was required was a simple browser—any browser. And by 2000, most organizations were already leveraging the power of the Internet to communicate, collaborate and improve productivity in a variety of ways. The use of a Web browser had become second nature to most organizations.

According to Mr. Mueller, there were numerous reasons why he chose CATSWeb over the other two vendors he researched.

Architecture

CATSWeb is a true, zero client CAPA system which provides access from any type of browser, running on any operating system, anywhere in the world. “CATSWeb met all the core design goals required by Bausch & Lomb. And since the information was going to be shared among the numerous geographically dispersed facilities, this allowed easy management of all CAPAs on a local level as well as knowledge exchange between management throughout the global organization,” said Peter Mueller.

No Client-side Software, Easy Validation

Since CATSWeb doesn't require any client-side software installation, validation was only required on the application server where

CATSWeb resided, and was performed in a very short period of time. Even though AssurX provides a comprehensive IQ/OQ validation package, Bausch & Lomb decided to use their existing standard set of IQ/OQ protocols. Validation was performed by one individual in less than two months. No validation was required on any of the client computers. If Mueller had chosen one of the competitive systems that utilize JavaScript, VB Script or ActiveX components within the client web browser, validation would have been required on all client computers. Mueller estimates that this would have tripled the validation costs and taken several months longer to perform, resulting in delayed deployment and other potential conflicts throughout the organization. Any system that uses client side scripting is performing a function on the client side, and must be validated.

Flexibility

The system had to conform to Bausch & Lomb's CAPA workflow, rather than the other way around. According to Mueller, “other systems would have required Bausch & Lomb to rework their workflow to meet the vendor's workflow process, and extensive customization would have to be done by the vendor. The workflow and form design in CATSWeb was exceptional, and fit into Bausch & Lomb's existing workflow very well.

We wanted to do this ourselves and not rely on the vendor for every customization.” The Global CAPA Manager worked with a pilot group comprised of quality managers from each business group to define their CAPA needs. Once this was done, the Global CAPA Administrator took the information and designed and created all the workflow forms, etc. directly in CATSWeb without the need for custom code or vendor customizations.

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Reliability and Scalability

AssurX is the first company to offer true zero client architecture in CAPA Systems. With 100% pure HTML being sent to the browser, compatibility, reliability and security problems disappear. Firms with mixed environments of Windows, UNIX, Linux and Macintoshes can freely collaborate. And because CATSWeb is an n-tier application, the system can grow with the organization.

The system can be used in a single-server configuration, or can be expanded to a multiple-server clustered system. CATSWeb utilizes either Microsoft SQL Server 7 or 2000, or Oracle 9i – both of which are very robust and highly scalable database platforms.

Peter Mueller may have other plans for CATSWeb in the future. Customer complaints and audit tracking are on his list of possible future uses of CATSWeb within Bausch & Lomb.

Conclusion

With the FDA clamping down on compliance, and CAPA issues cited in up to 50% of 483 warning letters, FDA-regulated companies can't afford to set aside their CAPA plans. In recent months, high profile FDA citations to pharmaceutical, biotech and medical device companies have run into the hundreds of millions of dollars. That excludes class action lawsuits brought by consumers, which are becoming more commonplace in today's litigious society.

A global CAPA solution provides information and visibility throughout the entire organization in real-time, and is no longer isolated to the quality assurance department. By implementing a closed-loop CAPA system, FDA-regulated companies can significantly minimize the possibility of receiving CAPA-related warning letters. Problems can be solved before they become a potential liability.

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