



The Case for Automated Management of Compliance Documents in Life Sciences, Pharmaceutical and Related Industries

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Introduction

Companies in the life sciences, pharmaceuticals, biotech, medical devices and diagnostics industries generate technical documents and product certificates to ensure they comply with regulations and to document product quality. These companies have long recognized the need for an integrated, coordinated and secure system of accessing and distributing these documents. Because these certificates are time- and labor-intensive to manage, companies seek technology solutions that will automate the management of these essential documents and enable secure access by customers.

In response to this need, Longwood Software, a technology innovator that developed RevBase, a software solution that manages, secures, shares, fulfills, and tracks a company's full range of marketing materials via a hosted online portal, has created a solution that addresses the specific and critical technical document-related needs of life sciences, pharmaceutical and related companies.

Life Sciences and Pharmaceutical Industries' Specific Needs

Life sciences and pharmaceutical companies' products must meet specific quality and safety parameters and regulatory requirements, and they must document that each product complies with these requirements. Customers who rely on these products need to have the certificates supplied to them upon request, and often are required to have copies available for their customers. Once the product is at the customer site, a new certificate for that product must be obtained on a yearly basis.

The Industry Challenge

1. Thousands of documents, and growing daily.

- Must enter new documents/certificates constantly.
- Must disseminate multiple updated product documents to customers.
- Must respond to all customer requests for documents.
- Impossible to manually track activity related to all items in system.

2. Staff is overwhelmed responding to requests.

- Labor-intensive for staff to respond to individual calls and emails requesting documents.
- Can't fulfill all requests in a timely way.
- Don't have time to attend to other important marketing tasks and responsibilities.

3. In the case of multiple global offices, time lags re: contacting appropriate offices in customers' regions.

- Contacting far-flung offices in different time zones results in delays getting requests to appropriate parties.
- Customers are frustrated they can't obtain needed documents faster.

The Solution

A high-availability, high-volume software platform like RevBase, a comprehensive Marketing Asset Management (MAM) platform, provides a repository for the ever-expanding quantity of documents. RevBase is a web-based solution that internal sales, sales support, technical documentation and Marketing staff have instant access to, and that also provides immediate on-demand access, via a "public" zone, to authorized customers for the documents they need, when they need them.

RevBase – A Complete Platform

In addition to delivering a solution customized for managing technical documents and helping companies meet regulatory requirements for their product documentation/certificates, RevBase offers multiple other benefits to marketers:

- Organization of all digital, print, physical, and print-on-demand marketing assets produced by an organization into one system.
- Presentation of and access to all assets via a web portal where users can search for an item by name, keyword, or category.
- On-demand web delivery of assets direct via the system's shopping cart.
- Ordering and fulfillment of assets on an as-needed basis.
- Notification to sender when items are accessed by the recipient.
- Data collection from the field through continuous monitoring of usage, surveys, and usage "click-through" tracking.
- Measurement of program effectiveness via up-to-the-minute usage reports detailing frequency and kinds of activities for selected time periods.
- Customization of individual assets to include specific dates, information, messages or user-supplied content.
- Creation of personalized web kits of collateral that sales can use with targeted prospects and customers.

- Reconfiguration of the system as needed for promotional programs, new product lines, acquisitions.
- Notification to administrator of assets that are expiring/outdated so they can be removed from the system.
- Auto-notification to users of new items, changes to existing ones, or featured items.
- Archiving of all marketing materials for safekeeping and future reference, including current assets, and those that are older or expired.
- Secure access to those areas of the MAM system as determined by the administrator.

Industry Example: Thermo Scientific

“The most effective tool we’ve implemented in years,” said Kent Nelson, eMarketing Communications Specialist for Thermo Scientific Cell Culture and Bioprocessing in Logan, Utah. The tool to which Kent is referring is RevBase.

RevBase was discovered by Kent as he sought to solve two related dilemmas: how to build an online Marketing Communications library of upwards of 500 marketing and technical documents for internal use, while also providing secure access to 22,000 (and growing by 100 a day) Product Certificates of Analysis, documents required by customers to identify exact formulas and to certify each product.

Nelson’s business unit is part of Thermo Fisher Scientific Inc. (NYSE:TMO), a company with annual revenues of \$10 billion, more than 3,000 employees, and serving over 350,000 customers in the pharmaceutical and biotech industries, hospitals and clinical diagnostic labs, universities, research institutions and government agencies, as well as environmental and industrial process control settings.

The Thermo Scientific Cell Culture and BioProcessing unit manufactures products for use in the cell culture and bioprocessing industry, serving organizations engaged in cancer and other medical research, and has more than 1,500 employees in the U.S., Europe, and Asia-Pacific. The unit provides essential instruments, consumables, reagents, media, services and software tailored to the needs of cell culture processes.

Kent needed a way to eliminate the 20 hours per week he and his staff spent responding to individual calls and emails requesting specific Product Certificates of Analysis. He also wanted to replace the CD’s Marketing burned and mailed out each time a new piece of product literature was developed. He said, “We wanted to find a way to make the Certificates of Analysis available via a customer portal, but, at the same time, avoid competitors accessing them.”

He found the way when, during a monthly corporate MarComm web conference in which best practices were showcased by different business units, Thermo Fisher Scientific's Air Quality unit talked of their use of a cloud-based solution: RevBase.

"I loved what I saw demonstrated during the web conference," Kent said. "I said to myself, 'I need that!'" He started the process of getting RevBase for his group, and having it configured for his unit's specific needs.

In addition to creating an internal MarComm library, used by 200 marketing, sales, sales support and technical documentation staff in Kent's unit, an Internet-accessible public zone for Product Certificates of Analysis was also created, in which customers enter the exact part and lot number of the desired certificate and then download it. "This is a powerful and unique use of RevBase for us," said Kent.

A related need was to be able to archive certificates in the system for at least five years. Storage space was added to RevBase to accommodate the growing volume of documents.

Once in use, Kent had another task for RevBase – give Thermo Scientific content managers authorization to add new certificates as products were developed. This was done, with a safety check put into place. RevBase automatically tracks all items added to the Product Certificates library from the previous day, generates an audit report on all new items, then emails the report to Kent and all content managers so accuracy can be checked, and any errors caught and changed before customers access them.

"It's been a collaborative process working with the RevBase team," said Kent. "They respond positively and quickly to any idea I throw out, and have 'pushed the envelope' on developing new features and ways to use RevBase. They are the most helpful and friendliest group of people I've ever worked with. As a result, I've recommended RevBase to other business units within the company, as well as corporate."

Industry Example: Mettler-Toledo

"Nobody was winning," said Robert Eggeman, Service Champion for Mettler-Toledo International's multi-million dollar Process Analytics Division. He stated this opinion when he took over the management of the company's Certificates of Calibration, numbering in the tens of thousands and growing daily.

These Certificates of Calibration contain critical information about the company's products – precision instruments for professional use in the Process Analytics industry. Each certificate includes product values, calibrated and recorded by a technician, which verify that the product meets specific quality assurance parameters before it is shipped. This process must be repeated yearly once the product is at the customer site, and a new certificate issued. Customers request copies of certificates for industry audits and regulatory compliance.

Before Robert got involved, customer requests for certificates were handled in a very inefficient and time-consuming way - each request was handled individually. It went like this: a customer would request a certificate through their Mettler-Toledo field office; the request was passed along to the company's Zurich or Boston production facility; a staff member at one of the facilities would search across the company's servers to find the certificate requested; once located, it was emailed back to the customer's local field office; then it was finally sent to the customer by their local field office. The entire process took up to a week and a half.

"This process was very labor-intensive with no good return," said Robert. "It was also frustrating for customers to wait so long for their requested certificates."

In addition to responding to the numerous customer requests, the staff manually had to enter new certificates into the database each day – typically 100 or so.

Robert knew his group needed a better solution, and he found it in his own company. His colleague in marketing had been using RevBase for several years to manage all marketing materials, including sales support and literature fulfillment. She recommended it to Robert to better manage the Certificates of Calibration process.

Robert decided to give RevBase a try, so he first did a limited roll-out as a test. He pulled a group of certificates, each stored in PDF format, and sent them via secure FTP to the test RevBase system. The data he sent was automatically imported into RevBase and a limited number of customers given access to it via a customer portal. It worked, and Robert decided to build an expanded system.

"The RevBase team established a structure and a great mechanism for implementing the system," said Robert. "Once everything was set up and all the data collected, the data was imported automatically into the system and available on our website. Everything went flawlessly."

Now, RevBase handles all customer requests for certificates on the company's initial product line, with additional product lines being added in the future. Now, technicians load certificates as soon as the product calibration is completed and are accessible the next morning. Customers simply enter a product's serial number to access a certificate. Each evening RevBase generates an automated report updating the system.

"We are saving a tremendous amount of time thanks to RevBase taking over all routine tasks related to certificates," Robert said. "Our customers have instant, on-demand access to certificates and can download, email, or save certificates as they wish for future access. The process could not be any simpler or smoother now."

Take the Next Step to Better Certificate and Technical Document Management

Longwood Software typically works with those in charge of technical documents and product certificates to discuss specific document-related needs and how to address them with RevBase. By automating many time-consuming manual tasks; making it easier for employees, sales channels, and customers to access important documents; and providing a leading-edge platform for improved management of all of a company's marketing assets, RevBase is your partner in success.

To explore RevBase further at no obligation, contact Longwood Software at 978-897-2900, or visit our website at <http://www.revbase.com>.

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