



## Case Study:

### Impact Systems deploys Compliance-in-a-Box™ SOP Edition and Compliance-in-a-Box™ Submission Edition for an International Biotech Company

#### Business Overview

A biotechnology company adopted the EMC® Documentum®/Documentum Compliance Manager platform in 2007 to meet their content management needs, but had yet to deploy the platform.

The company had been dependant upon both an internal, shared network as well as outsourcing solutions to manage their SOP content and regulatory submissions respectively. Specific to regulatory submissions and in alignment with the industry, the company also needed to put a system in place in order to manage electronic submissions to regulatory agencies (as opposed to traditional paper submissions). And, an end-to-end solution, including implementation of new infrastructure, needed to be put in place in a short timeframe.

#### Project objectives for the new system implementation included:

- Facilitate coordination of end users between geographic locations.
- Expedite their ability to compile and submit electronic applications/updates to regulatory agencies.
- Effectively manage their SOPs and regulatory submission documents, while at the same time, staying compliant with relevant regulatory requirements.
- Implement an industry best-practice validated system, quickly.
- Ensure that current versions of critical documents/procedures are being disseminated company-wide at any given point.

#### Solution

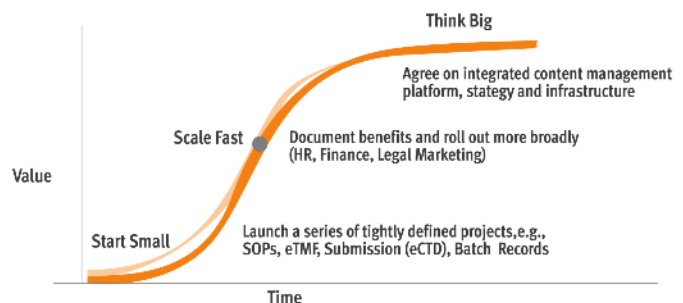
The client engaged Impact Systems to identify the approach, deliverables and services that would best meet these enterprise content management needs. Through the course of the initial meetings to establish high level requirements, the team determined that their requirements were extremely close to two pre-configured solutions developed by Impact Systems and EMC Documentum, Compliance-in-a-Box (CiB) SOP Edition and Compliance-in-a-Box Submission Edition. The company agreed to pursue this deployment option, which would provide a much quicker implementation period at a more affordable price than a traditional deployment.

They were confident that CiB would withstand their compliance requirements, since CiB is a proven, best-practice enterprise application in the heavily-regulated life sciences industry. And, the client knew that CiB was developed specifically for mid-market organizations in need of enterprise content management systems for controlled content. Hence, the client felt good about working with Impact Systems, as they knew Impact understood their small-company mindset.

Additionally, they agreed to deploy the latest Documentum Compliance Manager (DCM) release, 6.5, which meant they would be one of the first companies to deploy 6.5 and take advantage of the latest features and functionality offered via DCM 6.5.

Built on top of EMC® Documentum® Enterprise Compliance Platform, Compliance-in-a-Box SOP Edition is based on EMC Documentum Compliance Manager (DCM) configured for SOP work processes and management, and Compliance-in-a-Box Submission Edition provides a turnkey solution for electronic submissions. Both are backed by Impact's consulting services, pre-configuration tools, templates, and document types. The result is a fully functioning, validated Documentum Compliance environment that is content-ready.

#### CiB Philosophy: It's not about technology but successful organizational adoption of technology



Also attractive to the client was the Compliance-in-a-Box (CiB) philosophy – start small, with the ability to scale quickly and at the same time, have the ability to “think big” with respect to a long-term enterprise solution. CiB allowed them to get a working EMC® Documentum® application up and running within eight weeks from installation in a Test environment through implementation in the Production environment, including validation. The use of this pre-defined solution with a tightly controlled project scope and set of configurations plus associated validation scripts would provide results in a condensed time frame, and prepare them with a solid foundation of compliance infrastructure for extended use of Documentum.

Also important to the client was the features and functionality provided by EMC Documentum Compliance Manager (DCM). The platform replaces manual processes with an automated, integrated, online environment for creating, reviewing, revising, approving, distributing and auditing controlled content. DCM dramatically reduces the time and effort spent managing controlled content.

DCM audits all controlled content activities, and enables all users, managers, and external agencies to know when and why changes were made. And by helping organizations meet quality objectives and comply with internal and external regulations and standards, DCM reduces company operating costs; minimizes waste, errors, and production delays; and may likely allow the client to deliver products to market faster.

**Specifically, DCM allows the client to:**

- Easily respond to external regulatory agencies
- Detect attempts to alter or remove documents
- Ensure content authenticity and immutability
- Quickly determine who has interacted with content, as well as when and why
- Enforce signatures and proper approvals
- Ensure document retention for required periods

## Summary: Outcomes/Benefits Realized

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An end-to-end solution, including implementation of new infrastructure, was executed. As a result of the implementation, a best practice SOP Management Process was adapted by the client. It took eight weeks to achieve the company’s initial objectives of deploying EMC Documentum pre-configured for SOP Management and eCTD Submissions. The company now has their first 21CFR Part 11 validated system, which they can scale according to their future needs, and the following objectives were achieved:

- Collaboration. The CiB solution ensures that all staff across geographies can collaborate and efficiently manage controlled content across the organization.
- Risk mitigation. The company can now be sure that current documents and procedures are being disseminated across the organization at any given point.
- Organizational efficiency. The company now has a system that allows them to much more efficiently manage controlled content.
- Increased compliance. They now has a 21 CFR Part 11 validated system.
- Organizational adoption. The client used Impact Systems’ OQ scripts to train their team internally, and the company has been very pleased with internal acceptance of the system.
- Efficiency gains. They now have the ability to manage their submissions to regulatory agencies.
- Cost and time savings. The rapid CiB installation and implementation provided significant cost savings, and reduced the client’s IT staff involvement. Compliance-in-a-Box **reduced the implementation period by 60%** than that of a traditional deployment, saving them significant time and money. The solution was implemented in eight weeks, compared to a traditional deployment period of four to six months for a regulatory compliant system.

The client, as a biotechnology company, is ultimately in the business of helping patients. The hope is that this solution will be of significant assistance in allowing them to make their products available to the marketplace earlier than the company would have expected prior to this solution being in place.

## About Impact Systems

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Founded in 1996, Impact Systems provides deployment and migration services for Enterprise Content Management (ECM) systems. Impact Systems specializes in deploying business solutions such as Compliance-in-a-Box for clients in the life sciences (medical devices, biotech, pharmaceutical and healthcare) and other regulatory markets. Impact’s deployment services are focused on helping organizations develop a roadmap to ECM implementation success, including up-front assessment, planning, installation, configuration, customizations, validation and deployment. Additionally, the company has developed a proprietary suite of configuration management, content and metadata transfer, and bulk load software tools that provide significant time and cost savings for deployments, migrations and ongoing electronic content needs. Impact Systems is a member of the EMC2 Consulting/Select Services Team, and is an Adobe® and Kofax partner.