

# Compliance-in-a-Box Submission Edition

## A turnkey solution for regulated content management and electronic submissions

### THE BIG PICTURE

- Automates the management of controlled content beginning with standard submission document types and scaling to support content and publishing across the enterprise
- Incorporates best practices for managing controlled content based on successful global implementations of EMC Documentum compliance solutions
- Integrates with best-of-breed submissions technology that promotes compliance with eCTD publishing for the major global regions, including United States, Europe, and Japan
- Enables rapid deployment based on a set of pre-configured templates with focused deployments running in production within weeks
- Provides the underlying content management, submission processes, and infrastructure that can scale as your organization grows

### Accelerating new drugs to market

Biotech and life sciences companies face a daunting reality: As of January 1, 2008, the U.S. Food and Drug Administration (U.S. FDA) will only accept electronic submissions in eCTD format. By the end of 2009, all agencies in Europe are planning to adopt eCTD as their electronic format, and to eliminate the paper requirement. To be prepared, mid-sized life sciences companies are looking for better alternatives than current approaches using file shares and basic document management. While these smaller companies would like to have the same regulated content and submissions capabilities used by large pharmaceuticals, they typically encounter a number of obstacles at implementation. These include high initial start-up costs, limited resources, and significant IT infrastructure requirements. Now they have an alternative.

In partnership with Impact Systems and Image Solutions, Inc. (ISI), EMC offers a specific solution to meet the needs of mid-sized life sciences companies. Designed to minimize initial investments, this solution enables companies to configure, install, and validate an integrated, regulated content management and publishing system. The solution and underlying platform will scale as clinical trials progress—from IND to NDA, from CTA to MAA, and ultimately to electronic submissions to the U.S. FDA and regulatory agencies in the EU.

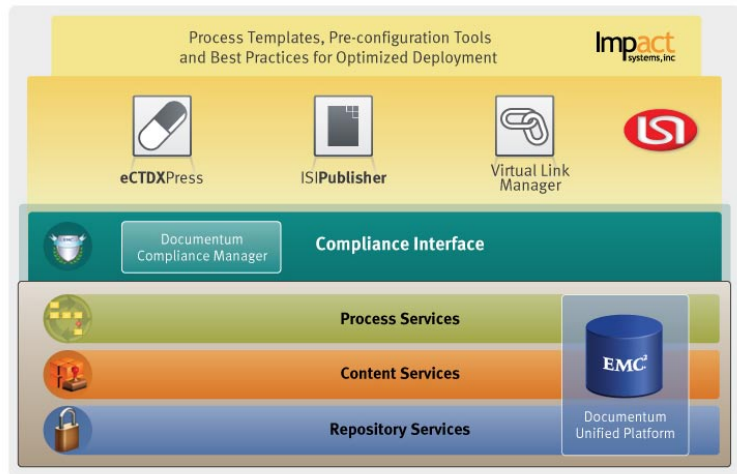
### Delivering Compliance-in-a-Box Submission Edition

The foundation of the solution is the EMC® Documentum® Compliance Manager combined with Impact Systems' pre-configuration tools, set of templates, and document types. The solution also includes three award-winning products by ISI:

- **eCTDXPress**—for submitting content electronically to regulatory agencies worldwide
- **ISIPublisher**—for supporting paper-based and non-eCTD electronic submissions (commonly known as hybrid or NeeS submissions)
- **Virtual Link Manager**—for maintaining cross-document hyperlinks even when both the source and target documents have changed

Working with a team of experts, your organization can rapidly configure and implement an integrated document management and publishing system. You can then extend the base system to support additional document types, workflows, and other business processes, while reducing the number of duplicative tasks. Leveraging best-of-breed technologies and the experience of successful implementations at companies like yours means you can deliver highly focused projects targeting specific document types within weeks.





Working together, EMC, ISI, and Impact Systems offer a specific solution to meet the needs of emerging life sciences companies.

## Leading the way in life sciences

EMC works closely with our life sciences industry customers, leading industry groups, and government agencies to design products and services that automate the entire content lifecycle—from research and development through commercialization. That’s why so many of the world’s top life sciences organizations rely on software products from EMC, including 25 of the largest pharmaceutical companies and seven FDA centers.

Impact Systems has extensive experience in process manufacturing, including chemical, pharmaceutical, and healthcare solutions. The company provides software tools and services for quick deployment of production-ready systems—whether for a new environment or migration of existing electronic content.

ISI has played a pioneering role in the worldwide movement toward acceptance and standardization of PDF-based electronic submissions. Today, ISI is a recognized leader in the area of electronic submissions.

## Solution features

This solution provides additional features, including the ability to:

- Start with preclinical, clinical, CMC, and regulatory content types, and expand to others such as safety, legal, and accounting to support Sarbanes-Oxley and financial reporting
- Enforce e-signatures and justifications while also ensuring content authenticity and document retention
- Control who has access to what content and when, and provide quick identification of interactions
- Create submission-ready documents with the ability to fix formatting issues
- Publish electronically as required by deadlines with the option to deliver printed submissions where required
- Capture electronic records and assure destruction based on defined business rules

## Benefits of EMC Documentum Compliance Manager

By replacing unreliable and inefficient processes, Compliance Manager offers an automated, integrated, online environment for creating, reviewing, revising, approving, distributing, and auditing controlled content. Compliance Manager dramatically reduces the time and effort employees spend managing regulated content.

Compliance Manager can audit all content activities, enabling relevant parties—users, managers, and external agencies—to know when and why changes were made, not only to content but its properties. And by helping organizations meet quality objectives and comply with internal and external regulations and standards, Compliance Manager can reduce operating costs; minimize waste, errors, and production delays; and deliver products to market faster and with greater confidence.

**EMC<sup>2</sup>**  
where information lives®

EMC Corporation  
Hopkinton  
Massachusetts  
01748-9103  
1-508-435-1000  
In North America 1-866-464-7381  
www.EMC.com

### Take the next step

Find out how your life sciences organization can benefit from EMC Documentum compliance solutions. Visit us online at [www.EMC.com](http://www.EMC.com) or call 800.607.9546 (outside the U.S.: +1.925.600.5802).