

The Enterprise Compliance Platform

A Necessity for Today's Life Science Companies

Abstract

In the life sciences industry, the demands of regulatory compliance are becoming more stringent. At the same time, the information management capabilities necessary to meet those demands without compromising business performance grow increasingly complex. This white paper describes the dual nature of information—a source of innovation and regulatory risk—and defines the three information imperatives that life sciences organizations must meet. The paper then introduces the EMC Documentum Enterprise Compliance Platform (ECP) for Life Sciences and explains how the components of the ECP can help meet these imperatives while streamlining drug development, accelerating the submission process, coordinating manufacturing, and speeding global commercialization.

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When the regulator comes calling

For any life sciences organization, an investigation by government regulators is serious business. Under the best of circumstances, it will be disruptive and expensive. And it could be much worse than that. It is the kind of event that keeps CEOs, CFOs, and regulatory affairs managers up at night.

So ask yourself the following questions:

- What is the likelihood of an investigation?
- How prepared is your organization to respond?
- What would it cost in time, money, and other resources?

Now, imagine the following article appears in trade publications about your company.

FDA Investigates Contaminated Drugs

In its continuing investigation of the contamination of over the counter drugs at InterPharmaBio, the FDA has found that some of the product subject to a company recall had been exported to at least 29 countries, including those within the European Union.

InterPharmaBio is recalling certain lots of a product made and distributed earlier this year after the discovery that some of it was contaminated with aflatoxin. The company has notified its distributors and asked them to hold the recalled products.

The FDA Office of International Programs has published recall notification to all countries on record as in receipt of the product. To date, worldwide, the FDA has received 41 reports of illness related to product consumption, with 23 having significant adverse reactions.

How would your company respond?

A tale of two drug companies

Reaction #1—Panic

The nature of this request requires the regulatory affairs group to manually pull together clinical trial information, manufacturing SOPs, and sales and marketing content, all of which resides on different systems in multiple locations, with no common integration platform. Therefore, responding to the request and ensuring information integrity will take several months and cost potentially \$2 to 3 million.

Reaction #2—Systematically assembling the response

InterPharmaBio has put in place an enterprise compliance platform that provides a unified view of regulated content across the entire organization. It is able to rapidly assemble a team to collaborate and review the relevant content and publish a response electronically to the FDA. The response will not take weeks or months, but days—avoiding sanctions, fines, and a potential avalanche of brand destroying bad publicity.

The information paradox

For a life sciences company, information is the source of innovation. It feeds the development pipeline while it protects against patent infringements by competitors. And it is the life-line for information exchange among researchers, clinicians, regulatory agencies, marketers, alliance partners, and customers.

That's the good news. But as our illustrative scenario "A tale of two drug companies" makes clear, the bad news is that information is an equally potent source of legal and regulatory risk. First, from the seemingly trivial e-mail message to the most closely guarded formulation, it is all subject to legal discovery. Regardless of format—R&D databases, clinical trial results, meeting notes, e-mail, inter-group presentations, discussion threads, annual reports—everything can become the object of regulatory scrutiny. And, in some cases, information must be retained for as long as 30 years.

Dual challenges: information volume and complexity

For life sciences companies, the challenges of compliant information management are compounded by the sheer volume and growing complexity of what must be managed—terabytes of structured and unstructured information in a practically endless variety of formats. In fact, Gartner estimates that 90 percent of unstructured information goes unmanaged.

The greater the volume of information the greater the possibility that something will be lost, misplaced, or simply overlooked. Further information is often spread across hundreds of systems and applications, many of which do not allow easy access to the information. So in many cases, point solutions become their own management problem and regulatory risk.

"Every day, we create and store more information (in the digital format) than has been stored for most of our history on paper."

— John Batelle: *The Search, How Google and its Rivals Rewrote the Rules of Business and Our Culture*

The volume and complexity of life sciences information is mirrored in the IT infrastructure necessary to support it. So much so that as much as 80 percent of IT budgets can be consumed by simply maintaining current infrastructure and point solutions.

The three information imperatives for life sciences companies

When pharmaceutical, biotech, and medical device companies effectively manage critical information across the life sciences value chain, it speeds commercialization, accelerates product development, and streamlines business processes. But to deliver these benefits, information management solutions must meet the three essential criteria for life science companies:

- Enforce regulatory compliance mandates without reducing productivity or increasing time to market
- Leverage and reuse high-value information assets, such as clinical studies, label updates, marketing content, and consumer information
- Automate policy enforcement across all information types and minimize human intervention

That's why today's life sciences organizations are searching for a long-term approach to information management that can handle the volume, complexity, and compliance demands in a common platform—an enterprise compliance platform for life sciences.

Solving the information paradox—the EMC Documentum Enterprise Compliance Platform

The EMC® Documentum® Enterprise Compliance Platform (ECP) meets the three information imperatives for life sciences companies through a common platform that integrates regulated content and business processes across physical and organizational boundaries, enhances collaboration, and streamlines and coordinates regulatory publishing.

Documentum ECP can manage an unlimited volume and variety of content. A typical life sciences organization will collaborate, author, control, and publish content in diverse formats pulled from many applications, file stores, departmental solutions, alliance partners, and external service providers such as contract research organizations (CROs) and contract manufacturing organizations (CMOs). ECP makes all of this content easy to search and access wherever it resides. It renders content into the correct format for departmental use and for submission via the electronic Common Technical Document (eCTD), a specification defined by the International Conference on Harmonization (ICH) for the exchange of data and content between pharmaceutical companies and regulatory agencies. This content may include:

- Product development plans including target product profiles
- Chemistry manufacturing and controls (CMC) content
- Clinical study reports
- Structured product labeling (SPL) and product information management (PIM) content
- Contracts for partners, clinical trial investigators, CROs, and CMOs
- Marketing material for direct-to-physician (DTP) portals

ECP manages all content, regardless of the source or format, with automated, secure, rules-based processes that can meet regulatory mandates, enforce internal records management and archiving policies, and support tiered, intelligent storage management.

Speeding commercialization while ensuring compliance

Documentum ECP seamlessly manages regulated content through every link in the life sciences content value chain—from discovery and research to preclinical and clinical trials through manufacturing, sales, marketing, and customer service. It enables companies to ensure compliance with regulatory requirements such as GCP, GMP, GAMP, ISO 9000, and 21 CFR Part 11—without increasing time to market. Based on industry standards and best practices, Documentum ECP:

- Streamlines processes and ensures efficient collaboration
- Seamlessly manages regulated content throughout its lifecycle
- Speeds development and deployment of validated applications
- Consolidates applications and content with a common platform that lowers TCO
- Lowers integration, migration, and validation costs

Documentum—a leader in enterprise life sciences deployments

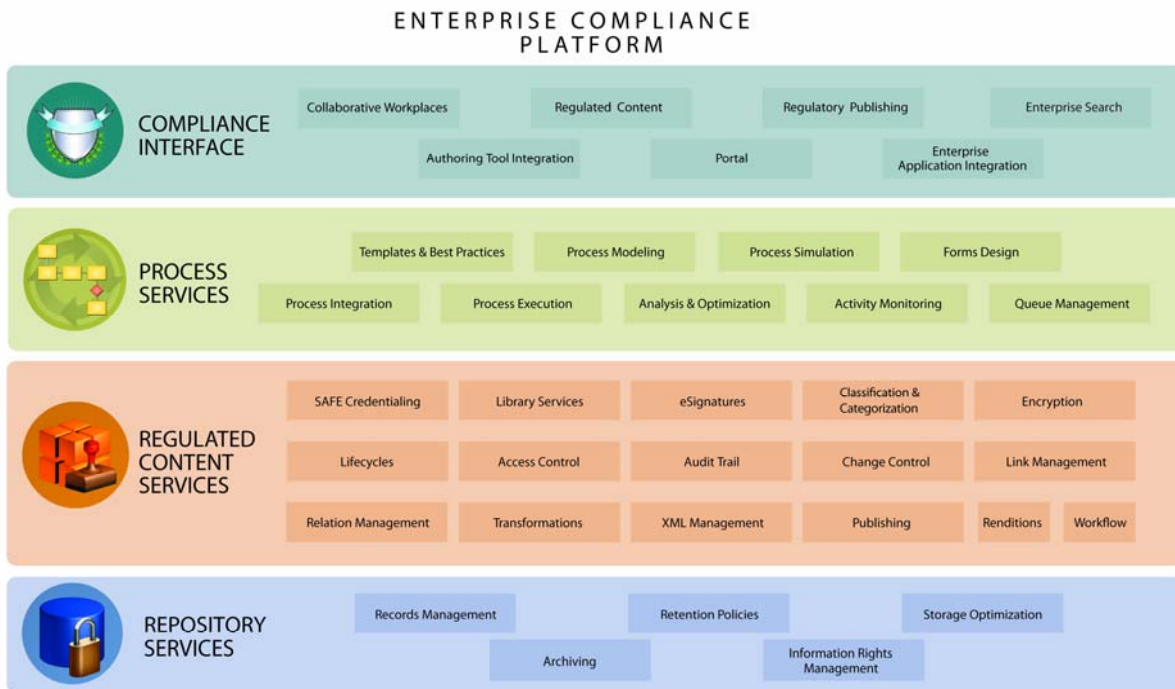
Documentum is privileged to have over 350 life sciences organizations as customers—including the top 25 global pharmaceutical companies and many regulatory agencies including the FDA. Since 1990, we've been helping life sciences companies decrease cycle time, ensure compliance, increase productivity, and bring products to market more quickly. Our dedicated life sciences group, our internal consulting organization, and our partner community have designed and deployed thousands of applications in R&D, regulatory affairs, manufacturing, quality assurance, sales, and marketing. We vigorously support industry

standards and rely on an active Life Sciences Advisory Council (LSAC) to ensure that our solutions meet or exceed industry expectations.

Components of EMC Documentum ECP

Documentum ECP has four components that work together to deliver unprecedented control, visibility, and flexibility for managing regulated content in a complex, team-oriented environment:

- Compliance interface—a web interface that delivers intuitive, graphical access to platform capabilities including regulated content and publishing, enterprise search, and collaborative workspaces
- Process services—a process suite including best practice templates that enables process analysis, modeling, simulation, testing, execution, and monitoring
- Regulated content services—content services that provide the standard EMC Documentum capabilities such as versioning, renditioning, check-in/check-out, and workflow, plus regulated services including SAFE credentialing, eSignatures, and compliance-ready audit trails
- Repository services—a services layer that delivers records management, retention policy services, information rights management (IRM), and intelligent storage management



The Documentum ECP combines a compliance interface, process services, regulated content services, and repository services in a single, unified platform.

Compliance interface

In any life sciences company, regulatory affairs personnel are the ones who must deal most often with the greatest volume and variety of content with time sensitive deadlines. They must also have visibility into the way that content is handled and formatted throughout the organization—as well as the means to create and enforce regulatory publishing policies.

The compliance interface—a web-based tool—delivers these capabilities, which enable staff to use automated lifecycles and workflows with built in business rules to govern the review and approval, effective, retire, and obsolete life cycle designations for all regulatory content. Any regulated content and process can also automatically enforce a 21 CFR Part 11-compliant signature page and audit trail. The compliance interface provides:

- **Collaborative workspaces**—team rooms—that enable knowledge workers to plan and execute projects with extended enterprise teams
Example: Exchange and track the resolution of adverse events during a clinical trial
- **Automated management** of controlled content within an audited, tightly-managed environment
Example: Manage SOPs as regulated content to enforce GMP
- **Regulatory publishing** to create, manage, assemble, track, and deliver controlled content submissions to regulatory agencies
Example: Assemble and publish submission content according to eCTD specifications
- **Enterprise search** to provide efficient access to content and analysis across unlimited content sources
Example: Conduct electronic discovery of all submission-related content (clinical study reports, CMC, etc.)
- **Standards-based authoring tool integration** between the content repository and authoring tools used to create and edit content
Example: Access standard document templates directly from Microsoft Office
- **Portals** to integrate information, applications, and processes across organizational boundaries
Example: Create team-specific portals for trial investigators, researchers, and marketers
- **Enterprise application integration** with external, transactional systems and processes such as ERP, CRM, CTMS, and more
Example: Access client medical information and billing account history from one interface

And, as content management has evolved, these tools are also available at the departmental level.

Process services

Process services work across an organization's functional boundaries while coordinating disparate IT systems and applications. In the life sciences enterprise, they can be applied to virtually any process including disease/condition modeling, pre-clinical study definition, NDA submissions, quality management, and packaging. Even within a process that cannot be fully automated, process services can automate many manual repetitive tasks.

Processes can be linked with team rooms to facilitate informal discussion, meetings, voting, presentations, and information exchange. They can also be triggered and managed from collaborative activities within team rooms—allowing full, bi-directional integration of business process management (BPM) and collaboration. Any type of interaction can be managed with ECP repository services, such as check-in/check-out, versioning, and records management. All activity within a process is captured via an audit trail, which not only serves compliance purposes but also captures best practices and metrics for continued process improvement.

Customizable templates

The Enterprise Compliance Platform features customizable process and activity templates that enable process workflows to be designed and revised without programming or systems integration expertise. For

example, ECP includes a clinical trials template based on an industry-standard process hierarchy, which can be modified to reflect company-specific variations. Templates help standardize complex, multi-step processes. In so doing, they also make it possible to refine processes and identify opportunities for improvement.

Forms

Electronic forms are an efficient method of collecting information, either to trigger a process or to provide necessary information. Typical data collection form examples are Case Report Forms (CRF), Data Correction Forms (DCF) and Patient Reported Outcomes (PRO). Serious Adverse Event (SAE) forms and manufacturing deviation forms are examples of forms that will trigger a specific regulatory review and approval process. ECP enables forms to be directly linked with process data, facilitating direct interaction with processes and underlying workflows. In addition, forms are context aware, ensuring that they present the appropriate UI based on user type, activity, and locale. For example, a form used to collect clinical trial data could be tested under two scenarios—being filled out by a trial participant and being reviewed by a research associate or physician. Just as easily, those scenarios could be simulated for forms in multiple languages.

Recognizing that many forms are still paper based and scanned in, the ECP is fully integrated with many forms applications, which automatically process paper-based forms and extract their data by deploying sophisticated image- and text-based recognition technology. Extracted data is stored in the Documentum repository where it is available to business processes and subject to content services (such as XML component management, versioning, security, library services, and lifecycle management).

Queue management

Work queues balance workloads among a large set of uniform end users—for example, a group entering clinical trial data. They are also used to prioritize large task volumes so that high-value requests receive a rapid response. A work queue is also a good way ensure compliance with internal business policies as well as external regulatory demands.

At a glance, supervisors can see how many items are in a queue versus its maximum expected threshold, the highest priority items, the number of users eligible to work on tasks, and how many items are assigned, waiting, or suspended. Supervisors can assign tasks to specific users, enable users to manually pull down tasks, and move items to another queue.

Activity monitoring

Process monitoring enables processes to be understood, corrected, and improved. ECP process monitoring is constant and execution based, which means activities can be viewed “in flight.” This in-flight capability delivers realtime dashboards to track key performance indicators (KPIs). Dashboards are flexible reporting tools that can be configured to display process results by region, facility location, or workgroup—in any way that’s meaningful to the organization. The report engine comes with 50 standard reports and users can create reports using its report builder feature.

Regulated content services

The Enterprise Compliance Platform automates the creation, management, sharing, assembly, tracking, and delivery of controlled and regulated content within an audited, tightly-managed environment. In place of elaborate manual processes, ECP creates a knowledge chain that links related processes to meet stringent quality goals and compliance requirements.

ECP enables control from the simplest standard operating procedure (SOP) to the most complex regulatory submission. Yet, for all its rigorous control functionality, ECP regulated content services are easy to use. Users interact with content and processes through a web-based application that requires little training. Regulated content services can reduce operating costs, minimize waste, errors, and production delays, and deliver products to market faster—with greater confidence. Users across the enterprise gain:

- **Centralized control**—review and approve all enterprise content from a single interface regardless of location
Example: Investigators and partners can remotely authenticate and sign documents.
- **Multiprocess functionality**—handle all types of content and the processes that control it including CRFs, SOPs, label information, contracts, product documentation, and regulatory submissions
Example: Serious adverse event (SAE) report attributes can be identified and automatically filed according to process rules.
- **Security controls**—enforce electronic signatures, print control with banner and watermark, and proper approvals, ensuring authenticity of content and process validity
Example: CFR Part 11 requirements for electronic signatures and records retention are easily enforced.
- **Role-based security**—expand user roles to reflect unique capabilities and job functions that can be defined through document access control lists (ACLs)
Example: To comply with HIPAA guidelines, patient records are accessible only to authorized care providers.
- **Multilingual support**—facilitate global deployment with support in English, French, German, Japanese, and Spanish with more to follow
Example: Product literature and marketing collateral can be published simultaneously in multiple languages.
- **Regulatory compliance**—manage content in compliance with good manufacturing practices (GMP), OSHA regulations, ISO 9000 quality guidelines, 21 CFR Part 11, and others
Example: Comprehensive audit trails can be used to demonstrate compliance.
- **eCTD lifecycle management**—create, assemble, and publish submissions, and deliver full life-cycle support for submissions, including rolling submissions
Example: Correct formats and renditions are automatically set as a document moves through the submissions process.
- **Automatic submission**—generate an eCTD backbone that is automatically validated against the eCTD specification and creates a checksum
Example: Submission-ready content is assembled, locked, compressed, and published electronically to government regulatory agencies.
- **Submission assembly**—leverage drag-and-drop, web-based virtual document assembly
Example: Content for specific applications, devices, portals, or websites can be dynamically assembled and delivered without changing the original content.
- **Configurable lifecycle model**—define lifecycles that maintain control over content and user privileges while enforcing business rules
Example: Upon Part 11 approval of a document a PDF rendition is automatically generated.

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- **Flexible relationship model**—create application-specific relationships between document types to manage document handling through approval and lifecycle promotions
Example: Formal “parent-child” relationships, such as a clinical study report and supporting content, are established and maintained.
 - **Complete workflow**—review and approve, lock and unlock submissions, and reuse of documents across submissions
Example: Required tasks and approvals are automatically completed and obtained before content is promoted.

Trusted Content Services—added protection for security-sensitive environments

Documentum Trusted Content Services (TCS) applies an advanced level of protection to the security and access control that resides in the ECP regulated content services layer. It is an ideal add-on module that ensures the safety of your most vital information assets, such as trial results and manufacturing formulas. TCS includes:

- Repository encryption—prevents intruders from reading content even if they obtain unauthorized access to repository files at the file system or storage level
- Electronic signatures—enables electronic signatures to be associated with any content item or event such as workflow activity or lifecycle change
- Mandatory access control (MAC)—combines multiple rules such as group membership and roles along with other rules to strengthen role-based security and access
- Digital shredding—ensures that information cannot be retrieved even with forensic methods that analyze residual magnetism on storage disks

Repository services

Documentum ECP repository services works behind-the-scenes to ensure compliance, optimize storage resources, and deliver a secure, yet user friendly working environment. There are three core functions of repository services: records management, retention policy, and intelligent storage management.

Records management and retention policy

A record is any type of content pertaining to the operations or transactions of an organization that has material value, regardless of physical form. Any content that conveys information on programs, policies, or decisions, or provides a rationale for decisions is typically classified as a record. This might include standard operating procedures, product presentations, annual reports, web content, e-mail, video, audio files, clinical trial results, submissions, and more.

In life sciences, there are a variety of government regulations in the United States that impose different retention periods for records. For example, 21 CFR Part 11 for pharmaceuticals stipulates that records concerning the manufacturing, processing, and packing of drugs must be retained for three years after distribution. On the other hand, HIPAA requires that medical records for deceased individuals must be kept for two years after death.

A retention schedule is a list of approved retention periods and disposition actions (that is, destroy or archive) for records. It must account for all forms in which records appear and must be applied uniformly to electronic and non-electronic documents alike. A retention schedule is unique to the organization for which it is developed, and is continually updated as business needs and accountability requirements change. By complying with its retention periods, an organization can ensure that documents will not be inadvertently destroyed while they might still be needed for legal, patent, operational, or regulatory purposes.

Supporting end users with ECP records management

The ECP records management client is unobtrusive and easy to use. End users typically declare and classify records from within Microsoft Outlook, which minimizes the effort required. Once a document is filed in the Documentum repository, it can no longer be modified or deleted. Retention periods and disposition dates can be set when filing occurs. This same flexibility applies to physical records, which can be checked out or passed on to other authorized users.

ECP enables users to easily retain and dispose of documents according to internal policies or external mandates. For example, litigation holds can be placed on retained documents by case matter. A dedicated user interface identifies “deletable” materials and enforces approvals to authorize document destruction. It will dispose of unofficial documents automatically as their retention periods expire. Any content generated by a Documentum or partner application can be managed through the ECP records management interface, without custom integrations.

Information rights management

The ECP platform gives users the option of adding EMC Documentum Information Rights Management (IRM) Services. These services can help life science companies secure, control, and track sensitive information wherever it resides. IRM services include modules for securing documents, e-mail, and mobile mail, with capabilities that include:

- Determining who can access a document
- Preventing documents from being forwarded
- Prohibiting printing
- Disabling copy/paste and screen capture options
- Protecting e-mail messages during and after delivery
- Controlling who can read and forward messages
- Expiring messages automatically upon recall
- Assigning expiration dates to messages
- Encrypting messages pushed to Blackberry devices
- Enforcing user access privileges for the lifecycle of a mobile message

Intelligent storage management

Storage management is a key component of information lifecycle management (ILM). For life sciences companies, it makes business-critical data available when and where it’s needed and meets service level agreements (SLAs) while reducing storage costs.

With advanced features such as content de-duplication and compression, the ECP goes beyond simple hierarchical storage management (HSM). It enables organizations to set automated rules that exploit and optimize a variety of storage options.

ECP business solutions

The following are typical business solutions enabled by the ECP. Additional solutions, as well as validation services, are offered by the EMC partner community.

Contract management

Contract management automates, controls, and streamlines the contract lifecycle from authoring and negotiation to analysis, execution, and compliance. It also ensures that authors consistently use approved, standard contract language.

With robust audit capabilities and workflows that enforce a hierarchical approval process, ECP strengthens internal controls and simplifies compliance with regulatory legislation while reducing cost. Visibility into the contracts lifecycle enhances the ability to track renewals and analyze the performance of executed contracts and other legal documents.

SOP management

Standard operating procedures (SOPs) help ensure product safety, regulatory compliance, manufacturing consistency, and the effective tracking of adverse events. The ECP manages the creation, modification, electronic approval, and archiving of SOPs.

For example, electronic workflow enables publishers to automatically rout the SOP through the review and approval queue. The publisher receives e-mail notifications that track the document's status with reviewers—dramatically reducing approval time, often from days to hours. Since SOPs are stored in a secure repository, publishers can attach access levels to each document that permit only authorized reviewers to make changes.

Promotional traffic

Promotional traffic, which includes marketing resource management (MRM) and web content management (WCM), relies heavily on rich-media assets such as audio, video, and image files—large files that need to be managed as seamlessly as text. The ECP delivers powerful indexing, search, and retrieval capabilities for these assets and employs rules-based workflow to eliminate publishing bottlenecks for marketing collateral and web content.

For example, to consistently deliver fresh web content that complies with brand standards, the compliance platform supports generic, XML-based templates and reusable lifecycles and workflows that permit non-technical users to manage multiple sites of any size.

ECP-based MRM automates the traditional process pharmaceutical brand teams use for creating, approving, and distributing collateral. It assures quality control for all electronic releases, enables the preparation of content to precise specifications, and electronically releases project files to vendors and clients.

Regulatory submissions—eCTD

A typical NDA submission is nearly one million pages. The ability to compile and submit these applications electronically via the eCTD format ensures that the content is approved and accurate, which means NDAs have a much better chance of being reviewed quickly, without delays to correct faulty

documentation. Avoiding such delays is no trivial matter: the longer it takes to approve an NDA, the longer it takes to get a product on the shelves earning revenue.

The ECP unites a pharmaceutical company's content value chain by controlling all upstream content such as discovery and pre-clinical data, ensuring that it has been produced in a compliant manner. This content is integrated with clinical trials results and managed through review and approval to publishing and submission. It fully supports 21 CFR Part 11, and produces a complete audit trail, effectively extending the content value chain to include regulatory agencies.

Clinical trials planning

ECP offers life sciences enterprises a flexible foundation from which to manage clinical information, documentation, and workflow. By standardizing, controlling, and securing clinical trials-related content, it reduces the costs of data acquisition and cleanup during trials, enables reporting and tracking of adverse events in patient records, and ensures regulatory compliance and faster submission preparation.

ECP streamlines trials by managing and organizing all documentation including Trial Master File (TMF) documents and Case Report forms (CRF) created and collected during the planning and execution of clinical trials. It provides a predefined workflow and lifecycle template that specifically addresses clinical trials processes and gathers reporting metrics.

R&D collaboration

R&D requires secure, managed collaboration between chemists, biologists, toxicologists, and clinicians internally—and with partners externally. E-mail is not an effective option for broad collaboration, nor does it provide any mechanism for accurately tracking document versions, maintaining research documents in a secure area, or capturing meeting results, reports, presentations, and test data.

With the collaborative capabilities of the ECP, research teams can work more efficiently, exchange information securely, employ digital signature verification, and even include partners beyond the firewall such as contract research organizations (CROs) in automated workflows. New drug feasibility studies, and other documents that require collaborative review and editing, can be tightly controlled and managed. And the ability to find the right information at the right time eliminates the necessity of repeating pre-clinical trials or laboratory tests, which take weeks to administer. Documentum ECP enables new research to move forward without repeating the mistakes of the past.

EMC Documentum ECP—boosting innovation, mitigating risk

Documentum ECP helps life sciences companies meet the challenges of compliant information management through every link in the life sciences content value chain—from discovery and research to preclinical and clinical trials through manufacturing, sales, marketing, and customer service. It enables these companies to leverage information as a source of innovation while mitigating its potential to create legal and regulatory risk.

EMC Documentum enables hundreds of pharmaceutical, biotech, and medical device companies to:

- Enforce regulatory compliance mandates without reducing productivity or increasing time to market
- Leverage and reuse high-value information assets, such as clinical studies, label updates, marketing content, and consumer information
- Automate policy execution across all information types, minimizing human intervention
- Use a standards-based architecture to integrate with a multitude of enterprise platforms

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- Retain comprehensive audit trails for compliance and process optimization purposes
 - Access rich content management services within a secure, controlled environment
 - Combine structured business processes with dynamic collaborative activities

With Documentum they can effectively manage the critical information that speeds commercialization, accelerates product development, and streamlines business processes. To learn more about the Documentum Enterprise Compliance Platform for Life Sciences, and our technology partners whose application integrations provide a consistent way of exposing EMC Documentum functionality, please visit the Documentum ECP web page at http://software.emc.com/solutions/industry/life_sciences/enterprise_compliance_platform.htm