Documentum Solutions for Life Sciences

Speeding Products to Market While Ensuring Compliance

Meeting rigorous compliance requirements simply comes with the territory in the life sciences. So to prosper, companies must meet that obligation while constantly striving to shorten time to market. And the only way to achieve those dual, and often competing, goals is to manage information efficiently across the content value chain.

Documentum — Up to the Challenge

The content value chain describes how essential processes are related in an organization and how content moves and is used across those processes. And in every area of the life sciences content value chain, Documentum helps reduce costs, ensure compliance, streamline production, enable collaboration, and get products to market faster.

In fact, for every content management challenge a life sciences organization faces, Documentum provides a solution. And with our standards-based platform and world-class partner integrations, the opportunities to leverage Documentum throughout your organization are virtually unlimited. Documentum can help you exploit the natural relationships between content and processes that start in discovery and extend all the way to customer service — which means your business becomes more agile, more responsive, and more competitive.

On the following pages, we profile solutions that illustrate the varied ways in which Documentum is being used in every facet of the life sciences enterprise.
The longer it takes to approve a drug or medical device for sale, the more of its patent lifetime is wasted. With a blockbuster drug, you could be losing millions of dollars per day.

Documentum Solutions for Life Sciences Organizations

Documentum has more experience providing solutions across the life sciences content value chain than any other enterprise content management company. These solutions demonstrate the breadth of expertise Documentum can bring to the business of a life sciences organization.

**Discovery/Research**
- Electronic Notebook
- Strategic Planning
- Competitive Intelligence
- Lead Generation and Optimization
- Knowledge Management
- Collaboration
- Alliance Management
- In Licensing/Out Licensing

**Pre-Clinical**
- CRO Collaboration
- Test, Methods, Protocol Management
- Studies Management
- Regulatory Submission Management
- Knowledge Management
- Alliance Management
- SOP Management

**Clinical**
- Clinical Content Management
- Investigator Training and Communication
- Study/Protocol Management
- Regulatory Submission Management
- Clinical Records Management
- CRO Collaboration
- Case Report Form Management
- Safety and Adverse Events Management
- CRO Contract Management
- SOP Management

**Manufacturing**
- SOP Management
- GMP Content Management
- Batch Records Management
- Plant and Facility Management
- Label and Packaging Management
- Corrective/Preventative Action Management
- Training Records Management
- CMO Collaboration
- CMO Contract Management
- Knowledge Management

**Sales & Marketing**
- Promotional Material Management
- Medical Information Management
- Sales Training Content Management
- Drug Safety Management
- CRM Portals
- Sales Force Enablement
- SOP Management

**Customer Service**
- Product Specific Web Sites
- Disease Specific Web Sites
- Physician Portals
- Product Complaint Management
- eDetailing
- Web Site Management

Today, in life sciences, optimizing the content value chain takes on a unique dimension. Because there’s more at stake than efficiency, profits, or shareholder value. Life sciences companies provide therapies that bring hope to millions.
Drug discovery is where decisions are made that can affect the profitability of a company for years to come. It’s where scientists and researchers try to distinguish between dead ends and lucrative opportunities. And where knowledge sharing and collaboration are critical to determining which therapeutic areas and compounds receive necessary funding.

Solution: Knowledge Management and Collaboration

Boehringer Ingelheim Pharmaceuticals

“Documentum eRoom enables us to fully embrace our partners in the pursuit of better, more effective, and innovative pharmaceutical products and services.”

Dan Greenwood, Associate Director Knowledge Management, Boehringer Ingelheim Pharmaceuticals

The Boehringer Ingelheim group of companies is a global pharmaceutical enterprise that ranks among the top 20 in the world. As thousands of pharmaceutical candidates work their way through the design and delivery pipeline, internal project teams must work with a growing population of geographically dispersed partners.

Challenge

Implement a Web-based, knowledge-sharing tool to help Boehringer Ingelheim capture existing practices, work with teams to improve workflow, and implement a uniform process that supports effective collaboration between employees and business partners. Effective collaboration, particularly with external partners such as academics and other pharmaceutical companies, is essential to keeping the new drug pipeline full and speeding products to market. E-mail, fax, and traditional mail were not adequate to support the high-volume information exchange on which collaboration depends, and they carried inherent security risks.

Solution

Boehringer Ingelheim found the eRoom digital workplace to be ideal for its needs. Easy to learn and use, eRoom provides the collaborative platform the company required to rapidly assemble, support, and manage cross-organizational research and discovery teams and respond to the dynamic nature of their work. Plus, eRoom requires no client software, which is particularly important when bringing external partners online.

Results

At Boehringer Ingelheim, scientists, partners, project teams, support functions, and management use eRoom. Through its ability to capture organizational learning over an extended period of time, eRoom has enhanced Boehringer Ingelheim’s decision making, research processes, and work methods. The solution has broken down departmental and geographic boundaries and accelerated the free flow of information.

Recommended Product Suite

• Documentum Content Server
• Documentum eRoom
• Documentum eRoom Enterprise
• Documentum Content Intelligence Services
• Documentum Content Rendition Services
• Adobe Acrobat
Solution: Collaboration in Drug Innovation and Approval (DI&A)

Aventis

“Documentum eRoom facilitates global project team collaboration and speeds access to the relevant information, enabling better decisions to be made more effectively.”

Simon Marlow, Senior Director, Lead Generation, Drug Innovation and Approval, Aventis

Aventis is dedicated to discovering and developing innovative prescription drugs and human vaccines in areas such as cancer, diabetes, cardiovascular disease, asthma, and allergies. The company employs more than 70,000 people with facilities in France, Germany, and the United States. With groups of researchers and clinicians throughout the company working on therapeutic compounds, efficient collaboration is a necessity.

Challenge
Deploy a collaboration tool that enables accurate version tracking of project documents and the ability to aggregate all project content in a secure, digital work area.

Solution
Aventis deployed Documentum eRoom to help control and streamline the collaboration between chemists, biologists, toxicologists, and clinicians. Prior to the deployment of eRoom, collaborative work was done using e-mail. It was impossible to accurately track document versions and maintain project documents in a single secure area, accessible to everyone. eRoom enables the capture of virtual team meeting results, reports, presentations, and test data. Documents, such as new drug feasibility studies, which require collaborative review and editing, can be tightly controlled and managed. All content is seamlessly archived in the Documentum repository.

Results
Documentum eRoom facilitates global collaboration in Drug Innovation and Approval (DI&A), where finding the right information can prevent the necessity of repeating pre-clinical trials or laboratory tests, which take weeks to administer. It allows new projects to move forward without repeating the mistakes of the past. In the future, Aventis plans to leverage tighter integration between eRoom and the Documentum repository. This will allow more efficient project data mining across eRooms, which will increase the value of collaborative knowledge even further.

Recommended Product Suite
- Documentum Content Server
- Documentum eRoom
- Documentum eRoom Enterprise
- Documentum Content Intelligence Services
- Documentum Content Rendition Services
- Adobe Acrobat
Pre-clinical trials screen drugs to ensure their safety for human testing. Safety and toxicity studies demonstrate biocompatibility and identify safe dosage ranges for clinical trials. Leveraging existing research enables better go/no-go decisions in this phase, which can significantly lower the cost of development by eliminating lengthy clinical trials.

Solution: Electronic Notebooks

Berlex Laboratories

“Our global R&D information management system, based on the Documentum ECM platform, is on the cutting edge of electronic laboratory notebook solutions. When we show people the old lab notebooks compared to the quality of the information being captured by our scientists today, they are absolutely astonished.”

Charlie Sodano, Manager of Information Services, Berlex Laboratories

Berlex is committed to bringing to market beneficial preventive, diagnostic, and therapeutic medicines in the fields of dermatology, diagnostic imaging, female healthcare, therapeutics, and oncology. The company currently owns a significant share of the market for oral contraceptives. As a research-based company, Berlex considers intellectual property to be one of its most important assets.

Challenge
Create a paperless system for storing the knowledge contained in the handwritten notebooks of its research scientists. Make that information more easily accessible and retrievable, while ensuring its security.

Solution
Berlex deployed the Documentum ECM platform in 1997. Soon after, the company brought in Documentum Consulting to help develop and deploy an R&D information management system that would also accommodate the creation and archiving of paper documents.

The Documentum system enabled Berlex scientists to use Microsoft Word and Excel to log their research, which was stored on local servers and replicated to a central repository each night. Today, more than 800 scientists at facilities around the world use the Documentum solution, with more research facilities slated for deployment.

Results
Berlex can now leverage its intellectual property in ways that were impossible with a paper-based system. Research that is easily searched, retrieved, and shared retains its value far longer than information archived in traditional notebooks. The initial investment that produced the research can be extended to meet the demands of more projects and revenue-producing initiatives.

Recommended Product Suite
• Documentum Content Server
• Documentum Records Manager
• Documentum Content Rendition Services
• Documentum Trusted Content Services
• Documentum Content Services for EMC Centera
• Adobe Acrobat
By the time a new therapeutic compound reaches clinical trials, the investment in it is already substantial. So the stakes are high. And the amount of data generated is enormous. Trial data must be concise, accurate, and compliant with stringent regulatory standards.

Solution: Contracts Management

A Global Healthcare Company

“Thanks to Documentum we can generate and manage our clinical trial contracts with a flexible, customized Web application. Considering the amount of legal documentation associated with clinical trials, that’s a significant productivity gain for us.”

Legal Affairs Administrator, Clinical Trials Compliance

Challenge
Replace a paper-based system with an automated system that enables clinical trial contracts to be created dynamically with custom attributes supplied by the authors. Manage and archive the contracts in a central repository that is accessible through a Web browser. Use workflow to enforce compliance-based business rules through all stages of review and approval. Attach lifecycles to contracts to ensure they are retained as corporate records.

Solution
The company deployed a Documentum solution that enables legacy contracts to be scanned into a repository and indexed according to project number, investigator number, trial size, and project description. Contracts are stored as PDFs and can be annotated using Adobe Acrobat. New contracts are authored in Documentum using a custom template and are automatically indexed as they enter the repository. Once a new contract template is opened, it initiates a workflow that routes the document to each relevant party in sequence. Alerts notify downstream reviewers when a contract has been delayed upstream more than 48 hours.

The system archives the contracts, as well as their associated confidentiality forms, and is searchable by any attribute or annotation.

Results
This company generates thousands of contracts and hundreds of thousands of pages of supporting documents annually. The Documentum contracts management solution enables the company’s legal group to efficiently create, manage, and store this enormous volume while ensuring that all clinical trial contracts meet relevant legal guidelines. When litigation arises, counsel can access contractual information quickly from any company location. Contract authoring, review, and approval require a fraction of the time needed using the paper-based system, while an audit trail ensures which version of a contract governs a particular trial.

Recommended Product Suite
• Documentum Content Server
• Documentum Content Rendition Services
• Captiva InputAccel
• Adobe Acrobat

This company specializes in the discovery, development, and manufacture of ophthalmic products and instrumentation. Managing contractual agreements that define and govern clinical trials is essential to the company’s product development process.
Allergan is a technology-driven, global health care company that develops and commercializes specialty pharmaceutical products for the eye care, neuromodulator, and skin care markets. To maximize product revenue while meeting FDA requirements, the company must accelerate the new drug approval process, which requires the aggregation and efficient management of enormous amounts of internal content related to new drug applications (NDAs).

Solution: Regulatory Submissions — Electronic Review and Approval

Allergan

“With Documentum, we can manage nearly 5 million pages of NDA documentation electronically, with increased speed, greater accuracy, and less cost. That means a new drug hits the shelf sooner and sells under patent longer.”

Jeff Kouba, Director, R&D Scientific Information Services, Allergan

Challenge

Securely and efficiently control the flow of NDA-related content, enable accurate versioning, authorize and verify recipients, and track changes involved for electronic submission to, and compliance with, regulatory agencies. Ensure that each document in a submission is the correct document.

Solution

Allergan had used Documentum since 1996, but originally as a document repository only. To streamline the company’s NDA submissions process and ensure its accuracy and compliance, Allergan deployed a fully controlled environment based on Documentum workflow and lifecycle management. The solution unites the 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. Documentum enables electronic submissions to the FDA, fully supports 21 CFR Part 11, and produces a complete audit trail, effectively extending the content value chain to include regulatory agencies.

Results

A typical NDA submission is nearly one million pages, including summary and clinical study reports. Allergan’s ability to compile and submit these applications electronically, and ensure that each one of the pages is approved and accurate, means its 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 Documentum solution at Allergan is used worldwide, enabling pending submissions to be reviewed simultaneously at sites in France, Japan, England, and the U.S., further accelerating the process. For Allergan, a faster, more accurate NDA submissions process translates to a sustainable competitive advantage.

Recommended Product Suite

- Documentum Content Server
- Documentum Content Rendition Services
- Documentum Compliance Manager
- Adobe Acrobat
Whether outsourced or in-house, pharmaceutical manufacturing must be tightly controlled and extremely efficient in order to meet production goals, minimize waste, and satisfy regulatory requirements. Good manufacturing practice (GMP) demands accurate information, precise specifications, and comprehensive records management.

Solution: SOP Management

**OSI Pharmaceuticals**

“Our Documentum SOP management solution slashed the review and approval process from 5 weeks to 3 days. That means QA, clinical, and validation processes aren’t interrupted waiting for an approved SOP.”

Jessica LeFur, Director, Document Management & Planning, OSI Pharmaceuticals

**Challenge**

Develop an electronic system for creating and managing SOPs that would ensure access from any of OSI’s three locations in New York, Colorado, and the UK. Reduce the cycle time for SOPs and ensure the accuracy of SOPs across functional areas.

**Solution**

OSI deployed the Documentum SOP management solution to gain streamlined review and approval; faster, more efficient access and distribution; and increased accuracy, global consistency, and regulatory compliance. With Documentum, electronic review and approval of a final SOP can take just 3 days — instead of 5 weeks using the old system. Once an SOP has been approved and certified with a digital signature, it cannot be changed without entering a formal workflow process.

**Results**

Streamlined SOP management means a reduction in the time and expense of rework. For example, if an SOP for clinical protocol writing is changed and delayed in review, an in-process protocol may have to be redone once the SOP has been approved. Through accelerated review and approval and tight version control, Documentum ensures that the distributed version of an SOP is the most recent and accurate. The Documentum repository also enables authorized access to all SOPs from any location.

**Recommended Product Suite**

- Documentum Content Server
- Documentum Compliance Manager
- Documentum Content Rendition Services
- Documentum Trusted Content Services
- GXPharma
- Adobe Acrobat
Influencing medical professionals and gaining consumer acceptance for new drugs are the top priorities of pharmaceutical sales and marketing. Targeting the right audience with the right information can mean gaining market share before competing products hit the shelves.

Solution: Web Content Management

**AstraZeneca**

“Documentum Web Publisher has enabled us to cut the cost of developing new Web sites by two-thirds. And keeping Web content fresh and accurate is quick and easy, too.”

*Stephen Taylor, Business Project Manager, AstraZeneca*

AstraZeneca is a major international healthcare enterprise engaged in the research, development, manufacturing, and marketing of prescription pharmaceuticals and the supply of healthcare services. To inform and assist employees, partners, and customers, the company has approximately 1,300 internal and external Web sites in multiple languages.

**Challenge**

Eliminate the “Webmaster bottleneck” and reduce the time needed to publish content to the Web. Empower business content owners to publish on their own while ensuring content accuracy and meeting compliance requirements. Reduce the cost of Web development to make short-term micro sites economically justifiable.

**Solution**

Documentum Consulting and an AstraZeneca project team delivered an XML-based, Web development infrastructure for quickly and easily creating Web sites. Their solution featured a generic set of XML templates, reusable lifecycles and workflows, defined business rules, updatable menus, and 24x7 support. Workflow automatically routes Web content through proper approvals in an auditable process, which increases content accuracy and diminishes legal liability. Now, publishing trusted content to the Web can be done in a matter of seconds, with no IT involvement required.

**Results**

Documentum dramatically reduced the cost of Web development from $75,000 per site to $25,000. At the same time, publishing speed increased and accuracy improved, while Webmasters were freed to focus on more value-added projects.

**Recommended Product Suite**

- Documentum Content Server
- Documentum Web Publisher
- Documentum Consulting
- Extensible Template Editor
- Documentum Site Navigation Editor
- Documentum Media Services
Solution: Marketing Content Management

CommonHealth

“We selected Documentum as our infrastructure for rich media assets and related content based on its market leadership, support for Mac environments, and strong base of existing life sciences customers. Documentum has worked with us to realize new levels of operational efficiency.”

Craig A. Cuyar, PhD, Senior Vice President & Group Chief Information Officer, CommonHealth

Challenge

The clients of CommonHealth need to distribute materials globally, maintain a consistent brand image, and reduce the costs of product marketing. Yet few have invested in automating their collateral production process. CommonHealth found that there were significant obstacles to efficient and cost-effective production, such as client/advertising agency interaction, last-minute changes, dissemination and review of comps, media production and courier expense, and the inability to verify usage rights. The result of all these factors, besides increased cost and time to market, was the frequent use of unapproved brand collateral.

Solution

CommonHealth created and deployed Synthesis, a Documentum-based solution that offers clients a way to streamline collateral production and revolutionize the agency/client business model. Phase one of Synthesis automates the traditional process pharmaceutical brand teams use for creating, approving, and distributing collateral. Subsequent phases will leverage additional Documentum functionality such as the eRoom collaboration platform, job-based lifecycles, inter-enterprise workflow, and asset distribution to other Documentum systems.

Using the Documentum ECM platform, Digital Asset Manager (DAM), and Media Services, Synthesis utilizes workflow to assure quality control for all electronic releases, enables the preparation of content to precise specifications, and electronically releases project files to vendors and clients.

Results

For two clients using Synthesis, CommonHealth sees potential ROI of over 300 percent, with a payback of less than one year. Synthesis virtually eliminates the time and expense of producing media and shipping comps and at the same time improves agency/client communication. It compresses the review cycle while accommodating up-to-the-minute revisions and making them available online. With centralized access to marketing content, clients using Synthesis are also able to improve the consistency of brand presentation.

Recommended Product Suite

• Documentum Content Server
• Documentum Digital Asset Manager
• Documentum Media Services
• Documentum Desktop for Macintosh
• Documentum eRoom Enterprise
• Documentum Authoring Integration Services
To ensure customer satisfaction, life sciences companies must focus on the speed, accuracy, and efficiency of their response times. They need to communicate effectively with customers who have varied needs throughout a product’s lifecycle, including those who participate in clinical trials. Customer service touch points can also provide valuable feedback for sales and marketing.

Solution: Call Center Support

Takeda Pharmaceuticals North America

“Documentum makes our call center much more efficient at fulfilling responses to customer inquiries. Plus, it enables that efficiency while giving agents increased flexibility in assembling custom packages that have a more personal feel.”

Andrea Kozak, Technical Project Manager for Regulated Systems, Takeda Pharmaceuticals North America

Headquartered in Lincolnshire, Illinois, Takeda Pharmaceuticals North America, Inc. (TPNA) is a wholly owned U.S. subsidiary of Takeda Chemical Industries, Ltd., Japan’s largest pharmaceutical company. With a foundation built on ACTOS, its successful type-2 diabetes medicine, as well as a robust, early-stage pipeline, Takeda is poised to become a world-class pharmaceutical company. As TPNA builds its reputation with physicians, pharmacists, and consumers, a responsive customer service call center is a competitive necessity.

Challenge

The majority of calls that come in to Takeda’s customer service center require a written response consisting of a cover letter and a variety of enclosures such as journal articles, product literature, and package inserts. Between 1,200 to 1,500 calls per month require a written response. Service agents needed to access relevant content through their Siebel call center application in order to make fulfillment less labor intensive and time consuming. With Takeda’s call center located in North Carolina and the head office in Illinois, maintaining information consistency was also difficult.

Solution

Takeda deployed an automated call center fulfillment system based on Documentum. The Documentum repository stores cover letter templates as XML components, issue-specific customer responses, and all supporting collateral, which is fully accessible to service agents through the Documentum integration with Siebel. When a customer call initiates a new case in Siebel, it also launches a “package wizard.” With the wizard, an agent can assemble and print a complete customer response package that includes a custom cover letter. All package components have workflow and lifecycles attached to ensure that only approved, accurate content is used. Response packages are compiled using Documentum virtual document management (VDM) technology. Each package rendition is stored as a PDF and automatically linked to its virtual document.

Results

With Documentum, information transfer between call center and home office is immediate. Agents can fulfill packages more quickly and, using XML, deliver customized packages with personalized cover letters. VDM enables efficient content reuse, while workflow and lifecycle management make the entire fulfillment process completely auditable. Documentum also stores all verbal responses to customer inquiries. Takeda expects the Documentum system to be crucial in handling increased call volume during product launches.

Recommended Product Suite

• Documentum Content Server
• Documentum Content Rendition Services
• Documentum Content Services for Siebel
• Adobe Acrobat
Documentum — The Solution of Choice for Life Sciences

The top 25 pharmaceutical companies in the world are Documentum customers and more than 200 life sciences companies employ Documentum solutions. To learn how Documentum can deliver improved business performance to your life sciences organization, visit us online at www.documentum.com/industry/life_sciences or call 800.607.9546.

About Documentum

Documentum, a division of EMC Corporation, provides enterprise content management solutions that enable organizations to unite teams, content, and associated business processes. Documentum’s integrated set of content, compliance, and collaboration solutions support the way people work, from initial discussion and planning through design, production, marketing, sales, service, and corporate administration. With a single platform, Documentum enables people to collaboratively create, manage, deliver, and archive the content that drives business operations, from documents and discussions to e-mail, Web pages, records, and rich media. The Documentum platform makes it possible for companies to distribute all of this content in multiple languages, across internal and external systems, applications, and user communities. As a result, Documentum customers, which include thousands of the world’s most successful organizations, harness corporate knowledge, accelerate time to market, increase customer satisfaction, enhance supply chain efficiencies, and reduce operating costs, improving their overall competitive advantage.

A Partial List of Documentum Customers in Life Sciences

Aventis
MedImmune
Novo Nordisk A/S
Roche
Biogen Idec
Boots Healthcare
Bristol-Myers Squibb Company
Boehringer Ingelheim
Millennium Pharmaceuticals
Daiichi Pharmaceutical
Celitech Group
Beaufour IPSEN
Aiza Nobel
Schering AG
Johnson & Johnson
Aiza Corporation

Pfizer
Guidant
Baxter Healthcare Corporation
Otsuka Pharmaceuticals
Vertex Pharmaceuticals
OSI Pharmaceuticals
Chugai Pharmaceutical
Serono International SA
Shionogi & Co.
Forest Laboratories
King Pharmaceuticals
Covance
Bracco SpA.
AstraZeneca
Novartis
FDA

Abbott Laboratories
Purdue Pharma
Sankyo
Berlex Laboratories
CommonHealth
Alcon Laboratories
Human Genome Services
Yamanouchi Pharmaceutical
Wyeth Pharmaceuticals
Takeda Pharmaceuticals
North America
Allegan
Solvay S.A.
Bayer AG
Schering Plough
Sanofi-Synthelabo

© 2004 Documentum, a division of EMC Corporation. All rights reserved. Documentum and the Documentum logo are the trademarks or registered trademarks of EMC Corporation in the United States and throughout the world. All other company and product names are used for identification purposes only and may be trademarks of their respective owners. Documentum cannot guarantee completion of any future products or product features mentioned in this document, and no reliance should be placed on their availability. Printed in the U.S.A.