Speed time to market with Adobe and EMC Documentum

Life sciences companies improve R&D and manufacturing processes, reduce operational expenses, and meet compliance requirements with interactive, intelligent forms

Forms and documents play a critical role in the drug and medical device development lifecycle. From collecting clinical trial data to collaborating on product specifications to submitting documentation to the Federal Drug Administration (FDA), documents are the primary communication vehicle between every stage—and every participant—in the lifecycle. But the manual processing of documents and forms hinders the ability of pharmaceutical and biomedical device manufacturers to get new products to market quickly, affecting their competitive advantage and cutting into bottom-line profitability.

Extend the value of enterprise content management (ECM)
By automating forms-driven and collaborative processes built on your Documentum ECM platform, you can bring new drugs and medical devices to market faster by streamlining R&D and manufacturing processes. Reduce operational expenses by improving secure collaboration among sponsors, investigators, and subjects. Meet compliance requirements by improving the accuracy of clinical trial data.

Combining the benefits of PDF and XML, Adobe® LiveCycle Forms™ for Documentum enables you to integrate captured data with the other content and documents housed in your ECM repository, providing a unified, protect environment for managing your company's information assets. Built on J2EE and XML, Adobe LiveCycle Forms for Documentum® is easily integrated into enterprise infrastructures through Java™ APIs and support for web services.

"Electronic submissions enable our agency to handle more information faster, streamline internal operations, and improve our service to stakeholders. Sponsors can save considerable time and money as well, ultimately improving revenue and time-to-market for products."

— Michael Fauntleroy
Director of Electronic Submissions,
FDA, Center for Biologics Evaluation and Research

Automate forms-driven processes for improved data accuracy and timeliness

COMMON LIFE SCIENCES FORMS

Research and development
- Investigator and patient enrollment
- New drug protocol
- Case report forms (CRF)

Manufacturing
- Engineering change orders
- Batch record
- Quality survey

Sales and marketing
- Trip report
- Sample drop
- Promotional material tracking

Regulatory submissions requirements
- Investigational new drug application (INDA)
- New drug application (NDA)
- Electronic common technical document (eCTD)

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- Links content and business processes with workflows
- Unites teams
- Provides unmatched scalability, reliability, and extensibility
- Enables rapid deployment and ease of use

The Best of Both Solutions

Adobe

- Eliminates inefficient manual work-arounds
- Extends forms processes beyond the firewall with free Adobe Reader®
- Improves quality and timeliness of business-critical data
- Offers standards-based solution that leverages Adobe PDF and XML

EMC Documentum and Adobe

- Increases return on investment in Documentum ECM platform
- Cuts costs by simplifying the design and management of forms for deployment in PDF and HTML
- Optimizes productivity by providing a single working environment for forms and other types of content
- Broadens and extends the reach of your processes across multiple systems and devices

Leverage data within and beyond your organization

By integrating Adobe forms with the Documentum ECM platform, your data works harder than ever.

- Deploy a single system for creating, managing, and deploying company-wide content, including electronic forms.
- Standardize both structured and unstructured content in the reliable and familiar Adobe PDF.
- Integrate captured XML data with other core applications and use the data to guide business processes.

Protect intellectual property and confidential subject data

With support for digital signatures and standard PKI technologies, Adobe PDF documents provide multiple levels of document security.

- Validate document authenticity and integrity, and approve round-trip processes with digital signatures.
- Enforce EMC Documentum's security model with enhanced document controls that protect confidential information, such as intellectual property and subject or patient data.
- Maintain document security throughout a form's lifecycle, even when it leaves the company's network.

Comply with regulatory requirements

Enhancing ECM processes with automated, interactive Adobe PDF forms makes it easier to adhere to stringent FDA guidelines.

- Easily design forms that replicate paper versions.
- Track forms-related events in the Documentum ECM repository.
- Create records of form templates and form submissions in accordance with records management regulations.

Adobe

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Streamline collaborative processes across the enterprise

The Adobe and Documentum integrated solution provides drug and medical device manufacturers a more secure, reliable, and efficient way to manage documents and facilitate collaboration among all participants in the drug and device development lifecycle. By using Adobe Acrobat® and PDF Annotation Services, sponsors, investigators, and clinical trial subjects can easily add comments to documents in parallel—without compromising the integrity of the original documents. This significantly streamlines the review process and reduces the time required to make informed decisions.

Increase productivity

- View and annotate electronic documents in parallel.
- Respond to comments in real time.
- Support reviewers inside and outside the enterprise.

Improve compliance

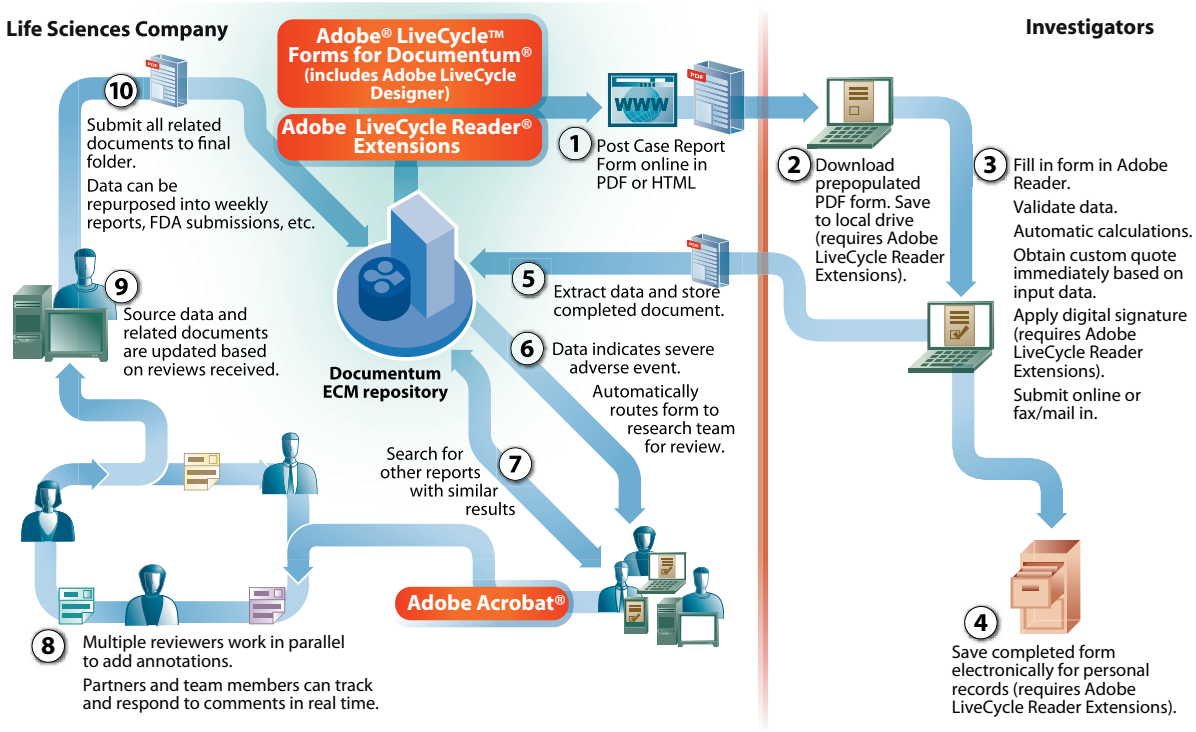
- Create detailed audit records to meet regulatory requirements.
- Separate and save annotations from each document version.
- Improve access and retrieval within the Documentum ECM environment.

Reduce risk

- Provide easy accessibility with appropriate authorizations.
- Preserve document integrity by tracking comments in a separate file.
- Allow viewing, copying, modifying, or printing by users only as needed.

Leverage standard Adobe PDF

- Easily exchange documents with research and development team members
- Generate Adobe PDF from virtually any native application.
- Ensure exceptionally reliable fidelity and quality.



The integrated forms solution from Adobe Systems and EMC Documentum simplifies the process of filling out and submitting case report forms (CRFs). Investigators can obtain prepopulated forms that replicate paper versions and fill them in offline at their convenience. Partners and team members can work in parallel to add annotations. Once submitted, the data is automatically integrated into the Documentum ECM repository and other enterprise applications, minimizing delays and errors. The captured data can then initiate other processes. For example, reports that indicate severe adverse events can be immediately routed to the research team to review. Comments can be exchanged in real time, enabling the team to gain greater insight into the drug's safety and efficiency. Throughout the process, data integrity is preserved, patient information and corporate intellectual property are secured, and records are archived in accordance with key records management regulations.

The Adobe PDF advantage

From PCs to PDAs, Adobe PDF files preserve the look and integrity of your original documents. Plus you can share them with anyone electronically, regardless of hardware or software platforms.

Adobe and EMC Documentum

The Adobe® Intelligent Document Platform bridges the digital and paper worlds. By leveraging the global acceptance of PDF and XML, documents become instantly smarter, with information traveling where it's needed, as it's needed, more simply and securely than ever before.

As the leader in enterprise content management, EMC Documentum provides a common content platform and repository that enables people to collaboratively create, manage, deliver, and archive the content that supports the way people work.

FOR MORE INFORMATION

To find out more about how your company can benefit from the combined forms and collaborative solutions from Adobe and Documentum, please visit *www.adobe.com/documentum* or *www.documentum.com/adobe*.

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