# EMC DOCUMENTUM FOR LIFE SCIENCES SOLUTION SUITE

## Unified Processes, Seamless Information Sharing Across the Extended Enterprise

The life sciences industry is in a state of flux. Against the backdrop of patent losses and pressure to accelerate time-to-market for new medicines, today's business realities and governmental reform are driving new models of healthcare. These new models demand lower costs and emphasize positive, measurable outcomes and patient well-being.

Life sciences organizations are tasked with thinking outside the box to find ways to identify, prioritize and develop promising therapies more quickly; to leverage their existing (and rapidly growing) data to derive meaningful insight; and to maximize efficiency across the full drug lifecycle. Bringing safe, high-quality drugs to market faster at a lower cost requires unifying processes that extend across domains, divisions and external partners. It requires the ability to link and seamlessly share documentation—the critical element inherent throughout the drug lifecycle. In short, it requires a business transformation that parallels the radical changes in the industry.

## EFFICIENCY IMPROVEMENTS VIA PURPOSE-BUILT SOLUTIONS

With over 25 years of experience in life sciences, EMC has over time developed and continuously improved upon a suite of comprehensive purpose-built solutions, leveraging industry guidance and best practices to meet these challenges head on. The EMC® Documentum® for Life Sciences solution suite breaks down information silos to transform how organizations access, manage and share regulated content. Available on premise or in the cloud, the solution suite is designed to offer you choice and flexibility with the ultimate goal of unifying and streamlining processes while reducing complexity.

The EMC Documentum for Life Sciences solution suite, built on the industry's leading content management platform, harnesses an information architecture based on the Drug Information Association (DIA) Electronic Document Management (EDM) and Trial Master File (TMF) Reference Models. The fully integrated suite of configurable solutions includes the following:

- **Documentum Electronic Trial Master File:**
  *Effectively plan, collect, track and maintain essential GCP-compliant clinical trial documentation*

- **Documentum Research and Development:**
  *Manage the creation, review and approval of regulatory submission documentation*

- **Documentum Submission Store and View:**
  *Simplify the search and retrieval of archived submissions and associated correspondence, while improving security and compliance*

- **Documentum Quality and Manufacturing:**
  *Control quality and manufacturing documents, automate workflows and ensure GMP compliance*

## SEAMLESS CONTENT SHARING AND A SINGLE AUTHORITATIVE SOURCE

Why introduce unnecessary complexity, inaccuracies and risk to business processes by exporting and importing content from one system to another?

The EMC Documentum for Life Sciences solution suite provides a single authoritative source for regulated content across the extended life sciences organization. Clinical documents that must be included in regulatory submissions can be linked to both clinical and regulatory stakeholders. Similarly, relationships can be created between Quality and Regulatory documentation to enable stakeholders to conduct quick impact assessments when a change is required. This capability, when combined with mobile and cloud options, provides ubiquitous access, an intuitive user experience, and efficient and compliant business processes.

## MOBILE: AUDITABLE ACTIONS JUST A SWIPE AWAY

The EMC Documentum for Life Sciences solution suite provides role-based, personalized views within each of its solutions to enable workers to simply and efficiently complete their routine tasks. Users can expect an intuitive, personalized experience; power users need not apply. And they can enjoy easy-to-use, consumer-like mobile applications on their phones and tablets to ensure that work continues even when they're on the go.

Whether you're a clinical investigator needing to capture required documentation at a site, a regulatory operations worker needing to approve a document, or a quality manager needing to distribute SOPs as part of a "To Be Read and Understood" process, the suite's mobile capabilities enable access and continuous workflows from your desk, phone or tablet. And with watermark support and rights management capabilities, control over distribution and use of the content has never been stronger.

## SOLUTIONS DELIVERED YOUR WAY—IN THE CLOUD OR ON PREMISE

Today's life sciences organizations need to maximize their resources and budgets in a way that enables innovation, seamless business processes and quick responses to changing business needs, while ensuring that their security, privacy and control requirements are met. Whether you are deploying in the cloud or on premise, there is no one-size-fits-all best fit. With a comprehensive portfolio of services that offer flexibility, agility and security, we deliver solutions *your* way to meet *your* specific needs—private, public, hybrid cloud or traditional on premise.

## SPECIALIZED VALIDATION, MIGRATION AND CONSULTING EXPERTISE

Especially because of the mergers and acquisitions so prevalent in the industry today, many organizations find themselves trying to maintain multiple content management systems that are often highly customized and function as silos. As you move to today's configurable, user-friendly solutions and leave operational complexity behind, EMC Services has the tools and industry expertise you need to ensure low-risk migrations, expert validation and comprehensive training.

The EMC Validation Package is a set of Life Sciences solution suite documentation templates, created to support the validation efforts of a computerized system, based on GAMP compliance. It is designed to help you jump start your validation activities and reduce overall validation effort. For cloud deployments, EMC provides a qualified EMC cloud environment that is compliant with regulatory requirements and is supported by the EMC Cloud Deployment Experts. An EMC Validation Template Package is also available for on premise deployments.

Unique tools for migration of data enable you to consolidate multiple systems, migrating both structured and unstructured information into a single, unified, accessible repository. With self-service and fully-delivered options, these tools are designed to expedite large-volume data transfer with minimal downtime and maximum data integrity—whether migrating in the cloud or on premise. And you can free up budget on maintenance and storage by decommissioning legacy applications while still retaining historic content such as testing and patient data in a live archive.

## A STRATEGIC PARTNER TO ENSURE YOUR SUCCESS

As life sciences companies transform, they require a partner that can address pressing needs and support a long-term vision. As digital officers and enterprise architects look at new business models built around effective, personalized and predictive medicines and healthcare, they need a partner that can deliver the complete content solution. The Life Sciences organization at EMC leverages the entire EMC portfolio of offerings, including records management, analytics, archiving and more. Our solutions are designed to provide flexibility and scalability as your organizational needs evolve.

## INCREASED VALUE WITH CERTIFIED PARTNER SOLUTIONS

The drug lifecycle is long, complex and often involves numerous systems that must work together to share complete, accurate and compliant documentation. Our partner-built solutions transform critical life sciences business processes and have been validated by EMC Proven Professional Certified Architects to achieve the EMC Certified designation. These solutions extend the value of EMC Documentum and our life sciences solutions to reduce risk, drive faster time-to-value and deliver a high level of confidence.

## GET STARTED TODAY

Now, with the EMC Documentum for Life Sciences solution suite, you are embracing the future with unprecedented efficiency, agility, document control and compliance that's key to getting products to market ahead of the competition. To learn more, visit us at http://www.emc.com/documentumforlifesciences.

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