



EMC Solutions for Life Sciences

Accelerating discovery and
development with an intelligent
information infrastructure



When information comes together,
your world moves ahead.



Drug Discovery and Development
Clinical Trials
Regulatory Approval
Manufacturing and Operations
Sales and Marketing
Customer Service

Today's life sciences organizations are confronting new challenges in every aspect of their business—from increasing competition and tougher regulations to slowing product pipelines with the need for greater operational efficiencies. These powerful industry dynamics highlight the importance of *intelligent* information infrastructure investments to help manage information, meet compliance requirements, and create greater R&D productivity.

When information comes together, breakthroughs are discovered faster

Over the past few decades, life sciences organizations have pushed the scientific envelope as they have developed new therapeutics, medical devices, and procedures to advance the treatment of disease. At the same time, clinical trials failure rates remain high and increasing industry regulations are adding to the time and cost of new drug and medical device development.

One strategy to address these market challenges is to deploy more innovative methodologies in how research and clinical trials are conducted. But a focus only on research innovation will not succeed in meeting today's challenges without new and innovative ways to apply technologies.

EMC is in the business of helping life sciences enterprises be more successful. We do this by focusing on the "I" in IT—information. We help you maximize the value of your information assets, improve service levels, react quickly to changes, and protect your information from loss and unauthorized use. And we do this by providing intelligent, flexible, software-enabled information infrastructure.

Reduce complexity, increase productivity

EMC helps life sciences organizations reduce the complexity of IT environments and ensure continuous uptime for your most critical research, clinical trials, manufacturing, and business applications. We enable your organization to better comply with regulations, including FDA GxP, 21 CFR Part 11, HIPAA, Sarbanes-Oxley, and others. Our solutions help provide security controls to prevent unauthorized access to electronic records, and offer computer-generated, time-stamped audit trails and ready retrieval of records throughout their retention periods to provide reasonable and useful access for regulatory inspectors.

An EMC® intelligent information infrastructure protects the confidentiality, integrity, and availability of your valuable intellectual property—while managing the explosion of information experienced today. We accomplish this by combining best-of-breed platforms, software, and services into high-value, low-risk solutions that solve information management challenges—such as compliance, content management, business continuance, backup, recovery, archiving, and consolidation. For small and medium-size biotechnology, medical devices, and pharmaceutical organizations, we offer storage solutions that are simple, economical, and easy to acquire and deploy.



Information lifecycle management addresses the changing value of information over time

EMC treats information as active and changing, with a lifecycle that can span years, even decades, during which its value fluctuates. To put information to productive use and harness its full power, life sciences organizations of all sizes need to store, protect, move, manage, archive, search, recover, publish, share, access, and delete their information, on their schedule, exactly as needed.

An information lifecycle management (ILM) strategy helps life sciences organizations get the most value possible from their information, for the lowest cost, at every point in the lifecycle of that information. Today's urgent e-mail regarding a drug's adverse effect is more important than last year's staff memo. Over time, the value of information may increase or decrease. It may need to be retained until your organization is ready to file that latest New Drug Application (NDA). An urgent e-mail may become a critical element for legal discovery. Based on its changing value to your organization, your information requires different levels of accessibility and protection.

Putting your information to productive use

The stakes are high for drug development where only one of every 10,000 potential drugs investigated makes it through the R&D pipeline and is approved for patient use. Shrinking any one of the phases in the drug development value chain—research, clinical trials, approval, manufacturing, or marketing and sales—can result in winning the race to patent a new drug, resulting in a patent-protected revenue stream and obvious competitive advantage.

An EMC information infrastructure can help streamline the drug discovery process, facilitate collaboration among researchers, protect against data loss, and ensure compliance with regulations. With EMC hardware, software, and services, time-to-revenue is accelerated as information is moved from the lab to patients. Information and storage management tools enable the electronic capture of laboratory data to speed the analysis and drug discovery process by accelerating “time-to-failure.” By leveraging EMC storage management software, users can manage, archive, publish, and share data on clinical trials, adverse effects, and submissions securely across multiple locations.

Trust the expertise of the information lifecycle management leader

EMC leads the way with comprehensive ILM solutions for the life sciences industry. We're helping clinical research organizations, regulatory bodies, pharmaceutical, medical devices, and biotechnology companies around the world turn ILM from vision into day-to-day reality, providing the speed and flexibility needed to compete.



Life sciences solutions streamline and secure information flow from drug discovery to patient care

Research and Development

EMC supports life sciences R&D by providing a flexible, secure, powerful and automated information infrastructure essential to speed processes governing research and clinical trials while reducing cost and complexity. Such an infrastructure can protect information assets and intellectual property and create an enterprise-wide repository that can share research and clinical trials data electronically. It can also make this information available to authorized personnel, allow for electronic submissions of New Drug Applications (NDAs) and Electronic Common Technical Documents (eCTDs), and archive information to meet regulatory requirements.

The EMC® Documentum® platform for content and document management provides life sciences enterprises with a secure foundation for enabling regulatory compliance, federated repositories can be distributed globally but administered locally, with a global platform that accommodates local language, culture and currency, streamlined Web content management, and native XML functionality for accelerated content reuse.



High-performance computing

EMC solutions for life sciences high-performance computing (HPC) environments provide researchers, biologists, and scientists with a flexible environment to analyze, organize, store, protect, and manage complex data. Molecular, cellular, and medical imaging analysis is further enhanced as new data is created in the multiple gigabytes-per-second range. EMC HPC solutions integrate NAS and SAN-based tiered, network storage platforms, software, and professional services with clustered file systems and computationally intensive applications.

Automated compliance for quality assurance and quality control

Life sciences laboratory operations continue to rely on costly, paper-based “systems” subject to human error and requiring constant checking and verification. Success can be limited by the time and resources required to meet compliance regulations, where an estimated 70 percent of laboratory resources in GMP operations are now dedicated. In conjunction with an automated compliance application provider, EMC offers Quality Assurance (QA) and Quality Control (QC) Solutions that enable researchers, analysts, chemists, and operators to interact with digitized Standard Operating Procedures (SOPs). Through a PC or handheld tablet PC, the solution creates a data entry and capture environment—either manually or automatically—from laboratory test instruments and stores that information in the EMC information infrastructure.

Manage Regulatory Submissions

With a typical New Drug Application (NDA) submission incorporating over one million pages of content, life sciences companies often experience lengthy approval delays in bringing new therapeutics to market. The EMC Documentum Submission Manager Solution for regulatory submissions helps life sciences organizations speed new drug applications while also meeting compliance requirements. It is designed to streamline and support the regulatory submissions process for the

Electronic Common Technical Document (eCTD) standard that harmonizes the exchange of regulatory data between pharmaceutical companies and regulatory agencies around the world—including the FDA, EMEA, and Japan Ministry of Health.

Manufacturing and Operations

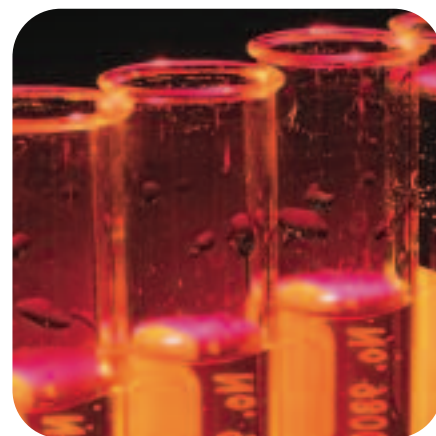
To comply with Good Manufacturing Practices (GMPs), regulatory bodies demand accurate information, precise specifications, and comprehensive records management. EMC offers a range of manufacturing solutions that maximize the value of your investments in manufacturing execution systems, calibration management systems, and enterprise resource planning.

Enterprise resource planning

EMC Automated BRBackup Replication for SAP eliminates the need to maintain complex, custom scripts to achieve split-mirror functionality—or experience the effects of backup-related errors and performance degradation. The EMC Automated BRBackup Replication for SAP combines EMC Replication Manager software with best practices and expert services to automate the SAP BRBackup replication of SAP production data. This, in turn, provides increased system availability, lower management costs, and reduced operational risk.

EMC Archiving for SAP with Documentum allows life sciences organizations to archive inactive data from mission-critical production systems and storage to more cost-effective, online storage systems, and is essential for sustaining an optimized environment.

EMC Replication Accelerator for SAP Productivity automates the creation of SAP database copies to support parallel business activities—including BW loads, reporting, testing, and other tasks. BASIS administrators and database administrators (DBAs) can non-disruptively create full copies of SAP production databases on demand, from their desktops, with a single mouse-click.



Marketing and Sales

To ensure both patient and consumer 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 or are prescribed medications through their physicians. Customer service touch points can also provide valuable feedback for sales and marketing for product enhancements.

Web content management and portals

EMC Documentum delivers solutions that manage the content and structure of websites and portals, including the framework and navigation, and the creation, editing, approval, and publication processes. These tools vastly simplify the task of managing a global Web presence, and enable better alignment with key business objectives with all Web properties. Built on top of the EMC Documentum enterprise content management platform, this solution offers unique capabilities to create, manage, and publish website and portal content.

Data mining

Life sciences organizations have begun deploying grid technology to “mine” large quantities of end-user customer relationship management (CRM) information to create “one-to-one” marketing campaigns. This sophisticated use of information to dramatically change the way pharmaceuticals are promoted is now being facilitated by technology and distribution partnerships between industry-leading grid technology providers and EMC with its portfolio of storage, information management, and resource management solutions.

Controlling explosive data growth

Managing large and growing amounts of structured data, such as sales or marketing databases, presents life sciences companies with cost and complexity challenges that EMC can help address. The EMC DatabaseXtender™ Accelerator for Oracle E-Business Suite—from EMC Services and Oracle Consulting—helps life sciences companies streamline their production application environment and control explosive data growth by relocating inactive transactional data from mission-critical production systems and storage to more cost-effective, online storage systems. The solution includes assessment and implementation for the EMC DatabaseXtender software family—based on fully documented and proven best practices for faster, more predictable results.

Enable Compliance, Minimize Legal Risk, Reduce Costs

With EMC storage and content management software, life sciences organizations can simplify and automate their most critical challenges—from server and storage consolidation, compliance, network and resource management, to security, backup, recovery, and archiving.

Compliance means not only following the rules, but also being able to prove it. With more than 20,000 regulations around the world governing the use of information, life sciences companies want to invest in infrastructures that automate compliance with state, federal, country, and FDA GxP regulations.

EMC's ILM approach to compliance allows your organization to index and classify your information, record level access for precise searching, automate policies for retention and deletion, and provide the flexibility to store information and move it around as regulatory needs demand. By approaching compliance as part of an ILM strategy, your organization can both build an information infrastructure and deploy best practices that deliver information integrity, confidentiality, and accessibility.

EMC eDiscovery solutions: proactive legal discovery and compliance

Regulatory investigations often require life sciences organization to incur great expense in producing relevant electronic records on a timely basis. Although electronic data comprises nearly 90 percent of business records, almost half of all corporate records management programs today fail to include electronic records. The EMC eDiscovery Solution provides a single, secure, centrally managed archive, plus automated e-mail capture and federated search capability, that eliminates the need to locate, mount, and search through records from backup tapes. This solution also enforces "legal hold" by importing litigation-relevant content into the solution's matter management application, where retention policies specific to the legal matter are applied.

Maximize Availability and Performance of Mission-Critical IT Resources

Life sciences companies today, both large and small, struggle with outdated or ineffective backup and recovery processes as complex research informa-

tion continues to grow rapidly. EMC's approach to ensuring continuous information availability begins by asking life sciences IT management "how much inactive data are you backing up that hasn't changed since your last back up and is unlikely to change in the future?" An EMC Backup, Recovery, and Archive Solution enables your organization to extract inactive, final-form data from the production environment and move it to an online archive, thereby shrinking the size of production application data. This results in immediate improvement in production application performance, more consistent performance, and shortened backup and recovery times.

Shorter backup windows and higher performance and reliability of restores translates directly to higher information and application availability. Now a restore request from the recovery process or a retrieval request from the archive can take place quickly from disk, without the need to load multiple tapes or worry about their sequence. EMC offers life sciences organizations a complete range of storage arrays to meet your service-level requirement for backup, recovery, or archiving.

Archiving solutions for compliance

FDA GxP and 21 CFR Part 11 guidelines require that records are protected with secure access to ensure accurate and ready retrieval over defined retention periods, including time-stamped audit trails and audit trails that track the execution of electronic signatures.

At the heart of EMC archiving solutions for regulatory compliance is EMC Centera™ content-addressed storage, offering fast access to online archived data to meet today's high service levels for application recovery and information. Centera's advanced content-addressed storage architecture delivers information location independence, self-healing and management, guaranteed content authenticity, and single-instancing to take the worry out of



archiving and ensure compliance with internal rules and external regulations.

Address Information Security Concerns

Information security—protecting your “digital assets,” particularly intellectual property, including research and clinical trials data—is at the top of the list of IT concerns and challenges. Exposure or loss of sensitive information can have significant negative impacts, from mitigation costs, to damage to company reputations and even stock valuation. EMC believes that security must become information-centric, starting with securing the data itself, then moving out through layers of increasingly intelligent infrastructure.

The EMC Assessment for Storage Security helps your life sciences organization understand the level of protection that’s appropriate for your business needs, and recommends the best combination of policy, management, and technology improvements to assure a comprehensive storage security strategy across your entire storage infrastructure. EMC offerings to address security concerns include Encryption, Data Erasure Service, EMC Secure Remote Support, and EMC Vulnerability Alert Services.





EMC partners with the leaders

To ensure life sciences organizations gain the most value from their information infrastructure, EMC has created one of the industry's strongest groups of business partners. We partner with industry-leading application providers to deliver unique life sciences solutions. EMC works with strategic application providers such as Microsoft, SAP, and Oracle to better manage and archive your Oracle databases, Exchange, NetWeaver, and mySAP application environments.

Investing in new technologies

EMC continues to invest in and integrate innovative and strategic technologies to enhance information lifecycle management for the life sciences industry. Through technology and product acquisitions from Documentum®, Legato®, Captiva®, Rainfinity®, Smarts®, VMware®, and others, EMC is enabling life sciences organizations to accelerate their drug discovery pipelines.

Our life sciences customers require solutions to move data and applications across a single pool of storage and server resources without interruption to the business. VMware, the market leader in virtual infrastructure, helps our customers simplify IT resources, fully leverage their Intel-based computing investments, and respond faster to changing business demands.

EMC Smarts software provides solutions for managing complex infrastructures end-to-end, across technologies, and from the network to the business level. With this innovative technology, your organization can model components and their relationships across networks, applications, and storage to understand the effect on services, analyze data from multiple sources to pinpoint root-cause problems—automatically, and in real time.

EMC Captiva is a leading provider of enterprise input management solutions. These solutions are designed to optimize the delivery of mission-critical information into an organization, transforming paper and electronic forms and documents into accurate, valuable data that can be stored and quickly accessed to speed daily operations, reduce costs, improve customer relations, and meet ongoing compliance initiatives.

EMC Professional Services

Life sciences organizations are under increasing pressure to simplify, maximize, and squeeze every bit of return on IT investments to ensure that their business operations run smoothly, without interruptions, and in compliance with a growing list of regulations. EMC Professional Services offer visionary strategies and practical results to help life sciences enterprises achieve their business goals and realize the benefits of information lifecycle management faster.

EMC Classification and Policy Services are tailored to your unique life sciences environment to meet your requirements more effectively by classifying information into logical groups, identifying business service-level requirements, developing a supporting tiered storage architecture, and then aligning applications to tiers for cost optimization.

EMC Data Center Consolidation Services help your organization consolidate and relocate data centers for improved quality, utilization, and management of storage systems—with less risk, in the shortest time, and in the most cost-effective manner.

EMC Platform Consolidation Services include services and solutions to help your enterprise consolidate applications, servers, and storage—to increase flexibility, improve asset utilization, and reduce risk and costs.



The EMC Difference

EMC Corporation is the recognized world leader in products, services, and solutions for information management and storage solutions. So it's no surprise that the world's leading life sciences organizations—from pharmaceutical, medical device, and biotechnology companies—use EMC solutions to:

- Reduce time and cost in bringing high-value therapeutics to market faster
- Streamline information sharing between research and development, clinical trials, manufacturing and operations, and sales and marketing
- Manage regulated content for clinical trials and electronic NDA submissions
- Consolidate data centers, servers, and storage resources to improve asset utilization and reduce overall cost and complexity
- Unify critical applications with an open, comprehensive and secure virtual repository for structured and unstructured data

Take the Next Step

To learn more about EMC Life Sciences Solutions, please contact your EMC account manager or visit www.EMC.com/lifesciences.



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