Conquering Regulatory Compliance Chaos in Life Sciences

The Definitive Guide to Taking Control of Your GxP Digital Assets with Engineering Document Management

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As a drug or medical device makes its way to the market, it passes through critical checkpoints–all with stringent documentation requirements for designs, plans, drawings, schematics, notes, and other proprietary files that comprise the R&D pathway.

Over time, more files get created, modified, and shared by a wide range of people from various locations and home offices. The documents are distributed across servers, personal hard drives, email inboxes, and there are paper copies as well. They're buried in complex folder structures unique to each department, discipline, or subsidiary. The result is that documents are lost and recreated, duplicates are rampant, accidental overwrites occur, and the wrong information is accessed. This black hole of document management chaos leads to costly mistakes, safety issues, inefficient collaboration, and wasted time.

These challenges are common across any industry that relies on digital assets and information. But there's more at stake in life sciences, where regulatory compliance depends on deep traceability, document audit trails, data integrity, and record retention. Without adequate technical and procedural controls in place, organizations can jeopardize their ability to operate and release product and risk introducing adverse effects to the patient.

That's why life sciences companies are increasingly turning to Engineering Document Management Systems (EDMS) rather than relying on their internal legacy builds or more generalized document management solutions that don't adequately support the needs of engineering. By centralizing files into an enterprise-wide, compliant platform, stakeholders can more easily control, access, and collaborate on them. With a single version of the truth, people can get back to the value-adding, innovative work that produces breakthroughs and saves lives.

In this playbook, you'll discover new opportunities for life sciences engineering document management and understand:

- What is engineering document management for life sciences?
- Why is engineering document management essential for life sciences?
- Implementation best practices: Insights from Merck*
- Keys to a successful document management journey

*Merck Sharp & Dohme LLC, Rahway, NJ, USA (Hereinafter MSD).

One source of truth to align your teams, drive standards and ensure compliance.

What is Engineering Document Management for Life Sciences?

"If it isn't documented, it didn't happen," is a well-known adage in the life sciences industry. There's a similar maxim at the core of an EDMS. "If a document isn't in the EDMS, it doesn't exist." The organizational EDMS serves as the single source of truth for all documentation related to a plant, facility, equipment, or products.

An EDMS, such as Adept from Synergis Software, ensures that all of engineering, quality, manufacturing, maintenance, and R&D documentation is version-correct, stored and managed in a centralized collaborative environment, auditable for compliance, integrated with computer-aided design (CAD) systems, and, accessible to stakeholders quickly and easily.

CAD drawings are far more specialized than traditional word processing files or spreadsheets–and those very nuances in turn require special handling. **"CAD designs are the foundation and the basis for critical aspects of the pharmaceutical and medical device business,"** said Todd Cummings, Vice President, Research and Development at Synergis. "And there are unique challenges with managing complex CAD file relationships (i.e., XREFs), versions, and the engineering change process across teams and business units."

Depending on the size of the organization, an EDMS can manage thousands, hundreds of thousands or even millions of documents. These documents range from CAD plans and drawings of entire facilities to equipment drawings to P&IDs, to assembly and maintenance documentation, SOPs, and other proprietary files. An EDMS supports nearly any file format, including AutoCAD®, MicroStation®, Inventor®, SOLIDWORKS®, PDF, Word, Excel, TIF, and PNG.

Essential EDMS Capabilities for Life Sciences

Here are 11 key requirements to consider for an EDMS. These capabilities should be available as standard, out-of-the-box features, without any customization.

Simplified compliance and validation for 21 CFR Part 11

Having a purpose-built, automated system in place for document management and workflow automation ensures you have control over your engineering information and processes, simplifying compliance and system validation for 21 CFR Part 11.

One source of truth that aligns everyone

With centralized management of plant, facility, and equipment documentation, you'll ensure that engineering, maintenance, operations, and construction teams are all on the same page. You'll improve data integrity, avoid safety issues and unplanned downtime, and provide enterprise visibility to plant and project information.

Improved traceability, security, and control

You'll have an extensive audit trail of who did what and when. Your documents and the intellectual property they contain will be secure. And you'll have granular control of user access rights to documents.

Fast, easy access to the right version from anywhere

You'll recover a day per week per person by eliminating wasted time searching for the right document. Your reliance on complex folder systems across enterprise servers will be over.

Automated workflow steps, alerts, and notifications

Ensure documents are approved by the right people at the right time, eliminating bottlenecks and delays from manual workflow methods.

Validated approvals and digital signatures

Require password authentication for document approvals and ensure digital signatures to meet your compliance requirements.

Digital print stamps and watermarks for controlled documents

Ensure controlled documents have a watermark or print stamp whenever viewed, printed, or published to PDF.

Tight integration with 2D and 3D CAD

Improve your design workflow by ensuring document management capabilities are available to CAD users right inside the CAD application, including AutoCAD, MicroStation, Autodesk Inventor, and SOLIDWORKS. Search or browse by metadata, preview designs, view metadata, open, insert check out or replace files, see where-used and composed-of details, and approve or reject drawings in a workflow.

Built-in view and markup tools to streamline digital feedback

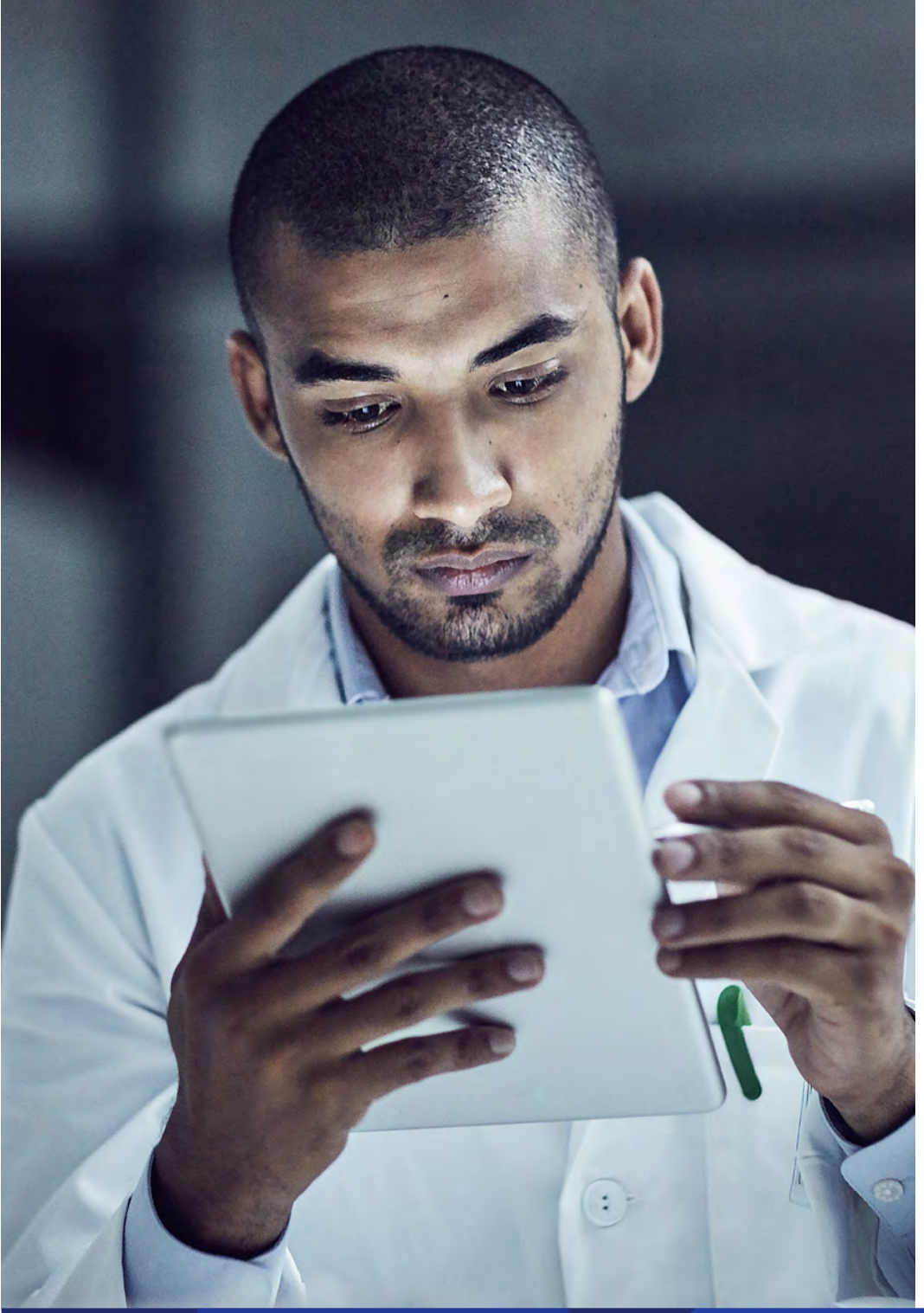
Make it easy for any user, including those without a CAD license, to view, print, and securely collaborate on virtually any document–from 2D to 3D engineering files to office documents and graphics formats.

Streamlined document transmittal processes

Simplify the process of finding files, validating version accuracy, tracking down reference files, creating cover sheets, packaging, sending, and maintaining an auditable record of each transmittal, so you can free up your resources for more valuable work.

Paperless document storage, access, collaboration, and control

Support your green initiatives and eliminate time-consuming, error-prone, paper-based processes with an all-digital document environment.



Why is Engineering Document Management Essential for Life Sciences?

FDA guidelines, and ongoing changes to those guidelines are a primary impetus for established companies and startups to reevaluate their document management processes and technologies and question their traditional models.

"From my experience, document management is the foundational aspect of all compliance in life sciences," said John Niziolek, Associate Director of Computer Systems Validation & Data Integrity at IPS-Integrated Project Services (IPS), a Synergis Partner and ENR Top 100 Design Build Firm that provides compliance and validation services for 21 CFR Part 11.

"Anything you do specifically in relation to life science GxP environments must be documented, validated, and tested," states Niziolek. "There must be a fully traceable audit trail from end-to-end in your process."

Said Niziolek, **"The FDA's new Computer Software Assurance (CSA) guidelines offer a risk-based approach to computer system validation whereby the focus is on what matters – patient safety, product quality, and data integrity. It's impacting the way people think about electronic systems, records, and data. Solutions such as Adept allow life sciences companies to be nimbler and to manage their data much more accurately in real time."**

In addition to new regulatory developments, external market forces such as labor shortages, tech advancements, and the imperative to centralize and interoperate have leaders rethinking the way they manage their digital engineering documents.

"Stressors like globalization, remote work, and M&A activity expose the limitations of manual processes, which are more onerous and error prone than automated solutions," observes Cummings.

"Companies are looking at digital solutions that have deep traceability as well as the ability to manage datapoints, access to metadata, and integrations with other platforms," Niziolek said. "They're looking for solutions that help them share data bidirectionally for better visibility into technical documentation and designs."

As leaders look to partners like Synergis and IPS to automate the management of engineering information, they're realizing value across multiple areas of investment return:

- **Compliance:** An EDMS provides the document control and automation needed to simplify and ensure compliance with 21 CFR Part 11 and a much easier path to system validation.
- **Risk:** Poor document control and approval workflow processes create chaos that life sciences companies cannot afford. Risks include human safety, unplanned plant shutdowns, compliance issues, delayed projects, and expensive rework due to errors.
- **Access:** Collaborators can easily find the version-correct documents they need when they need it, from anywhere. With the average knowledge worker spending 20-30% of their time looking for information, an EDMS saves time and shortens project cycles.
- **Costs:** The costs of manual methods of document management and workflow routing or supporting legacy home-grown systems are high compared to the costs of commercial solutions that meet life science requirements and are maintained and improved ongoing by a proven 3rd party provider.

Another way to quantify the importance of engineering document management is to consider the value of what you are managing. Let's say one design document takes five hours to create, plus time for review, rework, and approve (these hours may vary depending on your business). Next, let's say the total cost to create and approve the document is $1,000.

If you are managing 100,000 documents, then your digital documents have a valuation of $100M. That's not even considering the value of the Intellectual Property contained in your documents. What's that worth?

"Commercial EDMS solutions can help companies at all growth stages transform their document management practices and processes," said Scott Lamond, Vice President of Marketing at Synergis Software. "They provide the engineering-focused features and functions to support an easier path to compliance that aren't available from general purpose content management solutions or internal builds."

Implementation Best Practices: Insights from MSD

While some organizations implement changes to their document management process and systems after a catastrophic situation or costly mistake, such as a human safety issue, unexpected plant shutdown, compliance challenge, or cybercrime it's best to identify your vulnerabilities and address them in advance.

Said Cummings, **"If your manual systems or processes put you at risk, identify the potential costs and make those part of your internal justification for funding."**

As a Synergis and IPS client, MSD had their own version of an EDMS story. Ray Kastle, Associate Director of Supply Chain shared, **"We tried for several years to get funding for engineering document management but were not successful until we had a near miss issue.** There was some excavation to take place, and fortunately, the people that were out in the field questioned the drawing, and they discovered it was an older version, and there had been other work in the area in the past. If they had dug where they were planning to, it would've resulted in digging up power lines, which we consider a bad thing."

Life science companies can identify their vulnerabilities and risks with a high-level computer system validation assessment from an organization such as IPS. External audits and third-party review might be the most important step along the pathway to digital transformation because they provide an unbiased point of view and a baseline to establish what is required versus what's not.

MSD had determined that its own legacy document management platform was unreliable and unsupported by the vendor. They needed a 21 CFR Part 11 compliant system that could store CAD files, ensure version control, manage approval workflows, segregate multi-site-level data, and support a range of use cases by various user groups such as maintenance teams, engineering groups, and support organizations.

"I'm in a pharmaceutical industry and am required to meet good manufacturing processes and be validated," said Kastle. "Additionally, we wanted to be paperless as much as possible, so I had to allow for digital signatures and a full audit trail. We also needed to support different file formats, such as AutoCAD, MicroStation, TIFFs, and PDFs. Some of the drawing files we had were very old so I needed an application that could support multiple versions of the CAD software."

"Why are we concerned with CAD? One, we're a pharmaceutical company", Kastle said. **"Certain CAD drawings need to be validated. They're part of the site validation master plan, plus they're used across the entire site. They fully represent the site, the manufacturing facilities, the above and below ground utilities, office buildings, and floor plans."**

Kastle spent time gathering requirements from groups in the US, Europe, and Asia Pacific and then, with a team of power users, reached out to potential solution providers. They narrowed down the selection to two suppliers and followed through with iterations of demos and interviews with customer references.

MSD ultimately selected Adept for its engineering focused feature set, comprehensive implementation process, robust compliance features, and excellent customer references.

Following partner selection, companies typically undergo a series of steps, from planning and testing to software installation, platform validation, data migration, and training.

"We had to go with all the system lifecycle of documentation, quality assurance plans, design specs, requirement specs," Kastle said. "We had to test. We had to write up the test scripts. We needed to be able to support the test execution and manage the project. When I say we, it was essentially me. So, there wasn't a whole lot I could do. I needed help doing all this. And thankfully we had selected the right partners."

> "What did we get from Adept? The big thing is my risk profile is vastly improved. And now I have a validated system. We now have version control. We have a centralized source of truth. We have the capability to set up workflows for different scenarios, like GMP, Safety, or Engineering. And we have the capability to do more with it.
>
> Ray Kastle
> Associate Director, Supply Chain at MSD

Keys to a Successful Document Management Journey

What's the best approach to finding the EDMS that best suits your needs? Here are some guidelines when you begin the journey.

Focus on both the solution and provider capabilities in the life sciences market

When companies make the decision to implement new technologies and processes for their document management needs, there is often great focus on the solution and ensuring that the use cases and compliance needs can be met. An equally important factor to consider is the vendor and their capacity to provide the necessary support and guidance during implementation, throughout the use of the system, and during maintenance and upgrade cycles. The transformative part of EDMS is as much about people as it is about technology.

Ensure your documents and data are not held hostage in a proprietary system

Understand how your drawings, documents and metadata will be stored by any potential solution.

Think through your potential exit strategy, including what it would take to get your documents and data out of that system in the future if desired for any reason. Be sure any system provides the security you need without scrambling the intelligence of your folder structure and filenames.

Leverage provider documentation and testing

Wherever possible, an organization should leverage vendor conducted testing and documentation to lighten the impact to internal compliance resources and allow for a more rapid and complete implementation of a compliant system.

Capture user requirements

Pivotal to the success of any project is ensuring that all requirements have been captured from the planned users of the system and that they support the need of the business. When implementing across multiple business units, it is important to understand how requirements may differ from group to group.

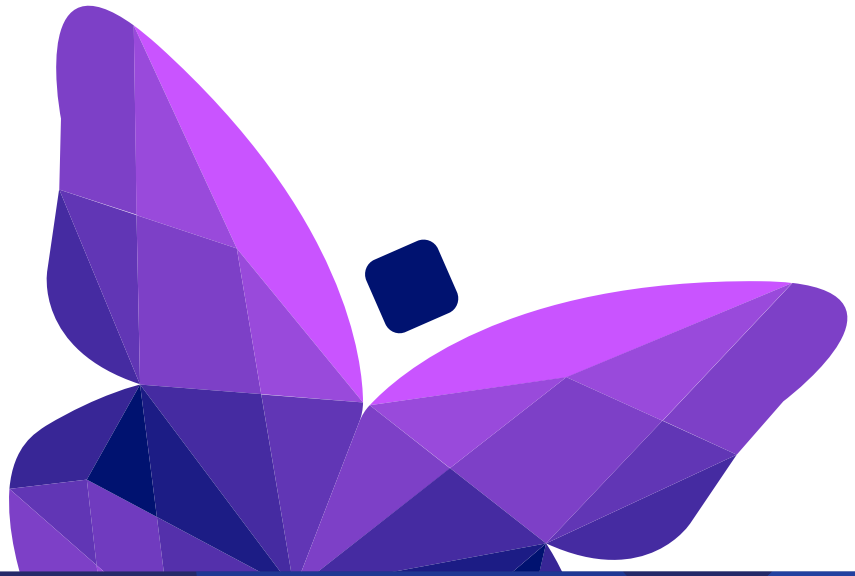
Questions to Ask Potential Partners

- Is the solution designed for life sciences and engineering teams, or is it a generalized document management solution?
- Do you have the resources and expertise to navigate us through the compliance and system validation process?
- Can you share success stories and customer references for life sciences projects like mine?
- Does this solution meet our requirements out-of-the-box, or will it require customization?
- What is the timeframe from project start to when we will begin to realize value from the system?
- How will you support us from project start through go live and ongoing through our use of the solution?

Summary: Take Control of Your Documents with Adept Engineering Document Management

The inability to manage and control one's documentation can pose great potential challenges to an organization's ability to operate efficiently and ensure compliance and may ultimately impact the patient. With recent changes to industry regulations for life science companies and with greater scrutiny being placed on an organization's document management processes and their integrity, it's no surprise that business leaders are rethinking the need for an EDMS.

Adept EDMS is trusted by life sciences companies such as Agilent, Astellas Gene Therapy, Bayer, bioMérieux, Dali Medical Devices, Dexcom, Elanco, Johnson & Johnson, Novozymes, Thermo Fisher Scientific, United Therapeutics, and others.



Adept provides:

- One centralized source of truth for all your plant, facility, and equipment documentation, ensuring that engineering, quality, maintenance, operations, and construction teams are all on the same page.
- Fast access to version-correct drawings and documents to authorized users from anywhere.
- Document control to protect your intellectual property, maintain an audit trail of who did what and when, drive standards, and deploy best practices.
- Automation capabilities for version control, workflow and approval routing, approval validation, digital signatures, file naming, print stamps, and watermarks.
- Compliance and system validation for 21 CFR Part 11 and EMA Volume 4, Annex 11.

With Adept engineering document management software from Synergis and compliance and validation services provided by IPS, life sciences companies can get back to their innovative and lifesaving work for the welfare of humans and animals.

Learn more about **Adept for Life Sciences** or **Schedule a Discovery Call** to discuss your requirements and get a personalized demonstration.

Synergis Software

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