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Sanofi Pasteur MSD Inoculates Itself Against Document Management Inefficiency

CUSTOMER PROFILE

Founded in 1994 as a joint venture between Sanofi Pasteur and Merck and Co. Inc., Sanofi Pasteur MSD is the only European company dedicated exclusively to vaccines. It employs more than 2,000 people, has a presence in 19 countries, and offers one of the broadest portfolios of vaccines available.

THE SITUATION

Sanofi Pasteur MSD had no standardized system for capturing, storing, and tracking the documentation required for regulatory submissions in 19 countries. This prevented Sanofi Pasteur MSD managers and executives from gaining deep insight into the status of document collection.

THE SOLUTION

Sanofi Pasteur MSD deployed the NextDocs Document Management System. Using Microsoft SharePoint Server as a foundation, the NextDocs solution provides a powerful document management, workflow, and collaboration solution that meets FDA 21 CFR Part 11 requirements.

RESULTS

Sanofi Pasteur MSD now has a streamlined and efficient document management process that helps it capture, store, and track documents originating in locations throughout Europe. This increases efficiency, fosters confidence in the integrity of the documentation record, and facilitates the preparation of materials for submission in the electronic Common Technical Document (eCTD).

Overview

Sanofi Pasteur MSD offers the widest range of vaccines of any company doing business in Europe today. It delivers vaccines to more than 390 million people in 19 countries, but before it can deliver those vaccines to those millions of people, Sanofi Pasteur MSD must collect and submit thousands of documents to as many as 19 separate regulatory agencies. The challenge for the company was the manual process of finding, capturing, reviewing, approving, and storing these documents. There was no consistent process for managing this task, no central document repository, and no significant automation. To overcome the inefficiencies and to enable process transparency, they began searching for a document management solution designed to meet the needs of Life Sciences companies. This solution needed to comply with recognized standards, had to be easy to use by employees in many locations, and had to fit in with the company's IT strategy. The solution? The Document Management System from NextDocs.

"The transparency of the system is a key improvement. Now we know at which step of a document's life cycle we are, and who is meant to do what."

— Marc Palatte, Systems Architect, Sanofi Pasteur MSD

The Situation

Before Sanofi Pasteur MSD can deliver its life-saving vaccines to the people of Europe, it must submit thousands of documents to regulatory bodies. One challenge lay in finding the key research and clinical trial documents. The originals were scattered among remote systems belonging to parent companies Sanofi Pasteur and Merck. Even after Sanofi Pasteur MSD personnel had found the documents, other challenges remained: Sanofi Pasteur MSD still needed to capture and prepare these documents for submission.

"As a company, we had no standardized process for capturing, storing, and freezing these documents," explains Marc Palatte, solutions architect at Sanofi Pasteur MSD. "So managing all these documents became very complicated. Everyone working on individual aspects of vaccine development knew where their key documents were, but other people in the company often had no idea."

Sanofi Pasteur MSD executives decided that an inconsistent and uncoordinated process was no longer a viable way to manage these key documents. Desiring greater process efficiency and transparency, they decided to embark on the search for a solution that would overcome these challenges.

The Solution

Sanofi Pasteur MSD executives wanted a single solution that would provide company-wide regulatory compliant document management. That meant an FDA 21 CFR Part 11 compliant solution and that authorized users could access easily and consistently, from any location around the world. Furthermore, no additional management or administrative burdens could be placed on the company's small IT department.

Sanofi Pasteur MSD uses Microsoft SharePoint Server for internal sharing and collaboration, so it wanted to find a standards-compliant document management solution that would leverage that investment. Mr. Palatte recalls reviewing several solutions, but quickly found the Document Management System from NextDocs to be the best fit.

"The NextDocs solution stood out," says Mr. Palatte. "Integration with SharePoint Server was excellent, and the NextDocs document management system was both more mature and easier to use than the others that were considered. It was also clear that we could extend the NextDocs platform to support other business areas—Quality Management, for example—and we knew we were going to need a solution to support those areas in the future."

Sanofi Pasteur MSD deployed the NextDocs Document Management System in March 2010. The software runs on an instance of SharePoint Server in the Sanofi Pasteur MSD data center in Lyon, France. A single IT employee performs local support and administration tasks for the NextDocs system, and NextDocs itself provides remote support for escalated issues on an on-call basis.

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— Marc Palatte, Systems Architect, Sanofi Pasteur MSD

The Result

Between March and November 2010, 20 Sanofi Pasteur MSD employees supporting eight different vaccine development programs used the NextDocs Document Management System to capture, process, and store more than 7,000 documents. Using built-in workflow and collaboration tools, the NextDocs software automated key tasks, including:

- Routing documents for review
- Reminding signatories when they needed to review and approve documents
- Capturing digital signatures
- Saving the final approved versions of the documents in a standard PDF format
- Storing these documents in a secure yet easily accessible data repository

During that same period, Sanofi Pasteur MSD used NextDocs to help prepare more than 180 electronic regulatory documents for submissions.

Gaining Transparency

With the deployment of the NextDocs Document Management System, program managers at Sanofi Pasteur MSD can instantly see whether a document has been brought into the system, who is reviewing it, who has approved it, whether there are outstanding issues, and more.

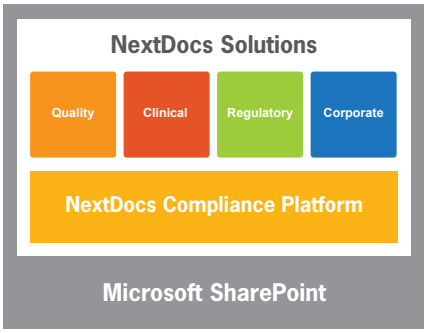
Previously, this information had not been instantly available. Documents were sent to different reviewers via email, and if a document disappeared during the review cycle it was sometimes difficult to discover who had it last. This required additional time and effort for locating lost documents. With the NextDocs solution, the documents are accessed from one central location with no possibility of getting lost. The workflow system makes reviewers aware of their responsibilities and points them to the single copy of the document residing in the system. All comments and issues collect in the single document and are visible to all reviewers.

"The transparency of the system is a key improvement," says Mr. Palatte. "Now we know at which step of a document's life cycle we are, and who is meant to do what."

Moving Forward with Best Practices

"People throughout the company are realizing the benefits of having a common system," says Mr. Palatte. "It demands a bit more of individuals up front; they must observe a set of rules that were not present before. But this makes it a lot easier to work with the documents in other parts of the company—and that's critical. When you have a company that is growing, that has teams working in several locations and in several countries, you have to be able to work on the same page. It's a matter of best practices."

For Sanofi Pasteur MSD, the deployment of NextDocs Document Management is just a first step. The company deployed the NextDocs Quality Management System (QMS) and Corrective and Preventive Actions (CAPA) management module in June 2010. It deployed the Audit process module of the NextDocs QMS in October 2010. All of these components of the NextDocs solution are coming together to bring improved business practices and improved insight. "Managers have been asking for these kinds of consolidated insights into documents and processes for a very long time," says Mr. Palatte. "Now, they're getting it. That's the beauty of the NextDocs solution."



NextDocs Regulatory Document Management

The NextDocs Regulatory Document Management Module is a complete solution for managing documentation needed for CTD/eCTD and related filings in a SharePoint based system. NextDocs guides users through the production of submission ready documents by enforcing the use of CTD/eCTD required granularity, requiring templates, producing PDF renditions that meet the myriad of agency requirements, and collecting 21 CFR Part 11 compliant electronic signatures.

The NextDocs Regulatory Document Management Module is specially designed to support regulatory submissions. ICH and regional authorities have published many documents specifying the required contents of various regulatory submissions. NextDocs is pre-configured for regulatory documents by implementing the EDM Reference Model. a taxonomy/metadata model developed by an industry working group that maps extensively to these regulatory requirements and incorporates best practices and lessons learned. If desired, the model can be modified to expand the inventory of documents managed, implement variations on the standard business processes, etc.

The NextDocs Regulatory Document Management solution is fully configured for use in managing submission documents, and could be validated and deployed by doing nothing more than adding specific information about your products, studies, etc. to pre-existing lists, importing your templates, and adding your users to appropriate roles. Alternatively, the system can be configured to meet specific objectives and accommodate exact business processes. Standard solution components includes:

- Complete inventory of Nonclinical, Clinical, Quality and Regulatory/Administrative documents.
- Best practice lifecycle and workflows for review, approval, finalization, and revision
- Smart Document Wizard that minimizes user metadata entry by auto-populating document properties and filing in a standard folder structure
- Role-based security
- Optional digital signature
- Audit trail
- Ability to archive a published eCTD
- 21 CFR Part 11 Compliance

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NextDocs is the global leader in providing Microsoft SharePoint-based document and quality management solutions to life sciences organizations. It enables businesses in regulated industries to achieve compliance with FDA and other agencies while automating processes, improving efficiency and dramatically reducing costs. NextDocs customers include Pharmaceutical companies, Bio-Techs, Medical Device companies and CROs.

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