

Zosano Pharma adopts Medidata Regulated Content Management to Streamline Search and Increase Compliance

Zosano Pharma

Zosano Pharma Corporation is an emerging central nervous system company focusing on providing rapid symptom relief to patients using known therapeutics and altering their delivering profile using the Company's proprietary transdermal delivery system. The company's goal is to make transdermal drug delivery a standard of care for delivering drugs requiring fast onset action.

The Challenge: Why Regulated Content

Life sciences professionals face progressively complex regulatory environments and require access to regulated and nonregulated content in the pursuit of drug development and innovation. Many life sciences companies use inefficient hybrids of paper and computer-based systems with siloed processes for document and content management. These dated legacy solutions provide a disparate user experience for access, search and workflow, resulting in low system adoption, increased compliance risks, and other significant challenges that delay trial timelines and time-to-market.

Zosano Pharma recognized similar challenges with their legacy solution and sought to adopt a new unified system and process. "Within this industry almost everything we do is regulated, so having traceability and an applied process of doing things is very important to us," said Hayley Lewis, VP of regulatory and compliance at Zosano. Previously, this California-based therapeutics provider utilized a file server system with folders containing PDF documents that needed to be tracked and traced manually. After being rendered from their original Microsoft Word documents into PDF versions, these documents were often unattended and incomplete. Employees found themselves wasting time and energy, manually tracking down documents from various file locations around the building.

"The user interface is extremely intuitive to use, and the mobile app makes reviewing and approving SOPs while traveling so simple. Most importantly we now have a system in place that lets me feel confident with our overall compliance and inspection readiness."

Hayley Lewis, VP Regulatory & Compliance, Zosano Pharma

The Solution: Medidata Regulated Content Management

Medidata Regulated Content Management (RCM) provides Zosano Pharma with a unified solution for Standard Operating Procedure (SOP) management, for both regulated and nonregulated content, that is cost-effective and quickly deployable. The solution is purpose-built for life sciences, providing Zosano with tools for workflow management that help create, edit and approve content with read and acknowledge capabilities, including reviewing documents via mobile platforms. Zosano introduced iPads equipped with Medidata RCM to their manufacturing area to facilitate training, and familiarization with and access to SOPs.

Medidata RCM is fully integrated with Box, the leading enterprise content management platform, allowing Zosano Pharma users to easily search both platforms for regulated and nonregulated content in one search. Lewis echoed the simple implementation and pre-built functionality: "Using Medidata is easy from a validated standpoint because it was delivered to us ready to use. Medidata RCM was the choice for us because the intuitive interface integrates quite well with our Box platform; there was no additional training we had to give our users because they were already familiar with the platform interface."

The Results: Simple & Quick Implementation with Greater Compliance

Medidata RCM was implemented at Zosano Pharma in a six-week timeframe, compared to other vendors who required four months and twice the resources. Zosano Pharma users can now search once for all regulated and nonregulated content with the seamless Box integration, and review and approve content from anywhere, anytime with mobile accessibility. In addition to reduced search and review time, the team has quickly adapted to the intuitive user experience and workflows.

Lewis' team is now able to increase compliance and familiarity with documentations, and decrease regulatory risks. The Medidata RCM solution is not only providing Zosano Pharma with greater compliance confidence and inspection readiness but also is increasing team productivity overall, allowing them to focus on innovation and accelerated time to commercialization without wasting time tracking down and indexing documents. "Having our documentation in a secure, validated environment enables an ease of use for authoring, review, and approval, which compliments the work we do and enables us to pay attention to other things so we can focus on our product development," Hayley said.

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