Dicema

Dicerna Harmonizes Quality Management with Veeva Vault Quality

End-to-end digital platform increases efficiency by 50% and reduces paperwork by 90%

Dicerna Pharmaceuticals, Inc., a leading developer of investigational ribonucleic acid interference (RNAi), creates medicines that silence or turn off the genes that cause disease. With a vision to maximize the impact of RNAi on medicine and deliver lifesaving therapeutic medicines, the company needed to modernize its vast and fragmented quality system landscape that was difficult to use and costly to maintain.

DICERNA PHARMACEUTICALS, INC. - AT A GLANCE

- Corporate Headquarters: Lexington, MA
- Employees: 225+
- Primary Therapeutic Area: RNAi-based therapies to treat both rare and more prevalent diseases

"We needed to transform our paper-based quality systems into one intelligent, data-driven, end-to-end digital platform to harmonize quality across all sites and operational areas while improving user experience and ensuring inspection readiness," said Anthony Davis, senior director of quality assurance and compliance at Dicerna.

Additionally, the company wanted to enhance efficiency, oversight, and decision making by:

- Improving quality management efficiency by 50% and reducing paperwork by 90%
- · Simplifying quality processes through automation and eliminating redundant steps
- · Increasing awareness of issues and risks for proactive mitigation
- · Centralizing data and making it widely accessible to all relevant parties

Our goals were to achieve better quality outcomes by improving efficiency, oversight, and decision making.

- Anthony Davis, senior director of quality assurance and compliance, Dicerna

Quality Innovation Drives Business Innovation

Improving quality, oversight, and compliance with unified quality systems

To automate and harmonize quality processes globally, Dicerna implemented Veeva Vault Quality – a unified platform of document, training, and quality management applications on a single platform.

The company deployed the solution in phases, starting with Vault QualityDocs to simplify GxP document management. Then they added Vault Training to streamline document and GxP training, followed by Vault QMS to achieve better control and visibility into quality processes across the globe. With strong collaboration across the organization and a robust change management strategy, the unification of the quality systems streamlined processes, increased efficiencies, and improved compliance.

"Our document processes are now harmonized across all departments," Davis explains. "Reassignment of critical changes occurs automatically. Deviations, CAPAs, and change controls are linked to documents, training, and risks. Easily managed training plans, automatic training assignments, and intuitive dashboards help ensure compliance."

All stakeholders now have access to Dicerna's QMS records and visibility into quality events. With the detailed insight of who, what and why, Dicerna is able to quickly resolve issues and trend the metrics for continuous improvement.

"Leveraging Vault Quality, we have optimized our business processes. We are now well equipped to meet our current and future business needs," Davis concludes. "The centralization and efficiency gains – along with the enhanced usability – have resulted in faster decision making, more motivated employees, and a significant reduction in maintenance overhead."

Dicerna will continue its transformation journey by implementing additional Vault Quality components delivered as part of Veeva's innovation cycle of three releases per year.

44 We reviewed the efficacy of our processes through the lens of inspection readiness, quality performance, and oversight ... and eliminated several non-essential steps.

- Anthony Davis, senior director of quality assurance and compliance, Dicerna

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