

MannKind Accelerates its Digital Transformation Journey with TrackWise Digital®



mannkind

COMPANY OVERVIEW

NAME:

MannKind Corporation

INDUSTRY:

Biopharmaceutical

DISTRIBUTION:

Global

EMPLOYEES:

400

SOLUTION:

TrackWise Digital

MannKind Corporation is a biopharmaceutical company that is focused on the development and commercialization of therapeutic products for patients with endocrine and orphan lung diseases.

Its lead product is Afrezza (insulin human) Inhalation Powder, which was approved by the FDA in June 2014. Afrezza is an ultra rapid-acting inhaled insulin indicated to improve glycemic control in adults with diabetes.

Afrezza consists of a dry powder formulation of human insulin delivered from a small portable inhaler. Administered at the beginning of a meal, Afrezza dissolves rapidly upon inhalation to the lung and delivers insulin quickly to the bloodstream. The first measurable effects of Afrezza occur approximately 12 minutes after administration.

At the center of breakthrough innovation is the need to provide the highest level of quality to ensure the end patient gets the product they need, when they need it. To manage its quality processes, MannKind has been using the Sparta family of quality management solutions.

“Everybody loves the functionality of the system, and it does make it a lot easier to navigate”

*Lauren Masthay, Senior Manager,
Quality Engineering at MannKind.*

THE OPPORTUNITY: Going from On-Premises to a Cloud-Based QMS

MannKind previously used the TrackWise on-premises solution. Eventually, MannKind was faced with a decision—upgrade its on-premises solution or move to the cloud.

When evaluating these choices, there were several aspects of a quality management system (QMS) that remained important to MannKind, including:

- Ease of use
- Functionality
- Productivity
- Time savings

Ultimately, MannKind chose to convert to TrackWise Digital, Sparta's fully digital, cloud-based QMS solution to continue to meet these needs.

THE SOLUTION: The Tools Needed for Proactive Quality

On March 31st, 2022, the MannKind team went live with TrackWise Digital. As users continue to get acclimated to the system, the company is looking forward to reaping the benefits of the digital system.

Conversion to TrackWise Digital provides benefits like advanced reporting and analytics to monitor quality events and metrics, as well as ease of use and configurability that helps enable greater efficiencies.

According to Lauren Masthay, Senior Manager, Quality Engineering at MannKind, it's already been easier in terms of accessing the items they need, and they enjoy the look and feel. With TrackWise Digital, MannKind has automated key quality processes including supplier quality management and out of specification (OOS).

THE RESULTS: Ease of Use and a Central Repository for All Data

When discussing TrackWise Digital, Masthay sums it up, "We love it." The functionality of the system has been a key benefit for MannKind. Masthay says, "The relationship of the records, the fact that you see everything in one place (which we didn't have before) everybody is saying they love."

Ease of use has been another key aspect. "Everybody loves the functionality of the system, and it does make it a lot easier to navigate," she says.



LOOKING AHEAD

MannKind is excited about the usability of the system as well as the look and feel. One aspect the company is looking forward to utilizing and sees great potential is the reporting feature.

"We're just getting into moving to that next level of the different views, the different reports and the different dashboards." says Masthay. "As we start to learn more about how to build those and use the filters, they're going to become very helpful to us in terms of our monthly key performance indicators (KPIs)."

Sparta is pleased to be a part of MannKind's digital evolution, and to provide digital quality tools that enable life sciences companies to focus on innovating, while providing a seamless quality management process.

ENABLING DIGITAL QUALITY BY AUTOMATING:

Quality Events	Complaint Handling
Corrective and Preventive Actions	Deviations
Document and Training Management	Change Control
Nonconformances	Product Registration Tracking
Out of Specification	Reporting
Audit Management	Investigations

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