

From Reactive to Proactive – How MannKind Optimized Lab Operations and Addressed Data Integrity Challenges With waters_connect Data Intelligence

Combining waters_connect™ Data Intelligence software with their Empower™ Chromatography Data System has provided MannKind with valuable insights to address key challenges in their QC laboratories.

INTRODUCTION

MannKind Corporation, a leader in innovative inhaled therapeutics, has built its reputation on addressing serious unmet medical needs in endocrine and orphan lung diseases. With a commitment to scientific advancement and operational efficiency, MannKind sought to enhance its laboratory processes to improve data-driven decision-making. In their search for a solution, they partnered with Waters™ to beta test waters_connect Data Intelligence, a cutting-edge software designed to optimize laboratory operations.

This case study explores MannKind's motivations for participating in the beta program, their implementation of the software, and the impact it has had on their laboratory operations and decision-making processes.

ABOUT MANNKIND

Founded in 1991 by Alfred E. Mann, MannKind Corporation has a legacy of innovation in biopharmaceuticals, medical technology, and aerospace. With headquarters in Danbury, CT, and additional locations in West Lake Village, CA and Bedford, MA, MannKind operates with a team of approximately 500 employees, including a significant number of field-based professionals.

The company focuses on developing and commercializing inhaled therapeutic products. Their Technosphere® platform differentiates them in the market, enabling unique drug delivery solutions. Their flagship product, Afrezza®, is an ultra-rapid-acting inhaled insulin approved for adults with type 1 and type 2 diabetes. Additionally, Tyvaso DPI®, a treatment for pulmonary hypertension, was developed in collaboration with United Therapeutics. Several clinical trials are also underway to expand their portfolio further.

MannKind's innovative approach and commitment to addressing unmet medical needs set them apart from competitors. However, like any cutting-edge organization, they face operational challenges—particularly in laboratory efficiency and data management.

INTERVIEWEE SPOTLIGHT: DONALD PREISS



Donald Preiss, Associate Director – IT Lab Applications at MannKind Corporation, brings a wealth of experience in laboratory informatics and IT management. Since joining MannKind in 2022, he has played a pivotal role in overseeing QC lab systems, computer system validation (CSV), and application management across the company. Under his leadership, the IT team has expanded its support to R&D operations and established an IT Project Management Office (IT-PMO) to enhance project governance for technology-driven initiatives.

With a background that includes six years as a Project Manager and Team Lead, Donald has a deep understanding of laboratory informatics solutions. His continued collaboration with Waters reflects his commitment to leveraging cutting-edge technologies to drive efficiency, compliance, and innovation in pharmaceutical development.

As waters_connect Data Intelligence is providing insights on their regulated Empower Software data, the ability to monitor reprocessed injections, aborted runs, and other data integrity concerns has strengthened audit readiness. "There is also an appetite to monitor usage by analyst, system, column, and other reasons for predictive planning," they note, highlighting the tool's potential for broader applications. Productivity has also improved, as analysts spend less time troubleshooting and more time focusing on critical tasks. To further optimize workflows, MannKind is considering expanding access to include data reviewers, which would enhance investigations and root cause analyses.

The software's ease of use has been another advantage. "There are three basic steps when building dashboards—choose your data, choose data to plot against, and then select your graphical output," they explain. However, MannKind believes the tool could be even more efficient with AI integration, reducing the need for manual setup. "If AI were to be implemented, it would be one simple step of telling the software what you want and letting the software build it for you in a fraction of the time." This potential for automation is a key consideration as they evaluate the long-term role of waters_connect Data Intelligence in their operations.

LOOKING TO THE FUTURE

MannKind sees significant potential for waters_connect Data Intelligence as it continues to evolve. As highlighted previously, one of their primary recommendations is the integration of AI and machine learning to further enhance automation and predictive capabilities. "The world is moving closer and closer to AI and ML. I would like to see Waters get ahead of the curve and start to implement AI in these tools ASAP," Donald emphasizes.

Donald also highlights the importance of Waters staying ahead of competitors by leading in data intelligence innovation. "It doesn't have to be perfect, but it is better to be the first at something than to just be a repeat of what is out in the market."



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CONCLUSION

Through their participation in the waters_connect Data Intelligence beta program, MannKind Corporation has taken a significant step toward proactive laboratory management and data-driven decision-making. The software has already demonstrated its value by improving efficiency, enhancing data integrity, and reducing wasted time on investigations.

As they finalize procurement and consider broader implementation, MannKind remains committed to leveraging advanced data analytics to optimize their operations. With an eye on the future, they continue to push for AI integration, ensuring that they remain at the forefront of innovation in the biopharmaceutical industry.

Their experience with Waters has reinforced the power of strong collaboration in driving scientific and operational excellence. "Ultimately, I am a big supporter of their products and services," Donald concludes.

For your local sales office, please visit waters.com/contact



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