CASE STUDY

ZS | medullan

ZS/Medullan, a Pioneer in Digital Health Technology, Turns to AssurX for a Future-Proof eQMS

AssurX

Without hesitation, Medullan chose AssurX. "The main factor was configuration. That nearly every aspect of the solution can be modified to meet our needs is what differentiated AssurX from other providers"

Some of the world's largest life science companies are dramatically advancing their use of digital health technology, thanks to ZS/Medullan. The company is the result of the acquisition in 2021 of Medullan by ZS, a global consulting, technology, and analytical services firm.

Massachusetts-based Medullan is known for innovative digital health solutions, especially VARA™, a pioneering virtual care and decentralized trial platform. The combined offerings of ZS and Medullan are dedicated to improving clinical trials and patient outcomes. ZS/Medullan counts 49 out of the top 50 life sciences companies as clients.

"We knew that an automated resource was the best route to reduce errors, increase productivity, increase organization, and ensure quality compliance. It only made sense for a software design and development company to use a highly configurable application to meet our needs,"

Dominique Winslow
Manager of Regulatory Quality and Compliance
RQC

BIGGEST EQMS CHALLENGES

Medullan, founded in 2005, focuses on solution design and development. It also boasts of research, quality, regulatory, and compliance capabilities that are critical in decentralized clinical trials.

Medullan's previous electronic quality management system (eQMS) served its basic needs, but the company was keen on improving its processes and adopting a more robust system.

Postmarket surveillance (PMS) was one of Medullan's biggest challenges in the past. The company's previous QMS was ineffective and insufficient in addressing PMS requirements. Users couldn't send electronic submissions to regulatory authorities from within the system. Specifically, the old system lacked the required fields and the capability for calculating metrics was also restrictive.

The RQC team determined the most critical functionalities Medullan needed before starting its search for a better eQMS. The team approached several software providers, which performed demos of their solutions, and then ranked the solutions based on their suitability.

IMPLEMENTING ASSURX EQMS

Life science companies face tremendous challenges in developing a new medical product, which typically takes many years and a lot of money to get approved by the FDA and other regulatory agencies. In the United States, it takes 10-15 years and costs about $2.6 billion to develop a new medicine, according to PhRMA, which represents the leading biopharmaceutical research companies in the country.

Medullan went live with the AssurX platform in December, 2022 with immediate positive results.

"As with any configuration, there were some unexpected issues. However, the AssurX team was always quick to respond and worked with us to resolve any issue, while also explaining why the issue occurred to begin with,"

Umer Rathore
Senior Quality Analyst
ZS

The challenges don't end after the product is launched either. Companies must maintain vigilance after their products reach patients and consumers—the very purpose of postmarket (PMS) surveillance, which refers to the monitoring of product safety. Companies must have a procedure for responding to any reports of quality problems, adverse effects, or complaints about their medical products.

Like most FDA-regulated companies, Medullan needed a robust PMS solution. Hence, the company prioritized the implementation of AssurX Complaint Management process, split into different views as required by Medullan's procedures:

- Complaints Management
- Complaints Management Overview
- Complaints Customer Service
- Complaints Clinical Investigations
- Complaints Engineer Investigation and Reporting

Medullan partnered with the AssurX Professional Services team for project implementation. AssurX implemented the complaints instances, followed by CAPA, Audit, Document Management, and Training modules. AssurX also provided training services to equip Medullan with the right know-how for a successful and smooth-sailing configuration of the system.

BENEFITS OF ASSURX

Medullan went live with the AssurX platform in [add month and year] with immediate positive results.

"The benefits were clear from the start. We were able to easily manage our eQMS with a configurable application. We had a small team to start up our SaMD manufacturing. Ensuring that we had the right system in place was critical," said Winslow. She explained the delicate balancing act of hiring the right number of people to achieve quality-driven goals without having to expand the staff beyond budget. Her team was able to generate cost savings by choosing AssurX instead of adding head count.

Rathore noted that AssurX addressed all of Medullan's PMS requirements immediately, adding: "We were able to implement a configurable solution that met all of our needs from the start." AssurX's complaints management solution also proved to be "perfect for the new EUMDR updates and FDA reporting requirements," said Winslow. The European Union's Medical Device Regulation governs the sale of medical devices in the region. The regulation, which took effect in 2021, raised the bar for device safety.

At the end of the day, the proof of the pudding is in Medullan's willingness and enthusiasm to recommend AssurX to other companies.

"While there is not a single eQMS that meets all the needs of a medical device company, AssurX is as close as it gets. It has the most features at a reasonable cost"

Dominique Winslow
Manager of Regulatory Quality and Compliance
RQC

Medullan lauded its partnership with AssurX. RQC team members praised how their AssurX counterparts were always available and quick to respond with any questions. "Anytime we had an issue, the AssurX team was generally able to resolve it on the same day or within the next business day," recalled Rathore.

After a successful project, Medullan is looking forward to implementing the design and development process and the validation management process.

CONCLUSION

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Jamieson Comer, RQC senior analyst, said she would recommend AssurX for its platform's configurable fit and its outstanding training services. "AssurX is highly customizable. Training with the team is extremely in depth, and learning to customize solutions is simple," she said.

Rathore agreed with Comer, saying AssurX's high degree of configuration meant "any workflow you need, you can create," plus you can always count on excellent customer service that provides immediate help with any issue.

"While there is not a single eQMS that meets all the needs of a medical device company, AssurX is as close as it gets. It has the most features at a reasonable cost," added Winslow.

ABOUT ASSURX INC.

With decades of expertise built into our extensive quality management and regulatory compliance software, the AssurX Quality Management Software Platform helps companies maintain quality and compliance standards, streamline workflows, and better manage any enterprise. Our configurable software and understanding of users' needs produce a unique system that easily adapts and scales as a customers' business evolves. AssurX is an ideal partner for regulated companies looking for better operational control and efficiency while staying compliant. Learn more.

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