

CASE STUDY

MIMEDX

MIMEDX, a Leader in
Placental Biologics,
Partners with AssurX to
Ensure Compliance and
Efficiency



AssurX



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Joanne Mowery
Electronic QMS (eQMS) project manager
MIMEDX

It's comforting to think that time heals all wounds, but it's not true for patients suffering from chronic wounds, a largely underdiagnosed, undertreated, and underserved population. Out of the more than 30 million Americans with diabetes, nearly three million suffer from hard-to-heal wounds that can sometimes lead to limb amputation.

MIMEDX, a leader in placental biologics, is helping address unmet clinical needs in advanced wound care, surgical recovery, and related areas. The company, founded in 2008, pioneered the processing and use of dehydrated amniotic tissue allograft, which greatly improves wound healing and prevents bacterial infection.

MIMEDX products are derived from human placental tissues, processed using the company's proprietary PURION® method. PURION allows the tissue to be dehydrated and sterilized, which lengthens the storage life of dehydrated human amnion/chorion allografts for up to five years instead of a few months. The company, based in Marietta, Georgia, has supplied over two million allografts to date.

BIGGEST EQMS CHALLENGES

Manufacturers of biologics products like MIMEDX are some of the most highly regulated companies in the world. For these companies, an effective quality management system (QMS) is critical to staying compliant and being competitive in the marketplace.

Some of MIMEDX's products are classified as a drug, while others are considered a tissue. Hence the company complies with the FDA's Current Good Manufacturing Practices for pharmaceutical companies under 21 CFR Parts 210-211, as well as the American Association of Tissue Banks (AATB) standards.

MIMEDX also adheres to ISO 13485, the international standard for medical device manufacturers, because it plans to expand its product line into devices. The goal is to eventually get certified under ISO 13485.

While MIMEDX has been using an automated document control system, many of its other quality processes were manual. When Joanne Mowery was brought in as the electronic QMS (eQMS) project manager at MIMEDX, the company had just chosen a new solution and was in the process of implementing it.

Right off the bat, Mowery saw that the new software was cumbersome and not user-friendly. "It wasn't the right solution," she said. The implementation was proceeding slowly. The software provider's unresponsiveness didn't help either.

Mowery's team began looking for a new solution. They turned to AssurX based on a recommendation. "The more I learned about the AssurX system, the more I loved it," she added.

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Dropping the ineffective software originally chosen and abandoning its implementation cost the company money. To justify the move and convince board members to invest in AssurX called for a strategic pitch. “We made a comparison chart with our rationale. We showed the board how our decision will save us money in the long run,” explained Mowery. The board approved the AssurX project.

IMPLEMENTING ASSURX EQMS

When it was time to implement AssurX, there was a change in MIMEDX’s senior leadership, which also affected the project. Instead of implementing the document control, training management, and change management solutions as planned, the team went with nonconformance management, corrective action and preventive action (CAPA), and deviation management solutions first because those processes were completely manual.

While an out-of-the-box implementation would have been faster, the team chose to configure the solutions according to their requirements. MIMEDX plans to move ahead with the second phase of the project, namely the implementation of document management, training management, supplier quality, and change management solutions. The company is also keen on integrating its homegrown system with AssurX down the road.

Asked what she would recommend to other companies when it comes to software implementation, Mowery said, “You need a good project plan in place. Do your homework and define your needs.”

BENEFITS OF ASSURX

Ease of use has always been Mowery’s top priority. It also turned out to be one of the biggest benefits of AssurX. “Selling a new system to users is difficult. If you don’t make it easy for them, they will not buy into it,” she said.

MIMEDX users have been performing trending of quality events manually, but with AssurX, the task has been automated. Other things Mowery likes are the system’s notification and reporting capabilities. “A supervisor can easily see the tasks that remain open. With just one click, the timeline and other information are available to the supervisor,” she said.

Mowery noted two critical factors in the project’s success: the AssurX platform’s configurability and the close partnership between MIMEDX and AssurX. “There was no need for us to submit a change order (to AssurX) for every item we wanted to modify because the solution was highly configurable,” she said.

She praised AssurX team members for their attention, expertise, and responsiveness throughout the implementation process, calling them “phenomenal.” It was quite in contrast to her experience with the previous software provider.

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CONCLUSION

Life science companies face enormous challenges in sustaining innovation and regulatory compliance in the face of fierce competition in the marketplace. MIMEDX is no exception. Neither the company’s old manual processes nor its initial automated system proved to be adequate for its accelerated growth, innovation and rigorous compliance needs.

Mowery described the old QMS as “up and down, in and out in every direction.” With AssurX, the company is finally getting the robust and effective platform it requires, and includes the ability to grow with them, befitting MIMEDX’s critical mission and commitment to patients and healthcare providers alike.

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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