intellect

Fluid Metering
Finds Their Flow With
INTELLECT QMS

THE COMPANY

Fluid Metering, Inc. (FMI) manufactures metering pumps and dispensers for OEM, Medical, Laboratory, Analytical, Industrial Process, and Environmental Services applications. The company pioneered the first valveless rotating and reciprocating piston metering pump concept in 1959 and has continued to drive leading innovation in the industry over the years, setting the gold standard for accuracy, precision, and durability.

FMI's mission is to continually drive innovation in partnership with Life Science technology providers to improve patient health and quality of life. To fulfill that vision, the company has built a culture of responsiveness and continuous improvement, providing industry-leading service to their customers and entire value chain around them. FMI's team prides itself on the high levels of trust and confidence their customers place in the company and its products.

THE PROBLEM

When Nazia Khan joined FMI as their Regulatory Affairs Manager in 2015, she found that the company cared deeply about quality, but they lacked the kind of agile, flexible processes and tools that could support them in delivering consistently on that commitment, and in doing so efficiently.

At that time, FMI's quality systems were paper-based. New requests involved completing a form and physically carrying that document to various managers for signoff. Document numbering was managed using a spreadsheet, and the resulting paperwork was uploaded to an internal portal so that others in the organization could access it.

Not only was this tedious and time-consuming, it also created significant challenges with respect to version control. Physical copies of the documents needed to be maintained for audit purposes, and every revision required the originals to be pulled, stamped, and refiled in a different location. Managing the flow of QMS documents was virtually a full-time job.

FMI was also having trouble maintaining accurate employee training records. This, too, was a paper-based system. Employee signatures were captured on physical documents, which were retained in filing cabinets to be retrieved later if needed. Training records were manually entered into a custom Access database as well, providing an electronic record for faster lookup.

Unfortunately, that database was highly unreliable, the data quality was poor, and it was only accessible to human resources and operations managers.

FMI's paper-based systems made it especially challenging to comply with ISO 9001 standards. Khan was spending an inordinate amount of time managing documents and ensuring accurate version control. That was preventing her and other FMI team members from performing higher value activities that could drive meaningful quality improvements at the company.

With FMI's decentralized paper-based systems, there was no way to produce meaningful reports about quality. Even if there had been a way to do it, the accuracy and completeness of the

company's paper-based data was highly questionable. Perhaps of greatest concern was the fact that FMI's manual methods placed the company at risk with respect to compliance.

When a new team of executives joined the company in 2016, they made quality one of the organization's strategic pillars. Top managers at FMI knew that in order to maintain the trust and confidence of their customers, their team needed reliable, repeatable quality management processes that could be executed both consistently and efficiently. They also wanted to get meaningful reports from their QMS system that could help them make better decisions. It was also important to reduce compliance risk and streamline access to information for improved audit performance.

THE SOLUTION

Nazia Khan and her team were charged with finding the right QMS software for FMI. She took what she called a "measure twice, cut once" approach to the process, – thoroughly researching all of the available options, talking to industry peers, and combing through software reviews from others in the medical device industry. She wanted robust QMS functionality that could address the needs of a highly regulated industry, but she didn't want the complexity and highly prescriptive processes that sometimes come along with that.

For Khan and her colleagues, flexibility and configurability were paramount. That's why, when they first saw a demo of the Intellect QMS platform, they loved what it had to offer. Khan and her team are not programmers, and they didn't want to hire expensive technical experts every time they needed to adjust one of their processes. With Intellect's extreme configurability, virtually any member of the team can design and deploy new processes and functions using a no-code platform, easily adapting the software to meet their needs.

Intellect was user-friendly, flexible, and affordable, and FMI found the Intellect team to be highly responsive to FMI's questions. Intellect's staff was extraordinarily knowledgeable about quality management, and they had direct experience with

QMS for medical devices. The team at FMI also saw Intellect's mobile apps as a strong plus, and they especially appreciated the automated flow of data across multiple QMS functions.

Nazia Khan and her team selected Intellect as their new platform for QMS. They opted for a phased rollout, deploying a few processes at a time in order to better understand the software's capabilities. As they did so, they came to realize just how powerful Intellect's no-code platform can be.
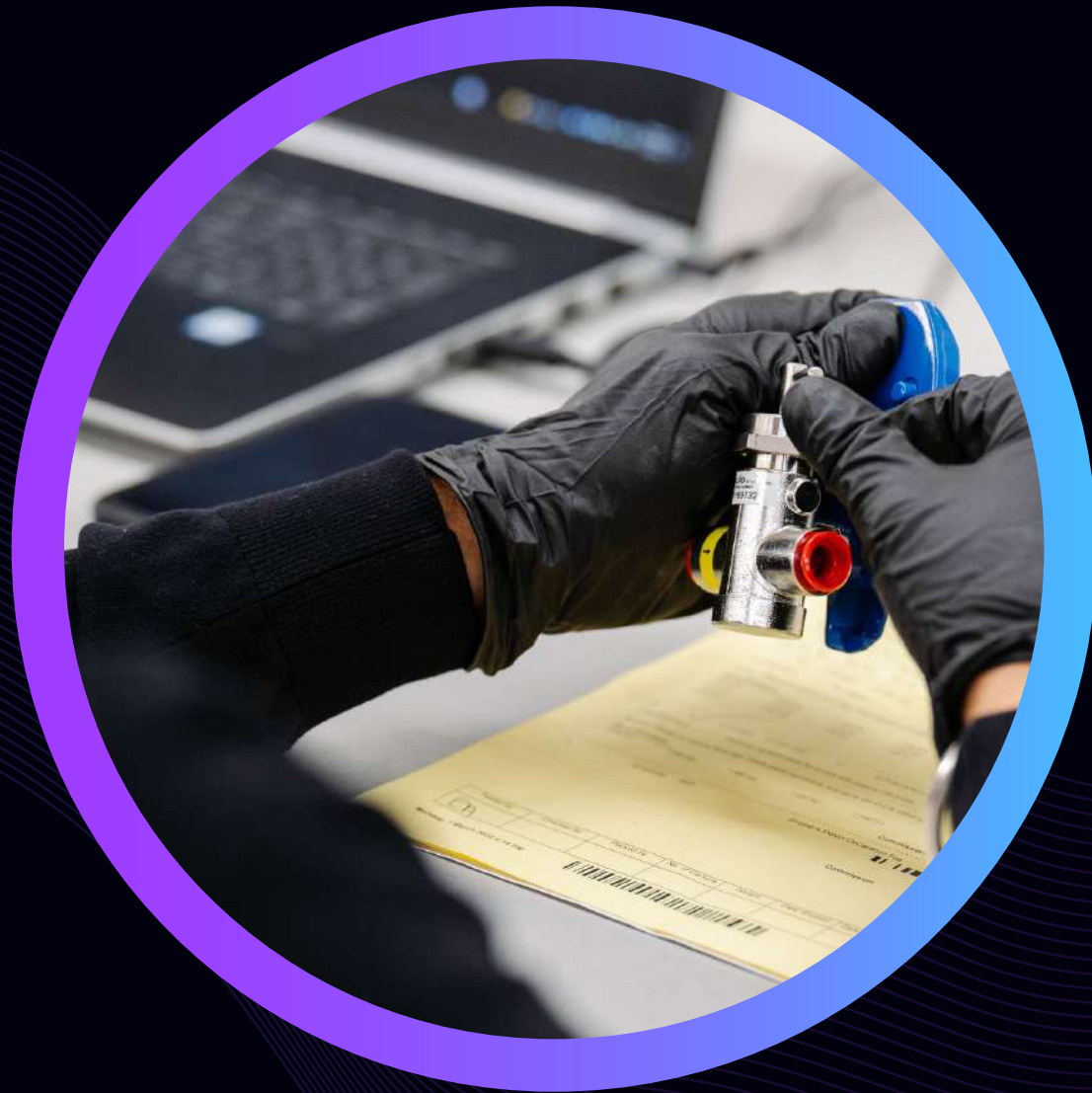
THE RESULTS

FMI's entire organization is thrilled with the results. They have eliminated their paper-based systems, freeing up valuable staff time to focus on high value tasks that advance the company's mission. The Intellect platform provides a unified database of information that covers all of their QMS and training processes.

Joe Caldarola, Quality Assurance Specialist at the company, describes his team's experience with Intellect QMS: "We are now able to track a process from the beginning to the end, and see how it was done." For FMI's team, that was a radical change for the better. Intellect's cloud access and mobile apps have been especially helpful in driving increased speed and efficiency. "For a user to have the capability to

sign in from their laptop or to use the app to review and sign documents is extremely helpful to make sure a process doesn't get stalled, or stop," Caldarola noted. This flexibility was especially important during the COVID pandemic, when employees were frequently required to work remotely. Intellect helped keep the company running smoothly throughout that period.

Intellect has also received high marks from the FMI team when it comes to flexibility and usability. "For me, having no prior experience in software programming or implementation," explained Caldarola, "it was very reassuring from a design aspect, to see how user friendly Intellect is. From the user side, it was really refreshing to see how easy the software is to use. From the quality

side, being able to have an automated system helps us immensely with regard to compliance."

Nazia Khan and the entire team at FMI are thrilled with their decision. They have successfully leveled up their approach to quality management, delivering on the strategic imperative set forth by the company's top executives.

"We have a lot of future plans for Intellect because we love the platform so much,"

Khan commented. "With the help of Intellect we have been able to successfully automate our document control and supply chain processes, which has enabled us to strengthen quality and compliance.

"IT'S A SUPER EASY AND EFFICIENT WAY FOR US TO CONDUCT OUR QMS FUNCTIONS. PEOPLE LOVE IT."