Streamlining quality processes with ETQ

Owen Mumford Slashes Audit Findings, CAPAs, and NCRs with ETQ Reliance

Owen Mumford is a leader in the design, manufacture, and advancement of medical devices, commercialising medical products for its own brand and custom device solutions for the world's major pharmaceutical and diagnostic companies. The company has a global presence across the UK, USA, Europe, and Asia and is committed to developing innovative solutions that improve patient care and healthcare outcomes.

Owen Mumford is widely recognised for its expertise in maintaining high-quality standards in the development and manufacturing of medical devices. To support this the company operates with a continuous improvement ethos, even when performing well, where their quality team identified the need to automate internal quality processes. This led the company globally deploying ETQ Reliance, to achieve improved efficiencies and optimise their resources.

Challenge

Like other life sciences and medical device organisations, Owen Mumford faced multiple competing challenges; it needed to adhere to FDA regulations, mitigate quality and compliance risks, and protect its brand value. And while the company's previous paper-based system seemed to be keeping pace, its quality team realised that to remain competitive and future-ready, an electronic quality management system (QMS) was needed.

The company's paper-based quality solution was resource-hungry at a time when the business needed to be lean, impacting its agility. Associates spent valuable time chasing paper trails rather than focusing on higher-value tasks. In addition, the paper-based quality approach didn't meet corporate social responsibility (CSR) goals or business objectives. And a changing workplace culture — including the rise of remote work, largely due to the COVID-19 pandemic and its nationwide lockdowns - reinforced the need to move to an electronic system.

"Having a paper-based QMS was a real challenge during the pandemic. As the world evolved with working patterns – more people working at home and hybrid working – having an electronic system made for a more compliant process that reflected these adaptations and improved our environmental impact at the same time," explained Paul Smith, Group Quality & Regulatory Affairs Director.

Owen Mumford's quality team had a strategic objective to achieve "one quality," ensuring that all the sites across the globe used a single set of quality metrics reporting into a single, centralised system that allowed the quality team to maintain oversight. The quality solution they chose needed to be flexible and scalable, as the company regularly added new sites.

Solution

Owen Mumford considered a variety of quality solutions, ultimately selecting ETQ Reliance.

The company took a phased approach to its quality journey, first identifying high-risk elements to prioritise and validating them internally. The quality team kicked things off with a global rollout of ETQ's document control module.

Next, the team focused on integrating with Epicor (an ETQ partner)— the company's enterprise resource planning (ERP) system — something they could accomplish directly with ETQ's project team without the need for third parties.

Previously, nonconformance and product control were separate workstreams. When a nonconformance was raised, associates had to log in to Epicor and put products on hold. With the ERP integration complete, ETQ successfully transformed what once was a two-part process into a single one, allowing associates to access necessary systems without having to log in to multiple pieces of software.

The rollout process wasn't without challenges, which the quality team and ETQ worked to overcome. Owen Mumford's quality team got buy-in for the electronic QMS from top leadership, helping quell concerns. They addressed change-resistant individuals and teams directly, explaining the transition to the new system and the benefits it would provide. To mitigate the chances of system issues, they performed data cleansing tasks before migrating to the new system, ensuring they were using the best data available when the system went live.

Results

Owen Mumford has realised numerous benefits thanks to its quality journey with ETQ. Specifically, the company has improved its audit performance compared to previous years. All four of Owen Mumford's manufacturing sites have been FDA-inspected since 2015, and no 483s — FDA forms issued after an inspection when an investigator concludes the firm may have violated the FDA act or other regulations — have been issued.

Additionally, corrective and preventative actions (CAPA) across UK sites are down 45% from 2016 to 2021. Decreased CAPA led to fewer nonconformance reports (NCRs) and fewer complaints in the UK — down 50% from 2016 to 2021. These factors have combined to improve customer perception, shifting customer opinion about the company from "average" (albeit it on the low side) to "excellent" (highest possible category) and award-winning.

With its collaboration with ETQ, Owen Mumford has achieved an atmosphere of unconscious compliance, creating a true quality culture across its organisation. The company is still at the beginning of its digital transformation, with plans to move closer

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to its goal of "one quality" by encompassing as many business areas as possible within the ETQ Reliance software.

About ETQ

ETQ is the leading provider of quality, EHS, and compliance management software, trusted by the world's strongest brands. Nearly 600 global companies, spanning industries including pharmaceuticals, electronics, heavy industry, food and beverage, and medical devices, use ETQ to secure positive brand reputations, deliver higher levels of customer loyalty, and enhance profitability. ETQ Reliance offers built-in best practices and powerful flexibility to drive business excellence through quality. Only ETQ lets customers configure industry-proven quality processes to their unique needs and business vision. ETQ was founded in 1992 and has main offices located in the US and Europe. To learn more about ETQ and its various product offerings, visit www.etq.com.

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