CASE STUDY

Owen Mumford slashes audit findings, CAPAs and NCRs with Octave Reliance

Key facts:

Company:
Owen Mumford

Website:
www.owenmumford.com

Industry: Medical Device Manufacturing

Country:
United Kingdom

Octave products used:
Octave Reliance® *(ETQ Reliance)*

Key benefits:

- Zero FDA 483s issued across all manufacturing sites since 2015
- CAPAs reduced by 45% and complaints down 50% (2016–2021)
- ERP integration streamlined nonconformance and product control workflows

Owen Mumford is a leader in the design, manufacture and advancement of medical devices, commercializing 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 recognized 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 Octave Reliance® (formerly ETQ Reliance), to achieve improved efficiencies and optimize their resources.

Challenge

Like other life sciences and medical device organizations, 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 realized 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, centralized 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.

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Group Quality & Regulatory Affairs Director, Owen Mumford

Solution

Owen Mumford considered a variety of quality solutions, ultimately selecting Octave Reliance. The company took a phased approach to its quality journey, first identifying high-risk elements to prioritize and validating them internally. The quality team kicked things off with a global rollout of the document control module from Reliance.

Next, the team focused on integrating with Epicor (an Octave partner) — the company's enterprise resource planning (ERP) system — something they could accomplish directly with the Octave Reliance 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, Octave 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 Octave 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 realized numerous benefits thanks to its quality journey with Octave Reliance. 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.

Quality journey

Manual
Processes were impacting OM from being agile in an ever-changing business environment

Document control
Global rollout to launch their "One Quality" strategic vision

ERP
Integration using Octave Partner Epicor

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 Octave, Owen Mumford has achieved an atmosphere of unconscious compliance, creating a true quality culture across its organization. The company is still at the beginning of its digital transformation, with plans to move closer to its goal of "one quality" by encompassing as many business areas as possible within the Octave Reliance software.

About Owen Mumford

Owen Mumford is a leader in the design, manufacture, and advancement of medical devices, commercializing medical products in its own brand and custom device solutions for the world's major pharmaceutical and diagnostic companies. It has pioneered the evolution of medical devices for almost 70 years with solutions for the ease and comfort of administering life-saving medication, safe and comfortable blood sampling and testing and rapid professional and self-diagnostic testing kits. The company has a global presence with facilities in the UK, USA, Europe, and Asia and is a trusted partner to many of the world's biggest diagnostic and pharmaceutical companies.
For more information, visit www.owenmumford.com.

About Octave

Octave is a leader in enterprise software, turning data into decisive action and intelligence into your edge. Our software solves for and simplifies complexity, from the design and build to operations and protection of people, property and assets – for any scope, at any scale. For decades, we've partnered with customers to sharpen performance, elevate efficiency and amplify results. From factory floors to entire cities, our solutions are tuned to scale up what's possible from day one onward.

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