CASE STUDY

Avanos uses more than 25 Reliance applications to automate several critical quality management processes

Key facts:

Company: Avanos

Industry: Medical Devices

Country: United States

Octave products used: Reliance *(ETQ Reliance)*

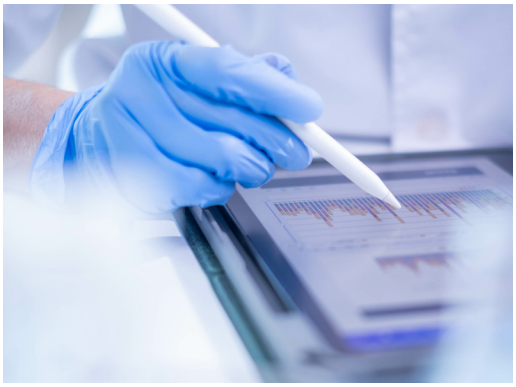
Key benefits:

- Achieved $2.79M in annual savings with 60-92% reduction in lead times across audit management, calibration and quality review processes
- Deployed 25+ custom and out-of-the-box applications for document management, CAPA, change management and non-conformance
- Early MDSAP adopter satisfying requirements of 5 regulatory jurisdictions through single audit program

In 2016, Avanos made the decision to adopt the Medical Device Single Audit Program (MDSAP). This program allows medical device manufacturers, like Avanos, to conduct a single regulatory audit of their quality management systems in order to satisfy the requirements of multiple regulatory jurisdictions for countries including Australia, Brazil, Canada, Japan and the United States.

As an early adopter of MDSAP, the company needed to revisit its quality management strategy and processes in order to ensure compliance and quality excellence under this new system. Avanos designed a unique Audit Management module on Reliance that was specific to MDSAP and satisfied the requirements of all five jurisdictions. The company also knows that it must continually improve EHS programs to continue to lead in an era of dynamic regulatory changes and stronger compliance obligations.

Avanos is a Medical device company focused on delivering clinically superior breakthrough solutions in the area of chronic and acute pain and digestive and



respiratory care that helps patient get back to the things that matter. Avanos develops and manufactures market recognized brands in more than 90 countries. recognized brands in more than 90 countries.

On October 31, 2014, Kimberly-Clark Corp. completed the spin-off of their Health Care Division as Halyard Health Inc. which then rebranded itself to Avanos Medical Inc. after divesting the surgical and infection prevention division to Owens & Minor.

Business challenge

Avanos' effort to automate its quality management system (QMS) was driven by the need for the company to:

- Reduce the complexity of its current systems
- Drive standardization across global manufacturing and marketing sites
- Reduce compliance and regulatory risks

Quality journey



Complex system
Reduce complexity of existing system



Harmonization
Drive standardization across global manufacturing sites



Regulatory
Reduce regulatory risks

Solution

After evaluating several quality management solutions, Avanos selected Reliance as its web-based, enterprise system for quality and compliance management in 2012. Reliance stood out because the software is based on quality management best practices — yet workflows, forms, sections, fields, reports and even the look and feel of the systems can be configured to enable configured without programming.

Through the various changes associated with multiple spinoffs and the ultimate rebranding to Avanos, Reliance remained the enterprise QMS IT tool of choice. With its robust, flexible automation capabilities and by design approach to holistic quality management, Octave's Reliance software managed Avanos' regulatory and compliance needs as it became MDSAP and ISO 13485:2016 compliant.

During the migration from Kimberly-Clark to Halyard to Avanos, all of the Reliance out of the-box solutions, as well as the range of configured and company built solutions and applications, were easily transitioned. Broadly, Avanos uses Reliance for document management, change management, corrective action (CAPA) and quality non-conformance.

Some of the firm's custom solutions built within the Reliance system include Reliance System Requests, Quality Review Board, Deviation, Quality Systems Strategic Planning, Calibration and Maintenance, Environmental Health and Safety Management, Design History File & Validation and Audit Management.

Results

Audit management: $500,000 savings annually and 92% reduction in lead time (time to complete a project)

Calibration: $400,000 savings annually and 80% reduction in lead time

DHF & validation: $900,000 savings annually and ROI of 326%

Quality review board: $990,000 savings annually and 60% reduction in lead time

Moreover, Avanos ensures compliance mandates are met by eliminating the risk of human error.

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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