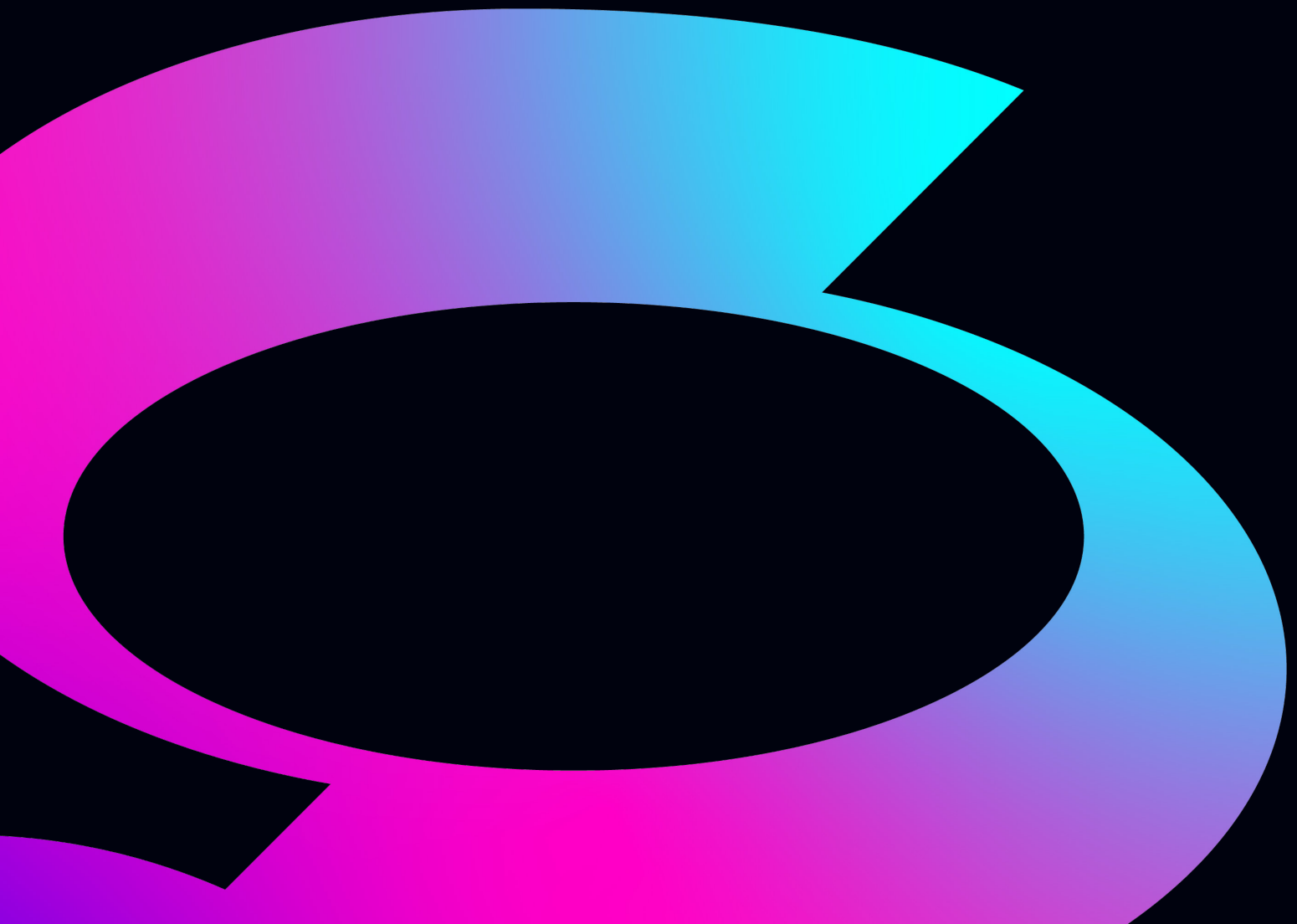




WHITE PAPER

Medical device industry challenges demand a best practices approach



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Medical device companies are navigating an evolving regulatory landscape that's rewriting the rules for how products reach markets in the U.S. and beyond.

The EU Medical Device Regulation (MDR) represents one of the biggest shifts in European device legislation in more than 20 years.

Manufacturers used to introduce products faster in the EU to collect post-market data before tackling the more stringent FDA approval process. The more rigorous MDR requirements are flipping that strategy. Companies may need to undergo FDA submission first, forcing many to rethink their marketing, sales and new product introduction approaches.

The stricter requirements have also cut the number of registration bodies in the EU by roughly half. This shortage could spell costly delays for companies that aren't proactive about certifying in accordance with the law.



The FDA is making moves too. Plans to replace the existing Quality System Regulation (QSR) with ISO 13485 for medical device risk management represent a paradigm shift in how the agency approaches regulatory approvals. Companies certified to ISO 13485 will have a competitive advantage. ISO 13485 also underpins the Medical Device Single Audit Program (MDSAP), which enables manufacturers to meet regulatory requirements in the U.S., Canada, Brazil, Japan and Australia through a single audit. Canada is the first country to require MDSAP certification, and a limited number of MDSAP-certified notified bodies means companies must act quickly to ensure continued access to the Canadian market.

Add to this the massive scale of mergers and acquisitions over the past decade that average more than 200 annually according to recent studies. Many companies now have an expansive global footprint that makes standardization difficult and creates hidden compliance risks.

Maintaining compliance while driving innovation at a globally competitive pace requires streamlined, agile quality processes that rapidly close the loop on quality issues. The balance of speed-of-innovation and compliance also requires a more sophisticated approach to managing quality data, one that enables the kind of deep insights needed to drive transformational change.

It's why big players in medical device recognize a critical need to implement automated quality management system (QMS) software, which provides a competitive edge through enhanced standardization and a best-practices framework for continuous improvement.



Octave Reliance (formerly ETQ Reliance) improves quality and shortens time-to-market

Some of the biggest names in medical devices use Octave Reliance because of its unique flexibility in helping solve their most pressing quality challenges

Avanos Medical

Avanos Medical is a medical device company focused on innovating new solutions for pain management, respiratory and digestive care. With 11 global sites and 12,000 employees worldwide, the device manufacturer needed a QMS that would reduce the time and resources spent planning, scheduling and reporting on up to 200 audits annually. The company's QMS also needed the flexibility to support multiple audit approaches that differed by location and division, including MDSAP, leading them to choose Octave Reliance to automate its internal audit program and streamline regulatory approvals.

Results

- 25% reduction in defects per unit
- Reduced cost of quality by 20%, saving \$30M in quality program costs
- \$10-12M in productivity gains over nine years

Virginia Blood Service

Virginia Blood Services (VBS) is a nonprofit organization that provides blood for nearly two-thirds of organ transplant patients in Virginia. One of the largest volunteer efforts in the state, VBS struggled with tracking a large number of documents as well as daily quality control (QC) data from its hematology analyzer. The organization used Octave Reliance's flexible platform to create customized, automated processes based on best practices that link together with QC review, document control and corrective action.

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- Reduced cost of quality by 20%, saving \$30M in quality program costs
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“Other systems could take a good year to get familiar with. We wanted something that users could springboard off of right from the get-go. We found Reliance to be that product.”

DiscGenics

DiscGenics

Biotechnology company DiscGenics develops innovative therapeutics to treat degenerative spinal diseases, including its Injectable Discosphere Cell Therapy (IDCT) made from donor-derived cells. Manual recordkeeping worked for the organization early on, but became error-prone and difficult to manage as the company grew. DiscGenics implemented Octave Reliance to integrate quality processes such as document control, corrective action, quality records and test validation, helping improve productivity and boost GMP compliance.

Results

- Replaces multiple manual processes with automated workflows
- Accelerates resolution of issues with electronic data capture and reporting
- Speeds up inspection process by eliminating many paper forms

Kimberly-Clark Corporation

A leading manufacturer of surgical and medical device products, K-C Health Care had a difficult time managing training requirements manually in order to comply with FDA GMP requirements. Octave Reliance provided the flexibility to create a custom employee training module that automatically creates a training profile for each employee and updates training records through integration with its learning management system (LMS).

Results

- \$650,000 per year in cost savings
- Payback period: three months
- Total ROI: 433%

If you'd like to reach out for a consultation,
contact Octave today or call: +1 (844) 293-3001

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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