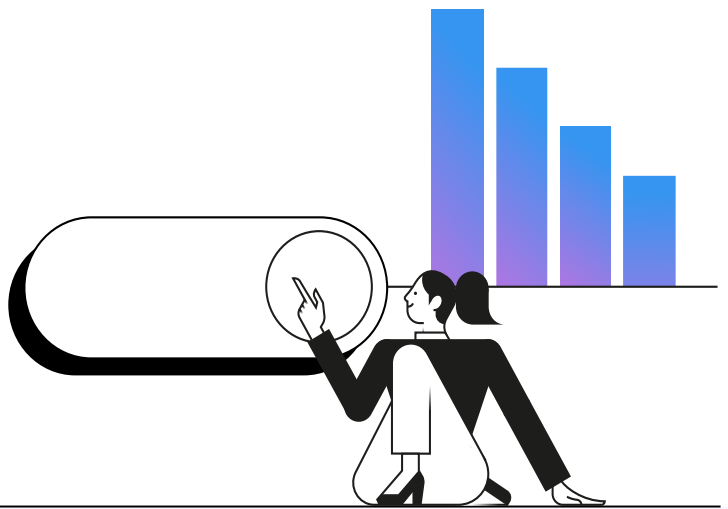


Driving MedTech Regulatory Compliance at CooperSurgical

Case Study

Powering International Market Access with Comprehensive Regulatory Lifecycle Support



Background

CooperSurgical is a global leader in fertility and women's health, providing innovative technologies that support IVF clinics and improve pregnancy outcomes worldwide.

As part of a strategic expansion of portfolio, they acquired several new products that needed to be integrated into their product lifecycle and regulatory framework.

Ensuring these products meet stringent global regulatory requirements is essential to maintaining market access and enabling registrations across multiple international markets.

The Challenge

- Integrating newly acquired products into an established regulatory framework created several operational and compliance challenges.
- CooperSurgical needed to rapidly align documentation, processes, and product files with evolving global regulatory requirements—including those from the EU, U.S., Canada, and other international markets.
- Consequently, they required specialized regulatory expertise and scalable operational support to ensure compliance while minimizing delays to product registration and market availability.

The Solution

Clarivate Regulatory Consulting

We provided end-to-end regulatory operational support across the product lifecycle, combining deep regulatory expertise with hands-on execution.

Working closely with CooperSurgical's regulatory team, we supported the development and alignment of key regulatory documentation and processes, including:

- Technical documentation aligned with EU MDR, U.S. FDA, Health Canada, and Brazil ANVISA requirements
- A change-management roadmap aligned with applicable legislation and ISO standards
- Execution of change controls and preparation of 510(k) Notes to File
- Development of Post-Market Surveillance (PMS) plans and alignment with Periodic Safety Update Reports (PSUR)
- Authoring and updating Risk Management Files (RMF)
- Design Input/Output Verification (DIOV) activities
- Biological Evaluation Reports (BER)
- Updates to labeling and readability documentation to ensure regulatory compliance
- This collaboration strengthened CooperSurgical's regulatory foundation and advanced product readiness for global markets.

The Results

A new partnership delivering strategic guidance and operational execution.

Through this collaboration, CooperSurgical gained a trusted regulatory partner capable of providing strategic guidance and operational execution.

"Clarivate is our trusted partner—bringing consulting expertise in regulatory compliance, from scientific writing and impact assessments to regulatory intelligence. Their insights help us spot trends early and stay ahead of change, so we can navigate complex frameworks and accelerate innovation—because families shouldn't have to wait. Together, we're shaping the future of women's health, raising the standard of care, and bringing hope to millions worldwide."

Giancarlo Occhipinti, Senior Manager, Global Regulatory Affairs,
Fertility and Genomic Solutions at Cooper Surgical.

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