Medistri

Providing Sterilization & Laboratory Services for the world's most innovative healthcare companies.

From the Blog

Regulatory Consulting Services

January 26th 2026

As medical devices and pharmaceutical products progress from development to market entry, regulatory compliance becomes a critical success factor. Beyond testing and sterilization execution, manufacturers are increasingly expected to demonstrate a deep understanding of regulatory frameworks, validation principles, and lifecycle control strategies.

At Medistri, our MedBraid's Regulatory Consulting Services are designed to support manufacturers in navigating these expectations with clarity, structure, and confidence.

Regulatory Expectations Are Increasing
Regulatory authorities worldwide, including the European Commission, notified bodies, and international health authorities, continue to raise expectations regarding documented evidence, process understanding, and internal expertise. Manufacturers are no longer assessed solely on outsourced test results or third-party certificates. They are expected to:

- Demonstrate control over critical processes
- Justify validation strategies and worst-case rationales
- Maintain traceable documentation aligned with applicable standards
- Ensure internal regulatory knowledge is embedded within their organization

This shift makes regulatory consulting an essential component of a robust go-to-market strategy.

Medistri's MedBraid Approach
At Medistri, our MedBraid Regulatory Consulting is delivered by consultants with deep industrial experience in sterilization, validation, and laboratory testing. Unlike purely advisory services, our approach is integrated and practical: we draw directly from our in-house sterilization operations (EO and steam), microbiological and analytical laboratories, and real-world regulatory interactions to provide actionable guidance tailored to your product and processes.

Our support is not limited to theory. It is grounded in real processes, real audits, and real regulatory interactions.

Core Areas of Support
We offer targeted consulting across the key domains that drive regulatory success:

1. Regulatory Frameworks and Standards Interpretation In-depth guidance on applying international standards critical to sterilization and product safety, including:
- ISO 11135 (EO sterilization)
- ISO 17665 (moist heat/steam sterilization)
- ISO 11737 series (bioburden enumeration and sterility assurance)
- ISO 11138 (biological indicators)
- ISO 10993-7 (EO residuals)
- Relevant sections of the European and U.S. Pharmacopeias

We help translate these requirements into clear, product-specific compliance strategies.

2. Sterilization Strategy and Validation Expert support in designing and justifying effective sterilization approaches:
- Method selection (EO, steam, or alternatives) based on product characteristics and materials
- Definition of validation protocols, worst-case configurations, and loading patterns
- Process qualification (IQ/OQ/PQ), revalidation planning, and ongoing routine monitoring
- Development of robust sterility assurance rationales and release criteria

Integrated Support Across the Product Lifecycle
Medistri's MedBraid Consulting is seamlessly embedded within our broader portfolio of sterilization, laboratory testing, cleaning/reprocessing, packaging, and validation services. This vertically integrated model delivers clear advantages:

- Coherent alignment between regulatory strategy and operational execution
- Faster iteration during development and reduced risk of late-stage non-conformities
- Consistent data integrity and compliance from pre-clinical proof-of-concept through commercialization
- A single partner for technical and regulatory needs, reducing vendor fragmentation

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3. Process Control, Documentation, and Submission Readiness Assistance in creating and reviewing high-quality documentation:

- Validation master plans, protocols, and final reports
- Regulatory justifications and technical dossiers for submissions
- Standard operating procedures (SOPs) integrated with your quality management system (ISO 13485, 21 CFR Part 820, etc.)
- Traceable records designed to withstand notified body audits and authority inspections

4. Knowledge Transfer and Capability Building To foster long-term independence, we deliver customized training and knowledge transfer:

- Practical workshops on sterilization science, validation principles, and regulatory expectations
- On-site facility visits or virtual sessions
- Mentoring to strengthen your team's ability to manage future changes and audits

Regulatory compliance is dynamic, product modifications, scale-up, new standards, or updated guidance require ongoing adaptation. By partnering with Medistri early and continuously, manufacturers position themselves for audit readiness, efficient change management, and confident, sustained market presence.

If you are navigating complex sterilization validation, preparing for regulatory submissions, or seeking to strengthen internal capabilities, our team is ready to support your success.

To learn more about Medistri's MedBraid Regulatory Consulting Services, please contact your dedicated Customer Success Specialist or or contact us at customerservice@medistri.com.