Regulatory insights to meet evolving IVD QSM requirements

As the landscape of *in vitro* diagnostics continues to evolve, diagnostic sponsors face the challenge of complying with the latest pre- and post-market IVD Quality System Management requirements. At Beaufort, we specialize in guiding sponsors through the intricacies of the latest regulatory proposals and updates with expertise in global regulatory affairs and quality consulting, clinical trial services, and data sciences.

YOUR ROADMAP TO REGULATORY COMPLIANCE

Our team delivers comprehensive insights and tailored solutions to seamlessly navigate the complexities of new and existing regulatory demands and help ensure the clearest and most efficient path to market.

IVDR Implementation

Our strategic and technical guidance assists with the implementation of any stage of the IVDR certification process.

FDA Oversight of LDTs

We can apply our knowledge and experience with laboratory developed tests to effectively align your product development with FDA's proposed rule for greater oversight.

QSR to ISO 13485:2016

With an eye towards MDSAP or FDA inspection-readiness, our team's expertise and operational support can help you address FDA's new rule to align the QSR with international standards.

HOW BEAUFORT STANDS APART

IVD FOCUSED

Beaufort's team of industry specialists are dedicated to meeting the needs of diagnostic sponsors

PROVEN EXPERIENCE

20-year track record of success across 1000+ global clinical trials and 500+ regulatory submissions

PARTNERSHIP DRIVEN

Our team brings a shared sense of purpose, collaborative spirit, and deep commitment to our client's success

BEAUFORT

IVDR

The European Commission proposal to extend timelines comes with new transitional provisions (conditions) for certain IVD products adding to the ongoing changes and challenges in IVDR compliance. Beaufort can translate these complexities to understandable requirements and support all aspects of your implementation.

- Legacy and new device support
- Conformity assessments
- IVDR-compliant QMS assessments and implementation
- Technical documentation preparation and review
- Clinical evidence strategies
- Performance Study Documentation preparation
- Responses to Competent Authority / EC Review questions
- Labeling and UDI compliance
- Distance sale ("LDT") requirements

LABORATORY DEVELOPED TESTS

FDA's proposed rule to amend regulations to make explicit that IVDs are devices under the FDCA, including when the IVD manufacturer is a laboratory, represents a dramatic shift and will lead to greater oversight of certain LDTs. Our team can assess and support the impact on your existing and new product development.

- Classification assessments
- QMS design and support
- LDT verification and validation
- FDA Inspection readiness
- Pre- and post-market submission support

QSR TO ISO 13485:2016

FDA's final rule aimed at harmonizing the QSR with international standards provides a February 2026 deadline for organizations to update systems to align with QMSR requirements. Our specialized experience can support your efforts to ensure compliance.

- QMS design and implementation
- Process and documentation review
- Gap assessment & remediation
- SOP development
- Auditing
- Inspection readiness
- Training

FIND MORE INFORMATION AT beaufortcro.com

GET IN TOUCH WITH US AT info@beaufortcro.com

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