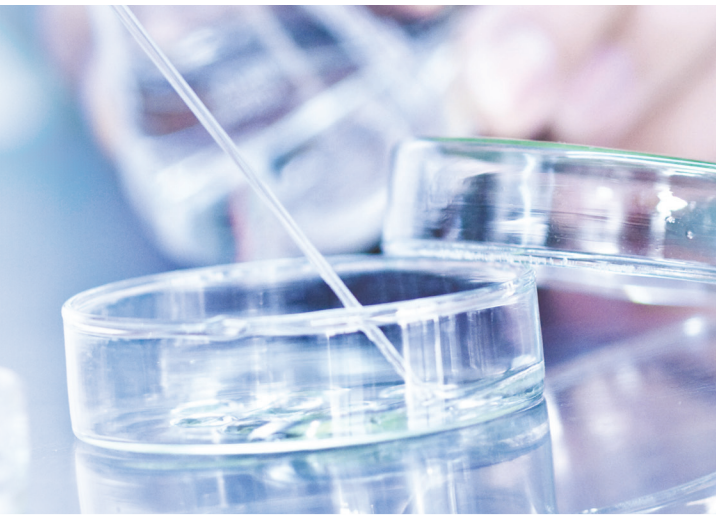
Beaufort®

Accelerating Medical Innovation



Are You Ready for IVDR?

The time for action is now!
The Beaufort IVDR Team Can Help

Beaufort is assisting sponsors with comprehensive services to optmize the transition from IVDD to IVDR.

Our IVDR subject matter experts understand the complex details, regulatory expectations and new mandatory requirements. We will design and implement a comprehensive IVDR Action Plan for your portfolio of IVDs on the EU market, which can include:

- IVDR Gap Analysis
  - Clinical data and documentation
  - General Safety & Performance Requirements (GSPR)
  - Quality system
  - Product classification
  - Technical documentation
  - Post-market surveillance
  - ISO 13485:2016
- Remediation and Implementation
  - Technical file and report updates
  - Clinical literature searches and data consolidation
  - Clinical trial planning and management
- Notified Body Support

Our IVDR team will provide the people, processes, and support needed to help you address the regulations.

About Beaufort CRO

Beaufort is an ISO 9001:2015 certified, global contract research organization that partners with in vitro diagnostic (IVD), companion diagnostic, medical device manufacturers and clinical laboratories to provide a full range of clinical, regulatory, and quality solutions, including IVDR expertise to meet new EU requirements.

For more than 15 years, companies worldwide have trusted Beaufort for its client-focused approach to research. Our deep industry expertise and tested and proven solutions have a track record of success in bringing our clients' products to market.

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