The *In Vitro* Diagnostic CRO

Beaufort®

Accelerating Medical Innovation

The Beaufort Difference

Focus on Diagnostics

Depth of Experience

Customized Solutions

ISO 9001:2015

Commitment to Quality

Founded In 2004

History of Proven Results

Choose Beaufort Because We Accelerate Medical Innovation

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Outcome-Focused Expertise

Our experience with hundreds of successful 510(k) clearances, PMA approvals, clinical trials, and consulting engagements ensures that our clients receive:

- ✓ Improved IVD research performance
- ✓ Well-run clinical trials
- ✓ Enhanced data integrity
- ✓ Better control and quality
- ✓ High-performing investigators, sites and labs
- ✓ Reduced time to market

"Beaufort's ability to grasp and articulate clinical value in the field of in vitro diagnostics enabled our company to strategically align our FDA trials and submissions to meet the ever-increasing standards of the FDA."

Manager, Clinical and Scientific Affairs, Leading Global Diagnostic Company

Beaufort Services

Beaufort maximizes operational and regulatory success by providing more specialized IVD experience than any other CRO

Clinical Trial Services

- Clinical Trial & Analytical Testing Management
- Monitoring Services
- Data Management & Biostatistics

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Regulatory Services

- Global Regulatory Strategies
- US Pre-market Submissions
- OUS Regulatory Expertise

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Quality Solutions

- Global QMS Compliance
- Remediation Services
- Mock Audits & Inspections

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Staffing Solutions

- Flexible Staffing Models
- Network of Clinical Professionals
- Global Reach

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We Know Diagnostics

Beaufort's team is highly proficient in managing all aspects of clinical trials and developing regulatory strategies across a wide range of technologies and therapeutic areas.

Areas of Expertise

- Professional Use *(Clinical Lab)*
- CDx
- POC
- OTC / Home Use
- LDTs
- CLIA Waived
- Artificial Intelligence / Machine Learning in Software

IVD Technologies

- Lateral Flow
- microRNA
- Molecular Dx
- NGS
- Immunoassay
- IHC
- FISH
- Flow Cytometry
- Clinical Chemistry

Global Regulatory

- 510(k), De novo & PMA
- Pre-EUA / EUA
- CLIA Waiver
- Pre-sub/Q Mtgs
- Risk Determinations / IDE
- Technical Files / Dossiers
- Int'l Classification & Conformity Assessments

Therapeutic Areas

- Infectious Diseases
- Oncology
- Cardiovascular
- Women's Health
- Nephrology & Endocrinology
- Immunology
- Neurology
- Hematology
- Pediatrics

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Beaufort By The Numbers

400+

Regulatory Submissions including 510(k)s, PMAs, IDEs and CE-Marks

375+

Clinical Trials Across a Wide Variety of Indications and Testing Platforms

2,650+

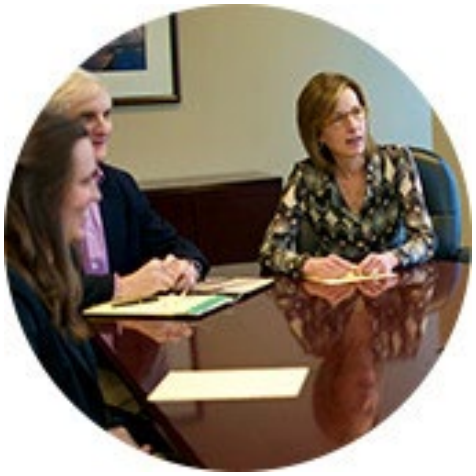
Clinical Professionals in Over 40 countries

15+

Years of Beaufort Leadership in the IVD Industry

600+

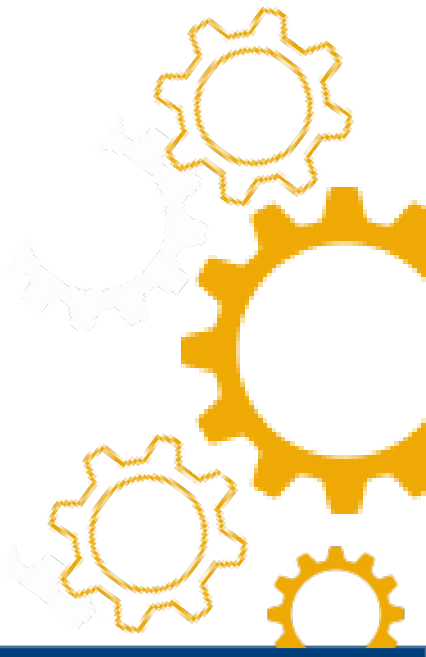
Clinical Study Sites Around the Globe



Beaufort's Commitment to Best-in-Class Solutions

Our People, Our Processes, Our Solutions

- ✓ Client-Driven Approach
- ✓ Tested and Proven Solutions
- ✓ Deadline and Communications Focused
- ✓ Flexible to Meet Client's Needs
- ✓ Highly-Skilled Global Team
- ✓ Deep Industry Expertise



"Beaufort was instrumental in helping us launch a product line that was a key component of our growth and strategic plans."

Divisional Vice President, Top 10 Global Healthcare Company

FOR MORE INFORMATION

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Beaufort®

Accelerating Medical Innovation

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