The *In Vitro* Diagnostic CRO

Beaufort®

Accelerating Medical Innovation

Choose Beaufort Because of Our People, Processes and Proven Experience

The value of expertise cannot be overstated, especially when it comes to streamlining complicated *in vitro* diagnostic research projects. At Beaufort, we bring to every client the knowledge gained from a leadership team that averages more than 30 years of industry experience. This has earned us a reputation for being responsive and efficient – and developing customized solutions that help establish and maintain excellence for our clients.

Beaufort maximizes operational and regulatory success by providing more specialized IVD expertise than any other CRO. We offer client-focused solutions across a wide array of IVD assays including personalized medicine, molecular diagnostics, biomarker verification and validation, and conversion of laboratory developed tests to globally regulated diagnostic assays.

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

- ***Improved IVD research performance*** through our deep understanding of the specific requirements and nuances of diagnostic studies
- ***Reduced time to market*** as a result of our effective regulatory submission and negotiation strategies
- ***Well-run clinical trials*** through efficient clinical project management
- ***Maximized project viability*** utilizing our successful protocol and study plan designs
- ***High-performing investigators and sites*** because of our rigorous evaluation process and proprietary site database
- ***Better control and quality*** through our established data collection and management plans

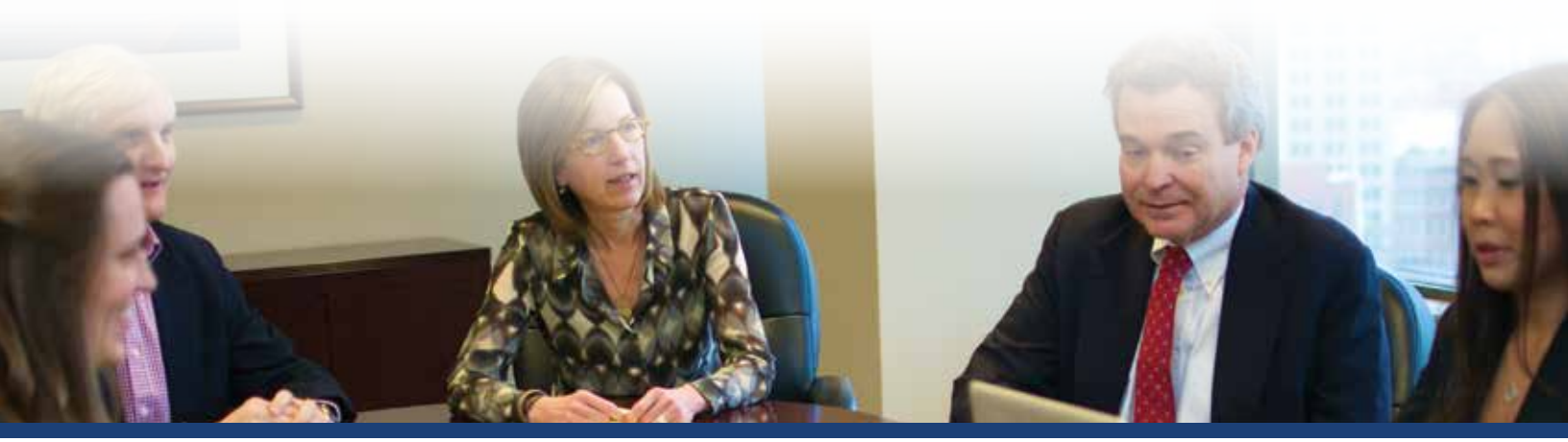
Whether you need Clinical and Regulatory Services, Data Management and Biostatistics, Quality Solutions or Staffing Solutions, Beaufort has earned a reputation for excellence as the diagnostic CRO with a commitment to best-in-class solutions.

Specialties

- Molecular diagnostics
- Companion diagnostics
- Genomic and proteomic testing
- Home use tests
- Laboratory developed tests
- POC / CLIA waived tests

IVD Therapeutic Expertise

- Allergens
- Cardiology
- Clinical chemistry
- Diabetes
- Genetic testing
- Hematology
- Immunology
- Infectious diseases
- Microbiology
- Oncology
- Respiratory diseases
- Women's health and prenatal testing



Clinical Trial Services

Beaufort specializes in comprehensive IVD study management and monitoring. We fully manage and provide strategic assistance for every stage of your IVD product development. Or we will provide one or more stand-alone services to complement your internal resources. Services include:

- Clinical trial strategy / Trial design
- Clinical site selection and initiation
- Clinical trial management and coordination
- Selection, training and management of clinical research associates (CRAs)
- Safety management
- Data management and biostatistics
- Clinical report preparation
- FDA BIMO / Clinical site / Sponsor audits and training
- SAS programming services
- CLIA waiver studies

Regulatory Affairs

A sound regulatory strategy sets the foundation for successful health care innovation. This is particularly relevant when developing medical devices including highly sophisticated IVD products as well as laboratory developed tests that face increased oversight and evolving regulations. With hundreds of submissions in our portfolio, Beaufort supports successful scientific innovation for IVD companies in the U.S. and globally. Services include:

- Regulatory strategy
- Device classification
- Intended use statement
- Predicate device identification
- Clinical protocol design
- Regulatory agency liaison
- Decision tree analysis guidance
- Regulatory consulting and training
- Regulatory submissions
  - Pre-submissions
  - Investigational device exemption (IDE)
  - Premarket notification (510(k))
  - De novo (evaluation of automatic Class III designation)
  - Premarket approval application (PMA)
  - Request for designation (RFD)
  - CE mark
  - CLIA waiver
- Post-market support
- Statistical support (sample size and SAP development)

Companion Diagnostics

As the delivery of individualized medicine becomes more prominent, so does the need for IVD companion diagnostic devices. Our broad therapeutic knowledge, worldwide reach and experience in developing specialized diagnostics make us a tested and proven choice for companion diagnostics. We help companies:

- Develop IVD companion diagnostic devices to identify patients most likely to benefit from a therapeutic product
- Identify patients most likely to be at increased risk for serious adverse events as a result of treatment from a therapeutic product
- Develop complimentary diagnostics that monitor patients' response to treatment with a therapeutic product
- Develop follow-on or me too companion diagnostics

Our services include:

- Biomarker assay verification and validation
- Clinical trial assay development
- CDx device protocols
- IRB submission and approval
- Quality system regulation (21 CFR 820) compliance
- Preapproval inspection readiness
- Regulatory expertise
  - Pre-submission
  - Investigational device exemption (IDE)
  - Premarket notification (510(k))
  - Premarket approval application (PMA)
  - CE mark

"Beaufort's ability to grasp and articulate the 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

Staffing Solutions

Beaufort Staffing Solutions is the global staffing expert for the *in vitro* diagnostic industry. Set apart by unparalleled client support and our unique recruitment model, we deliver staffing solutions that drive client performance.

Our strength is a vast network of highly experienced IVD professionals and how we put that experience to work for clients. Because our network spans more than 40 countries, we can rapidly deploy a skilled and dedicated team to meet your needs wherever you are and ensure a fluency of the language and the culture.

Beaufort offers solutions across a full range of functional roles, including:

- Project Management
- Clinical Operations
- Quality Assurance
- Regulatory Affairs
- Data Management
- Biostatistics
- Medical Monitoring
- Medical Writing

Beaufort Staffing Solutions gives you flexibility. Whether you're staffing a single position or an entire team, seeking interim support or a permanent staff member, we deliver the professionals you need to get the job done.

"Beaufort's clinical trial monitors represent the Gold Standard!"

Senior Associate Director,
Top 15 Global
Healthcare Company

Quality Solutions

Beaufort's global operations provide unparalleled expertise in quality assurance services for IVD development. We go beyond establishing compliance to ensure conformance, control and continuous improvement.

With a full suite of services including GxP auditing, Corrective and Preventative Action (CAPA) management and compliance consulting, we help you design, optimize and review processes to ensure your product development adheres to regulatory guidelines and expectations.

Our services include:

- ***Quality system assessment and support*** including gap analysis, risk management, and system design, training and implementation
- ***Supplier management*** including audits, management programs and strategic sourcing
- ***Inspection readiness and support*** including mock inspections, interviews, and inspection management
- ***CAPA system design and management*** including system design and implementation, root cause analysis, tracking, prevention management and reporting
- ***Compliance*** including quality system audit execution (FDA QSR, ISO 13485, etc.) and FDA 483 responses

About Beaufort

Beaufort is a contract research organization that provides *in vitro* diagnostic, medical device and biopharmaceutical clinical and regulatory services, and a full range of quality solutions and staffing solutions. For more than a decade, companies worldwide have trusted Beaufort for its client-oriented approach to research. With operations spanning the globe, Beaufort has a proven track record working closely with clients and regulatory agencies internationally to bring our clients' products to market

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Learn more about Beaufort online at beaufortCRO.com. You can also contact us at info@beaufortCRO.com or 757-383-6000 to find out how we can put our experience to work for you.

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