Beaufort®

Accelerating Medical Innovation

Beaufort Quality Solutions

Beaufort's experience in guiding research has formed the basis for innovative quality services that assure data integrity and protect the safety of clinical trial subjects. Our primary focus is to assist our clients with the conformance, control and continuous improvement of their quality systems. We offer independent CRO quality oversight, good clinical practice (GCP) auditing solutions, GAP assessment and remediation and other quality and compliance services. Beaufort provides GCP services in over 45 countries worldwide.

Quality Oversight

Beaufort's quality oversight program critically assesses and provides objective and unbiased feedback on CRO and site performance in multiple GCP categories. Our assessment of CRO and other vendor performance, results in opportunities for early process improvement and cost and time savings. We offer:

- Third-party assurance to regulatory agencies of sponsor's commitment to CRO oversight
- Independent assessments to ensure the integrity of clinical trial data
- Better adherence to trial plans to reduce regulatory non-compliance
- Real-time CAPA to prevent delays and reduce costs

Quality Oversight Step-by-Step

- Quality oversight plan
- Strategic site selection
- Assessment and data gathering
- Metrics and reporting
- End-of-trial reporting and inspection readiness

"Beaufort's quality oversight provides exactly the type of feedback we need regarding CRO performance."

Director, Quality Assurance, Global Pharmaceutical Development Company

Proven Results

Challenge

The U.S. subsidiary of a large, international pharmaceutical company needed assistance in preparing for several regulatory inspections.

Solution

A majority of the company's clinical and regulatory staff had never participated in a regulatory inspection, and therefore, the company felt unprepared and ill-equipped to begin the process of ensuring regulatory compliance. Beaufort began the project by interviewing all pertinent personnel to ascertain their experience levels and determine the company's inspection preparedness. Then, Beaufort conducted extensive document reviews, mock audits and focused training sessions, both in seminars and one-on-one. Beaufort also developed white papers to share with regulatory authorities during the inspections. After a series of mock inspections and follow-up activities, the client passed all regulatory inspections — including a major FDA pharmacovigilance inspection — with minimal inspection findings.

GCP Auditing

Beaufort provides complete auditing services to assure compliance to regulatory requirements, industry standards and sponsor-specific expectations. Beaufort delivers clear and concise audit reports, rapid reply to client feedback, responsive change management, and global expertise in more than 45 countries. Our service areas:

- Clinical Audits
- CRO Audits
- Internal GCP audits
- External supply chain audits of vendors
- Pharmacovigilance

Compliance Services

- Quality system audit execution (FDA QSR, ISO 13485, etc.)
- Inspection and audit readiness (FDA, EMA, Brazil's ANVISA, etc.)
- Quality system and regulations training
- FDA 483 responses
- Warning letter remediation

Inspection Readiness and Support

- Mock inspections — interviews
- CAPA management
- Inspection management
- Post-inspection support

Quality System Assessment and Support

- Gap analysis to applicable standards
- Risk management
- Quality system design and implementation
- Quality system training
- SOP design, harmonization and implementation

Supplier Management

- Supplier audits
- Supplier management programs
- Strategic sourcing

Strategic Consulting

- Safety Surveillance and Pharmacovigilance
- Strategy & Document Management of the TMF
- Clinical Quality Program Development
- Rescue Compliance Support

"Beaufort's ability to perform gap assessments against multiple regulatory requirements made it possible for us to determine areas requiring quality system improvement and develop practical solutions and timelines for implementation of resulting CAPAs."

Divisional Vice President,
Quality, Top 10 Global Health Care Company

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Beaufort is a contract research organization that provides biopharmaceutical, medical device and *in vitro* diagnostic 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.

An ISO 9001:2015 Certified Company