

CASE STUDY: *The Value of Independent Quality Oversight for Sponsors*

WHY QUALITY OVERSIGHT HAS BECOME AN INCREASING NEED FOR SPONSORS

As the FDA is applying increasing pressure on sponsors to validate the work of their CROs, the need for independent quality oversight has become a critical element of the clinical trial process. Beaufort has been at the forefront of recognizing this unique need, and we are the first CRO to offer independent quality oversight services to help sponsors ensure CRO's are performing according to expectations and commitments as mandated by the FDA.

Beaufort's comprehensive approach to quality oversight is based on developing a QO plan that helps maximize CRO performance and identifies opportunities for early process improvement to help prevent delays and save cost. A key component of our QO service is a customized online dashboard that provides a quantifiable analysis of high-risk issues, allowing sponsors to easily identify key factors early in the process and make any corrections to maintain the integrity of their trial.

“The FDA investigators reviewed the Beaufort Quality Oversight reports and told us we’ve provided the proper oversight of our Phase III trial.”

Associate Director, Quality Oversight and Compliance, Top 20 Pharmaceutical Company

The Business Challenge

A global pharmaceutical firm needed in-process oversight of its CROs for a pivotal Phase III trial. Its rationale was twofold:

1. To obtain assurance that the clinical data could support a new drug application.
2. To demonstrate to global regulatory authorities that the sponsor had actively overseen the work of its CROs.

The Beaufort Solution

Beaufort developed a comprehensive quality oversight plan in collaboration with the sponsor which included detailed recommendations on assessment methodologies and timelines, site selection, KPI's, and monitoring and reporting strategies. Beaufort QO services included on-site assessment visits, managing CAPAs and other remediation activities, and early process improvement monitoring to identify protocol deviations and preventable non-conformances. Beaufort's assessors conducted site visits with CRAs in 35 countries and evaluated CRA and site compliance across 16 different GCP categories.

The Value-Based Result

Beaufort's quantifiable approach to independent quality oversight identified several key areas of non-conformance across multiple sites that would have potentially jeopardized the integrity of the study. For example, Beaufort's on-site assessors reported protocol violations in sample collection and storage across multiple sites which led to immediate corrective and preventive actions at over 30 regional sites. Additionally, our assessors discovered multiple discrepancies between the sponsor and CRO manual and provided recommendations for immediate corrective action. Beaufort's real-time reporting and process corrections improved CRO efficiency and prevented significant cost overruns and delays.

Upon completion and review of Beaufort's field assessment and monthly data analysis reports, FDA investigators determined that the sponsor met all contractual and regulatory requirements. In fact, the sponsor reported that Beaufort had "saved the day" in terms of inspectional efficiency.

Beaufort Reporting

Beaufort's team of highly-experienced assessors provided the sponsor with a detailed report including an executive summary, program overview, key findings including key risks and trends and patterns, and dashboard reports across all metrics. This action-based report was focused on immediate recommendations for their current study as well as actions to take for future studies. Sample reports are detailed below:

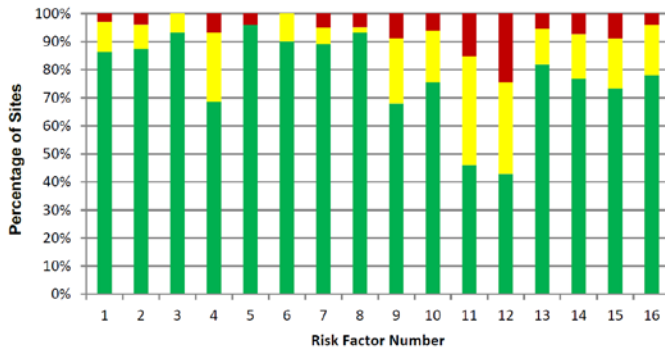
Key Risks Identified by Assessors: Cumulative Dashboard	Red	Yellow	Green
1. Adequacy of CRA resourcing	3%	11%	86%
2. CRA knowledge and understanding of study product, therapeutic area, project goals, objectives, timelines	4%	9%	87%
3. CRA organization and efficiency	-	7%	93%
4. CRA adherence to the Clinical Management Plan	7%	25%	68%
5. CRA communication style appropriate and has established positive working relationships with site personnel	4%	-	96%
6. CRA ability to identify problems and recommend solutions	-	10%	90%
7. CRA management of investigational product issues	5%	6%	89%
8. CRA oversight and management of maintenance of site personnel blinding status	5%	2%	93%
9. Adequacy of PI and site staff qualifications and training	9%	23%	68%
10. Adequacy of site facilities	6%	18%	76%
11. Site compliance with protocol	15%	39%	46%
12. Site compliance with GCP	24%	33%	43%
13. Site compliance with ABC Pharma/IRB/EC safety reporting procedures	5%	13%	82%
14. Site compliance with data entry and query resolution timelines	7%	16%	77%
15. Site compliance with investigational product management procedures	9%	18%	73%
16. Adequacy of PI oversight	4%	18%	78%



Beaufort identified 16 key risk factors customized to pivotal study parameters to be assessed by the quality oversight team during site visits with the CRO CRA's. Through a dashboard that showed cumulative scores across 103 sites, we quantified and identified areas that represented significant, potential, or no risk of regulatory non-conformance.

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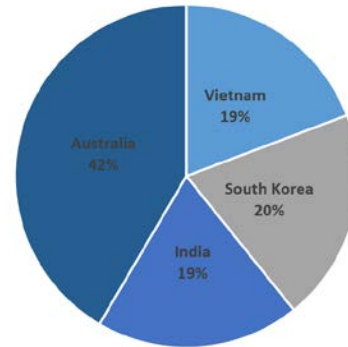
Key Risk Factor Scores



These are examples of several aggregate-level reports that Beaufort utilized to identify trends, patterns and relationships across all risks factors and sites.

Regional and country charts were used to demonstrate the areas that had the greatest percentage of high risk ratings.

Results by Region as Percentage



Beaufort also reported on the overall number of sites, as well as the specific site locations, that demonstrated a high risk of non-conformance across all 16 risk factors. This helped further identify any trends by site, and guide recommendations for compliance.



“Beaufort’s innovative quality oversight program allows us to ensure the integrity of our clinical research data and exceed FDA requirements.”

Director of Clinical Operations,
Top 20 Global Pharmaceutical Company

Key Risks Identified as “Red”	Number of Reds	Site ID Number
Site compliance with GCP	24	3111, 3167, 3190, 3166, 3014, 3268, 3145, 3003, 3276, 3221
Site compliance with protocol	15	3111, 3167, 3166, 3014, 3145, 3003, 3276, 3221
Adequacy of PI and site staff qualifications and training	9	3111, 3268, 3145, 3003, 3276, 3221
Site compliance with investigational product management procedures	8	3166, 3014, 3268, 3145, 3003, 3276, 3221
CRA adherence to the Clinical Management Plan	7	3111, 3167, 3190, 3166, 3014, 3268
Site compliance with data entry and query resolution timelines	7	3111, 3167, 3190, 3166, 3014
Adequacy of site facilities	6	3014, 3268, 3145, 3003, 3221
Site compliance with ABC Pharma/IRB/EC safety reporting procedures	5	3111, 3167, 3003, 3276, 3221
CRA management of investigational product issues	5	3111, 3167, 3190, 3166, 3014
CRA oversight and management of maintenance of site personnel blinding status	5	3014, 3268, 3145, 3003
CRA knowledge and understanding of study product, therapeutic area, project goals, objectives, timelines	4	3268, 3145, 3003, 3221
CRA communication style appropriate and has established positive working relationships with site personnel	4	3111, 3003, 3276, 3221
Adequacy of PI oversight	4	3111, 3167, 3276, 3221
Adequacy of CRA resourcing	3	3111, 3167, 3190

Beaufort can help you be better prepared for your next FDA inspection with a proactive approach to independent quality oversight.

Let us demonstrate how we can help you today.

Contact us @ info@beaufortCRO.com or call 757-383-6000