

Case Study: The Value of Being Inspection Ready



Situation:

A commercial stage biopharmaceutical client discovering, developing, and delivering cancer treatments was preparing for Health Authority inspection activities as part of their upcoming submission for their Phase 3 program.

To obtain approval and maintain their product on the market, compliance with relevant GxP (Good Practice) regulations and guidelines is required, and the client understands the value of GxP conformity and the consequences of noncompliance.

Halloran offered a customizable suite of GxP inspection readiness activities to select from to ensure study teams were prepared and successful during their anticipated inspection.

Challenge:

The client did not know where to begin, what to select from the full suite of inspection readiness activities, and how to turn those priorities into an actionable timeline.

Most personnel working on the program were hired after the study commenced, resulting in limited study history and institutional knowledge.

Additionally, the client recognized the need for additional expertise to perform GxP readiness assessments and required an independent review of their systems, processes, and documents to reduce any internal bias, offering a fair and objective lens of their gaps and challenges.

Solution:

Halloran began with an inspection readiness GxP gap assessment aligned to GMP QMS criteria and FDA's Bioresearch Monitoring (BIMO) manual. The assessment focused on identifying disparities people, processes, and electronic systems, compared to study, regulatory and training requirements and training, while identifying low, moderate, and high priority risks to provide the most value to the client.

Halloran's package right-sized for the client's needs included:

- Introductory inspection and storyboard training with Subject Matter Experts to ensure the foundational practices were in place
- Program-specific GCP assessment to examine inspection readiness state and identify remediation actions for the given clinical program

- Good Manufacturing Practice (GMP) quality management system assessment with associated actionable steps to redress any deficiencies
- Two-day on-site and virtual Subject Matter Expert and behavioral coaching to apply principles of answering questions during an inspection
- Three-day on-site BIMO mock inspection to practice learnings from prior inspection readiness activities and fine tune any learnings before the Health Authority inspection

Halloran's inspection readiness methodology, paired with the practical recommendations from the assessments with actionable inspection readiness timeline of activities, enabled the client to have a successful mock inspection, ultimately moving them one step closer to inspection success.

Lessons from these readiness activities motivated the client to incorporate this strategy and approach to other programs, providing an inspection readiness excellence roadmap.

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The guidance, training, and support that Halloran provided in our preparation for inspection was immeasurable. The team appreciates the challenges and questions from the Halloran team which provided awareness and identified opportunities for improvement in our systems, procedures, and presentation.

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~Dana Eisinger, Senior Director, Deciphera Pharmaceuticals

Inspection Readiness

A Health Authority inspection of a clinical trial can occur at any time in the product's lifecycle. Preparation is critical to ensure a strong opportunity for a successful inspection without findings, often leading to marketing approval. Sponsors ought to establish culture of quality in everyday activities yielding processes and behaviors that assert compliance and guarantee preparedness. Our quality, clinical operations, and regulatory experts understand exactly what the Health Authority is looking for and how to ensure your processes demonstrate compliance, and personnel are prepared to successfully endure an inspection and bring your company to the next stage.

To learn more about our inspection readiness services visit our website at hallorancg.com



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