

WCG AVOCA CASE STUDY: NOT JUST A MOCK INSPECTION

With Storyboarding, WCG Avoca Gives Pharma Client the Insight and Tools for a Successful Regulatory Inspection

OVERVIEW

By providing a mid-sized pharmaceutical client with more than a standard mock inspection and having the agility to pivot as the client's needs changed, WCG Avoca positioned the company for a successful regulatory inspection. WCG Avoca not only delivered clear and actionable findings; it helped the client design and execute a remediation strategy.

THE CHALLENGE

The client is preparing to submit an NDA and needed to ensure readiness for the upcoming regulatory inspection. That included knowing where it fell short and having the insights and tools to address any problems that emerged. A conventional mock inspection report would not be adequate, so the company turned to WCG Avoca.

SOLUTIONS

WCG Avoca customized a suite of solutions for the client that included the following:

- **A rigorous mock inspection:** WCG Avoca conducted a thorough three-day mock inspection that included all functional groups. Two weeks later, it delivered an extensive and exhaustive report – but that was just the beginning.

- **A comprehensive readout session:** After giving the client time to absorb the findings, WCG Avoca led a presentation in which it reviewed the observations, identified those of particular concern to regulatory agencies, and then facilitated a cross-team discussion. This collaborative approach to remediation included insights from WCG Avoca's subject matter experts (SMEs), which helped the client identify and address the root causes. WCG Avoca's SMEs talked through each observation, prioritized them based on highest inspection risk, and reviewed recommendations for remediation.
- **A pivot to storyboards:** The client had already scheduled a second session to discuss strategy. However, after the readout meeting, the client realized that one of the three highest-risk observations identified needed particular attention. So, they requested to transition the planned strategy session to an interactive storyboard session, which WCG Avoca SMEs participated in the next day. The client wanted to ensure the entire team – from QA to operations to clinical – was aligned. The storyboard session accomplished this: It helped everyone understand the issue in question and how to explain it confidently and consistently during an inspection.
- **Ongoing support:** WCG Avoca's SMEs remained available to answer questions that may arise before the actual inspection.

LESSONS LEARNED

A mock inspection is just the first step: Simply being handed a list of observations in a mock inspection report can be overwhelming. Sponsors need complete clarity on mock inspection observations – and cross-functional alignment – for inspection readiness. Sponsors also need a nimble partner who can adjust to meet its needs. In this example, once the client saw the observations, they decided to change course and ask for storyboard assistance. WCG Avoca pivoted and gave the client what it needed.

OUTCOME

The client dramatically improved its inspection readiness. They have clarity on mock inspection observations with awareness of those that pose the highest inspection risk. They also have a completed storyboard to ensure alignment on the most critical issues and an ongoing opportunity to connect with SMEs as needed.

Learn more about [WCG Avoca's Inspection Readiness Consulting Services](#). Contact us today to discuss your company's needs and ensure an inspection readiness state throughout your entire clinical program.