CASE STUDY:

MOCK INSPECTION CONSULTING PROJECT FOR A CLINICAL-STAGE BIOPHARMACEUTICAL COMPANY

AUGUST / 2020

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Background

As the GCP landscape continually evolves, sponsors are encouraged to pursue innovative approaches. Mock Inspections are a critical tool to ensure inspection readiness and a quality control step to confirm that the innovative approaches are being implemented in a regulatorily compliant way. Inspection Readiness needs to keep pace with this philosophy and to be proactive, risk-based, and agile.

A mid-sized clinical-stage biopharmaceutical company intended to submit a Biologics License Application (BLA) mid-year in 2019. The company requested that The Avoca Group conduct a 4-day on-site Mock Inspection with a regulatory agency focus on the FDA.

Because the company was a Member of the Avoca Quality Consortium® (AQC), Avoca's project team leveraged AQC leading practices, where applicable.

Solution

Based on discussions with the client, the scope of work outlined below was executed by Avoca.

Mock Inspection

- One mock inspector was present on-site.
- The mock inspection consisted of 4 days on-site to inspect the appropriate materials.
- The inspection included all the functional groups to mimic a true inspection. Avoca recommends that a point-person be provided for each function and the remainder of the staff is "on-call" for the mock inspection as a top priority.
- The final deliverable was a mock inspection report.
- Assumed FDA-focused prep.

Post-Inspection Remediation and Strategy Planning

- Avoca led a 4-hour on-site, post-inspection read-out and strategy session to prioritize findings and remediation efforts.
- Two Avoca Subject Matter Experts (SMEs) were present for the session. The expertise of the SMEs chosen for this remediation and strategy session aligned directly with outcomes and findings of the mock inspection.
- An implementation roadmap was built based on the outcome of the mock inspection and the remediation strategy meeting.
- The remediation strategy meeting occurred within 4 weeks from delivery of the mock inspection report.

Remediation Assistance

- Avoca provided up to 10 hours of remediation assistance time to provide consulting hours or manpower to close any of the gaps identified in the mock inspection.

Final Deliverables

- Mock Inspection Report
- Strategy Session Slide Deck which identifies and prioritizes all gaps identified in mock inspection
- Refined Remediation Plan from Strategy Session

Results

The Mock Inspection Report provided the company clear and actionable findings for the company to correct prior to the health agency inspection. In addition, the company was able to prepare and revise storyboards prior to the Remediation and Strategy Planning Meeting for the Avoca SMEs to review and provide feedback.

The company was an AQC Member company, therefore AQC leading practices, tools, and templates were utilized during the Remediation and Strategy Planning Meeting.

A specific finding in the Mock Inspection report was related to inadvertent omission of site information in the addendum to the CSR. The company shared that they were able to rectify this issue as part of the BLA filing.

Teachable moments were shared by Avoca SMEs with the Sponsor team during the Remediation and Strategy Planning Meeting regarding the similarities and differences in expectations among regulatory authorities.

In addition, the findings and lessons learned from the Mock Inspections and Remediation and Strategy Planning Meeting were able to be used and deployed by the company for new studies.

Conclusion

The company provided feedback to Avoca that going through the Mock Inspection process allowed them to identify and remedy issues prior to the regulatory inspection and BLA filing. The company shared with Avoca that the BLA submission was successful.

To inquire about Mock Inspection consulting support for your organization, contact Dawn.Auerbach@theavocagroup.com.