CASE STUDY

27 Days to Inspection Readiness: Leveraging Quality Expertise, WCG Avoca Provides Root Cause Analysis to Drive Process Improvement for Biopharmaceutical Operations

OVERVIEW

A mid-sized biopharmaceutical company approached WCG Avoca for quality improvement assistance with several Phase III clinical trials and overall clinical study operations. The goal was to achieve global process improvement in clinical operations as well as proactive inspection readiness utilizing mock audit observations from their Phase III programs anticipated for submission.

The client chose our team based upon our access to real-world data and leading industry practices from the Avoca Quality Consortium (AQC) plus our history of consulting success. A previous working relationship with WCG Avoca gave the client confidence that our quality standards and expertise would prepare them for regulatory submission and position them for continued future success.

THE CHALLENGE

The client was initiating inspection readiness activity for an upcoming regulatory submission. They had complex mock inspection findings in hand and needed subject matter expert assistance to perform root cause analysis. They also wanted corrective and preventative action (CAPA) plans developed to solve systematic issues and highlight the urgency in defining process improvement strategies.

This client needed an experienced consulting team with deep expertise in operational quality management for clinical trials. They also wanted a team that would work collaboratively with their internal stakeholders, leveraging combined industry knowledge and best practices. Together, we faced an extremely tight timeline – 27 days to inspection readiness. The WCG Avoca team confirmed that the client's objectives could be fulfilled within this ambitious timeline

SOLUTIONS

We accommodated the client's evolving requirements during the proposal process, designing a custom-fit project plan. To manage the short timeline, we enacted systematic communications to ensure that, as a collaborative team, we could achieve milestones and perform troubleshooting as needed. Communications included email correspondence two to three times per week minimum and four huddle-type meetings with stakeholders over the 27 days.

WCG Avoca provided the client with quality improvement solutions, including:

Review of mock inspection findings and root cause analysis:

We began by conducting an in-depth, expert analysis of the client's mock inspection findings. This analysis deepened our understanding of their current state regarding critical, major, and minor observations that could lead to regulatory authority citations – and potential damage to the client's brand. We then assessed the results and completed root cause analysis on key inspection observations determined to be critical, including systematic errors in their operations.

Corrective and preventative action (CAPA) plan development and review:

We developed one new CAPA plan and reviewed four CAPA plans drafted by the client, structuring them to be cohesive and comprehensive. One essential item missing was an effectiveness evaluation, which is now included in their process and embedded in their revised CAPA form.

Overall process improvement support:

Clarity of root cause analysis and in-depth CAPA plans improved the client's overall clinical trial operations. These process improvements and new insights will proactively prevent similar issues in their future study operations. The client has already engaged WCG Avoca to continue these holistic process improvement efforts.

Inspection readiness activity:

A successful project allowed the client to continue their inspection readiness activities – including operational procedural development – and helped them take a deeper look at their quality program while following their aggressive timeline for regulatory submission

LESSONS LEARNED

Clients need flexible support – rather than off-the-shelf solutions – to ensure that they receive the services and results needed. We listened to their problem statement and customized a fit-for-purpose solution to meet their needs.

Communication is key to ensuring collaboration among the WCG Avoca and client team and progress toward on-time, successful completion of all activities. Our consulting team was agile and handled changes in the plan – including the client's request for more frequent virtual collaboration – while remaining within a feasible project scope.

Next, today's sponsors expect cutting-edge quality improvement activities. Our leadership in the AQC allowed us to offer fresh insights and best practices for determination of the client's operational and inspection readiness needs. This experience, combined with the deep knowledge of our subject matter experts, made us this client's partner of choice.

The return on investment from implementing new quality improvement techniques is realized not only In accuracy and efficiency but in greater agility to move a molecule toward regulatory submission. During the project, lessons learned at the client site exponentially improved their overall quality program

Their team is now applying these new quality improvement skills and tools to their subsequent research programs.

Outcomes

The client was very satisfied with the perspective, recommendations, and work WCG Avoca delivered throughout the collaborative project. We met all their goals, supporting them in their race toward the 27-day finish line for inspection readiness. The client rated us "10 out of 10" for all service aspects in our Client Satisfaction Survey upon project completion. This perfect rating applied to the Net Promoter Score (NPS), signifying that they would recommend our quality services to others. The client noted:

"The (WCG Avoca) Client Delivery Team was professional, and I enjoyed working with them. They stayed in constant communication with me throughout the process. The agreement for the budget was very specific and detailed as to what would happen, so there were no surprises"

How can we help you improve quality as you strive to achieve meaningful clinical trial execution?

With WCG Avoca's range of services, you can choose the right solution for your organization's needs. To learn more, contact

Dawn.Auerbach@theavocagroup.com