

A Thorough Approach to Deviations

How a Structured Approach to Assessment Led to the Closing of More than 500 Deviations



In the wake of the COVID-19 pandemic, Azzur Group partnered with a leading CDMO to expedite the closing of a backlog of deviations that occurred due to accelerated demands. Azzur Group was engaged to handle the project management and technical writing aspects of the large project, including:

- Root Cause Analysis
- CAPA Management
- Close deviations within specified time frame
- Team leadership and stakeholder communication
- Escalate any issues to client stakeholders
- Schedule & attend client meetings to ensure timely closure of deviations
- Work cross functionally with stakeholders for root cause analysis & CAPA initiation
- Provide biweekly metrics to the client's Leadership team
- Utilize eQMS systems for deviation approvals
- Established several 'One Point Lessons' for continuous improvements resulting in faster deviation closures

THE CHALLENGE

Azzur Group was brought on board to advise and address the closing of a backlog of more than 500 deviations within a specific time frame of 10 months, despite various hurdles. These included changes in deviation closures, communication barriers, and a deficit in eQMS system training and staffing.

THE TEAM

A team of more than 25 Azzurians from multiple disciplines collaborated directly with the client, both remotely and on-site. Providing flexibility and access to a wealth of subject matter experts.

Azzur Washington, DC
Azzur Princeton
Azzur Austin
Azzur San Francisco

Azzur Denver
Azzur Philadelphia
Azzur San Diego
Azzur Raleigh

THE SOLUTIONS



Strategic Teams

Creation of strategic teams assigned to related deviations, prioritized according to risk profile



SWAT Teams

Collectively, authors and stakeholders work towards removing barriers and processing requests



Daily Open House

With stakeholders where authors can ask questions, both remote and in-person



Daily Internal Check-Ins

Enables the project manager to quickly identify and address urgent matters

THE IMPACT

The team successfully closed more than 500 deviations over the course of 10 months. In addition to Azzur's expertise and advisory services, this was accomplished through prudent project management, diligent teamwork, and open lines of communication between the client and Azzur.

Throughout the entirety of this collaboration, the Azzur team was able to address challenges head-on through mandatory daily huddles and SWAT team meetings. All issues were escalated for resolution to avoid delays in closing deviations. Azzur Group's technical writing experts helped the client get one step closer to resuming production.