Case Study:

Deviation Backlog Reduction, CAPA Management, and Long-Term Staff Augmentation

The FDA Group was pleased to support a large multinational pharmaceutical company's (Company) QMS remediation efforts. This project principally included deviation and CAPA backlog activities, signi icant corrective and preventive remediation throughout the quality system, and extended support to assist in staff onboarding, training, and maintaining the continuity of improvements made across the QMS.

A large team of contracted full-time consultants, sourced and managed by The FDA Group, served vital roles throughout these projects' planning and execution phases. These external professionals provided the Company with a convenient, cost-effective workforce option that circumvented the administrative costs and practical burdens of traditional hiring.

The Problem

The Company, citing a lack of bandwidth and specialized QMS remediation experience among internal staff, was experiencing a backlog of approximately 150 deviation investigations at one of its newest state-of-the-art pharmaceutical manufacturing sites. This backlog was growing at a rate of as many as 20 deviations a day and had taken the site out of compliance with the Company's internal SOPs. The site was also underperforming against industry-standard deviation closure rates.

Many of the deviations contained in the backlog were recurring. This indicated that the investigation backlog was preventing the Company from opening and executing the requisite CAPAs to address these underlying problems, thereby allowing them to express themselves as repeat deviations.

The deviations were primarily focused in six areas:

1. Automation and engineering
2. Upstream manufacturing
3. Downstream manufacturing
4. Validation/C&Q
5. Utilities engineering
6. Microbial control (environmental monitoring and critical utilities)

The Company approached The FDA Group to secure the skilled specialists needed to assess these deviations in detail, develop a strategic action plan for addressing them, execute that plan, and provide day-to-day project oversight and management.

The FDA Group's Approach & Solution

The first phase of the project involved a joint effort between on-site staff and The FDA Group's resources to:

- Analyze and precisely classify the deviations
- Determine which specific skillsets were necessary to conduct requisite investigations
- Determine how many external personnel were needed and how this team would be divided into groups to address the deviations by category
- Assign external personnel to address the existing CAPA backlog and handle additional CAPAs that would need to be opened as the backlog of deviations was worked through

The FDA Group, in cooperation with the Company, developed a strategy that consisted of mobilizing 17 external resources to carry out work projects over an initial three-month timeframe. Ten of these resources were assigned to handle investigations into the deviations. These resources brought a combined skillset in technical writing, investigation handling, root cause analysis, CAPA development, and GMP compliance, among other areas. These resources were further organized to address each of the six deviation categories prioritized by criticality.

The remaining seven resources were dedicated to CAPAs and other deviation prevention initiatives focused on eliminating the underlying problems expressed through the deviations and preventing them going forward. Each of these seven resources was assigned to a different role:

- Manufacturing execution system (MES) editor
- Electronic batch record testing and approval lead
- Systems lead
- Automation engineer
- Commissioning, qualification, and validation lead
- Manufacturing process and development lead (including URS and SOP writing)
- Equipment maintenance and reliability engineer (focused on manufacturing equipment and critical utilities)

Both the deviation and CAPA backlogs were then broken out with milestone goals throughout the three-month project timeline, with an overall goal of eliminating the backlogs.

Results and Extension

By deploying the expertise and strategic thinking of a team of traditional life science consultants through a convenient staff augmentation workforce model, The FDA Group accomplished its goal of eliminating all backlogs by the ~~end of 2020~~ on time and under budget.

The FDA Group was able to deploy all resources and start them on assignments within the same week. In addition, The FDA Group's development of a week-long intensive training program enabled the team to begin delivering on deviation closure by the end of week two. All external resources assigned to the project stayed on for the entire course of their involvement, with zero turnover.

After successfully completing its backlog remediation activities, The FDA Group's resources uncovered, resolved, and prevented all underlying problems expressed through deviations, thereby bringing the site back into compliance with corporate governance standards, specific SOPs, and industry benchmarks.

After this project, the Company requested an extension for select resources to stay on and address several issues that had emerged in the interim. The remaining resources were tasked with:

- Maintaining the continuity of the newly-strengthened quality system by leading or assisting in the onboarding and training of new staff following a period of internal turnover
- Temporarily filling internal roles that had been vacated as a result of recent turnover
- Providing extended assistance to execute and close CAPAs which required long-term remediation beyond the end of the initial project timeline
- Provide deviation investigation and closure assistance for new, critical projects related to COVID-19 vaccine production

This secondary project was given an open-ended timeline. The FDA Group's involvement concluded eight months later. Upon completion, the Company expressed total satisfaction with the results of all work projects.

- All impacted internal teams were fully staffed and trained.
- All outstanding deviations were addressed, and proactive improvements to deviation handling procedures and other components of the QMS resulted in a documented and verifiable state of control.

- Company SOPs were aligned with specifications and electronic batch records.
- The Company was outfitted with “deviation task templates” fit to the unique needs of its state-of-the-art manufacturing facility, improving closure rates.

Impressions & Feedback

Company leadership has consistently praised The FDA Group for its effectiveness in understanding the Company’s resource requirements, quickly stepping in and establishing familiarity with internal systems, and leading critical projects to timely completion.

The resources’ depth of knowledge, level of niche expertise, and professionalism were all cited by department leadership as uniquely valuable aspects of The FDA Group’s services. The Company continues to keep a close relationship with The FDA Group as continued growth brings more and more significant needs for outside support.