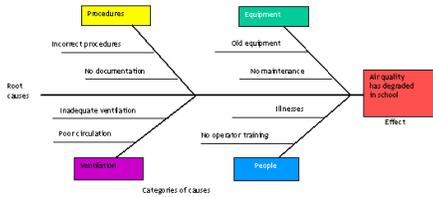


Compliance Support Leading to Reduction and Closure of Quality Notifications



In order to meet the constant demand for their products, our Global Pharmaceutical client retained the services of Brevitas consultants to provide compliance support and address open Quality Notifications by special investigation and effective root cause corrective actions.

AT A GLANCE

INDUSTRY

Pharmaceuticals

AREA OF EXPERTISE

Compliance & Operational Effectiveness

SERVICES PROVIDED

- Root Cause Corrective Actions
- CAPA and Change Control Management
- Technical Writing

DURATION

6 months

IMPACT

The special investigations into compliance-related issues prevented the initiation of repetitive Quality Notifications and contributed to the reduction of overall Q-Notes.

Business Challenge

As a leading Global Pharmaceutical Company, our client became concerned with their capability to close all their Quality Notifications (Q-Notes) in a timely fashion. They were also very committed to developing an overall understanding of all compliance issues affecting their operations and applying new processes that would allocate their resources more appropriately without having a significant impact to their overall Quality Operations. Excellence in investigation, root cause analysis and corrective strategies were vital to technical service effectiveness and regulatory compliance.

Our Scope

We played an active role in providing optimum reports into compliance related-issues by performing special investigations, gathering, analyzing and summarizing all data. This involved a thorough, exhaustive investigation into all initiated Q-Notes and implementation of effective root cause corrective actions (RCCA) and change control management activities.

Value Added

The compliance support we provided assisted our client in planning and organizing their day-to-day operations on a more consistent basis. Some of the key benefits that Brevitas consultants brought to this project included:

- Reducing the number of Quality Notifications by:
 - Collaborating with Quality Operations, SME, Sterility Assurance, Validation and Lead Investigators in a cross-functional team in order to determine the root cause and identify any other possible root causes
 - Developing metrics to highlight the performance of completion of quality deviations
- Developing effective CAPAs and associated Change Controls related to Q-Notes
- Identifying the recurring issues and implementing improvement plans in collaboration with the area managers and other stakeholders in order to reduce the occurrence of new deviations

Results Achieved

From beginning to end, the Brevitas consultants contributed to the success of this project by:

- Decreasing the number of open Q-Notes by 50% on target within a 6-month period:
 - Organizing and tracking the status of all open Q-Notes, corrective actions and change controls
 - Ensuring that all the work provided was in compliance with all updated SOPs, regulatory requirements and established standards
- Providing recommendations and follow-up of CAPAs, Change Controls and training to personnel related to technical service deviations

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