

**Deviation Management Addresses Key Compliance and Production Issues for Global Client**



**AT A GLANCE**

**INDUSTRY**

Pharmaceuticals

**AREA OF EXPERTISE**

Regulatory Compliance

**SERVICES PROVIDED**

- Project Management
- Deviation Management
- Business Process Improvement

**DURATION**

12 months

**IMPACT**

Within one year and with the support of Brevitas' services, the overall number of deviations was successfully reduced by the targeted 25%.

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After dealing with ongoing compliance issues, our global pharmaceutical client retained the services of Brevitas to provide strong leadership and project management support in managing and improving their deviation management quality system.

**Business Challenge**

Site-wide deviation management, as a quality system, is often challenging due to the many deviations involving cross-departmental teams and competing priorities. As a leading global pharmaceutical company, our client required a strategic and comprehensive view of all the challenges affecting their deviation management system.

**Our Scope**

Brevitas consultants were retained to play an instrumental role in implementing project management methodologies to properly manage the deviation system across the client site. This involved complete lifecycle management of the project and associated change management activities, through communication and stakeholder management. Due to the large scope of the project, the deviations were prioritized and tracked regularly through performance metrics and communication tools.

**Value Added**

- Assisted client in undergoing a review of their existing processes and implementing a successful improvement strategy
- Provided a well-defined scope to reduce the total number of deviations
- Prioritized deviation completion through criteria established by upper management
- Facilitated meetings and working sessions with internal and external stakeholders, to aid in deviation closure
- Worked with upper management to gain their buy-in and support of new processes
- Tracked and reported KPIs & metrics to upper management, for regular progress updates

**Results Achieved**

- Reduced the overall number of deviations by the targeted 25% within one year
- Increased the deviation closure rate
- Achieved a 0% overdue deviations rate in three consecutive months
- Systematically organized and tracked the status of approximately 300 deviations
- Supported the logistics of deviation closure through effective project management
- Developed an approach for addressing communication gaps using SharePoint