COMPLIANCE REMEDIATION

OQSIE

www.oqsie.com

Contents

OQSIE

We lead and support remediation activities.

483s | Warning Letters | Consent Decrees | Quality System Assessment and Improvement Initiatives

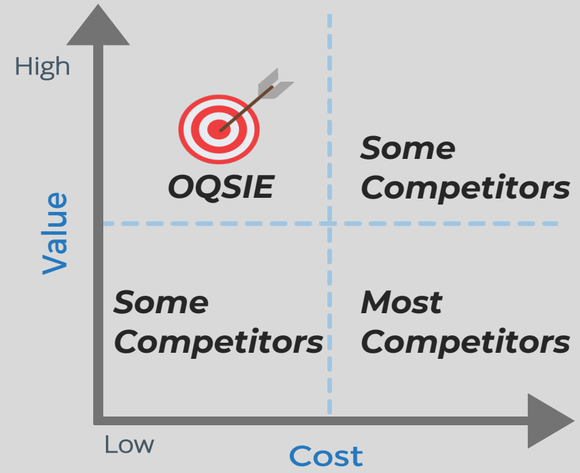
- ***Response Development***
- ***FDA Interaction Support***
- ***Third Party Assessments***
- ***Document Reviews***
- ***Remediation Planning and Execution***
- ***Deep Dive on QS Improvement Opportunities***
- ***QS Simplification and Harmonization***
- ***Training and Mentoring***

WHY OQSIE?

*We offer the **best value** for our client's money in the industry.*

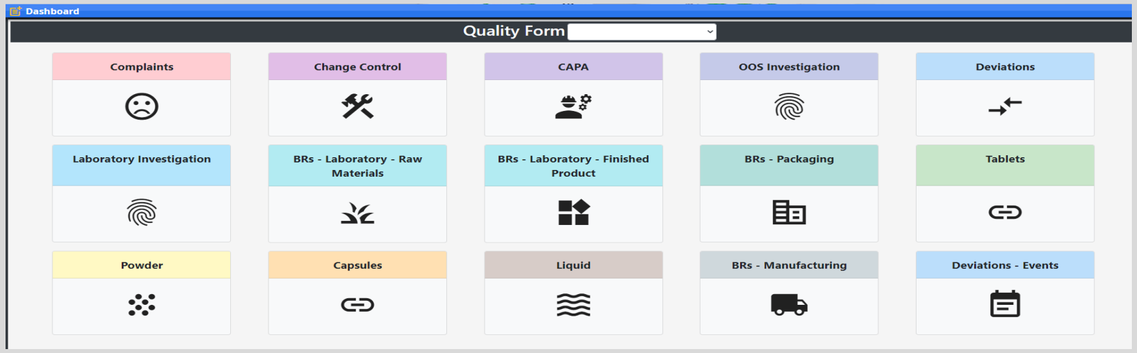
1. Our Value Proposition

- *Cost structure: high value, low cost*
- *Highly experienced industry professionals*
- *Strong framework and advanced tools*



2. Project Execution & Sustainability

- *Fast and effective resolutions of compliance issues , leading to lower costs*
- *Improve operations and transfer knowledge in a way that is sustainable for your team*



3. *How?* - Our Technology

- *Templates and checklists*
- *Advanced analytics*
- *Performance management*
- *Real-time alerts on potential compliance issues*

Warning Letter Lead Role

Case Study 1: OQSIE **led** a Warning Letter remediation for a large Generics company, scope included:

- *Led response to the Warning Letter*
- *Set-up PMO and governance structure*
- *Developed protocols for third-party assessments*
- *Executed retrospective, 4 years, & prospective document reviews across six Quality System Elements*
- *Guided and supported FDA interaction*
- *Implemented proprietary technology for real time performance management and issue escalation.*

Objectives:

1) Implement processes to meet FDA's requirements for third party assessments
2) Execute document reviews within 12 months
3) Develop and implement remediation actions

3 Major Areas of Concern

- Data Integrity
- Laboratory Operations
- Quality Systems

Results:

- *Resolved Warning Letter observations in 12 months*
- *Completed Third Party assessments on-time, delivered comprehensive reports of findings on a monthly basis*
- *Completed Third Party document reviews ahead of plan*
  - *Batch records including packaging records, laboratory records associated with production*
  - *Manufacturing investigations; Laboratory investigations / OOS*
  - *Complaints; CAPAs ; and Change Control*
- *Deployed advanced analytics solution to convert findings on document reviews into insights on compliance gaps*
- *Based on advanced analytics, delivered comprehensive remediation plan two months after start of document reviews*
- *Prioritized remediation activities to optimize impact and sustainability*

Warning Letter Support Role

Case Study 2: Top 5 global pharmaceutical company received a Warning Letter at one of its sterile injectables manufacturing sites. The client asked OQSIE for support to augment internal capacity to remediate across multiple functional areas.

OQSIE provided broad support for large number of initiatives. Supported both the site PMO and Management team as well as the above-site Corporate Quality leadership team.

Initiatives Supported:

- *Integration PMO, backfilled internal resource that moved to remediation PMO; this was a recently acquired site and business process integration was on-going*
- *Business Continuity expert supported gap assessment and execution*
- *EHS expert supported remediation activities / commitments*
- *Industrial Engineers (team of 3) supported new equipment implementation, e.g., visual inspection equipment and workflow mapping*
- *Supported shop floor supervisors for process & cleaning activities for improved quality compliance*
- *Aseptic Process Engineers (team of 4) supported process assessments, identified opportunities to reduce human errors*
- *Supplier Quality Management – PM , Investigator, and Tech Writer supported remediation commitments*
- *Validation Engineers (team of 15) supported site expansion and remediation activities: i) Parts Washers installation commissioning and qualification, ii) revalidation of all packaging and inspection lines, and iii) Program Mgr. organized and led all validation activities*
- *Tech Writers (team of 6) supported SOP & Batch Record revisions to meet remediation commitments*

Results:

- *Teams were supervised by client Managers; OQSIE management was on-site bi-weekly to meet with client Managers and consultants to ensure OQSIE support was meeting expectations*
- *Client gave OQSIE high marks for the support and performance of our consultants*

PROJECT EXAMPLES

Problem Solving

US - Deviation / CAPA Backlog

Deployed integrated team of investigators to reduce large backlog of deviations and CAPAs.

Germany – SOP Harmonization

Guided and led harmonization of SOPs across network of six aseptic manufacturing plants.

Brazil – Quality System Assessment

Deployed Portuguese speaking team to perform comprehensive assessment of gaps on product documentation, led gap remediation activities.

Capacity / Capability

China – Subject Matter Expert supported API supplier audits ahead of critical product launch.

U.S. – Subject Matter Expert resolved complex CAPAs in the client's cold chain distribution system.

Canada – Program Manager led PMO for Warning Letter remediation.

U.S. – Program Manager led PMO for remediation of 483 Observations.

Austria – Project Manager led remediation of training program.

U.S. – Four Project Managers led several work streams in Warning Letter remediation program.

Work With Us

OQSIE

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