# OQSIE COMPLIANCE REMEDIATION

## HOW WE HELP OUR CLIENTS

We lead and support remediation activities in response to 483s, warning letters, and consent decrees. Our compliance remediation expertise includes:

- 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

### Project Examples

1. Warning Letter Lead Role
2. Warning Letter Support
3. Deviation/CAPA Backlog
4. SOP Harmonization
5. Quality System Assessment

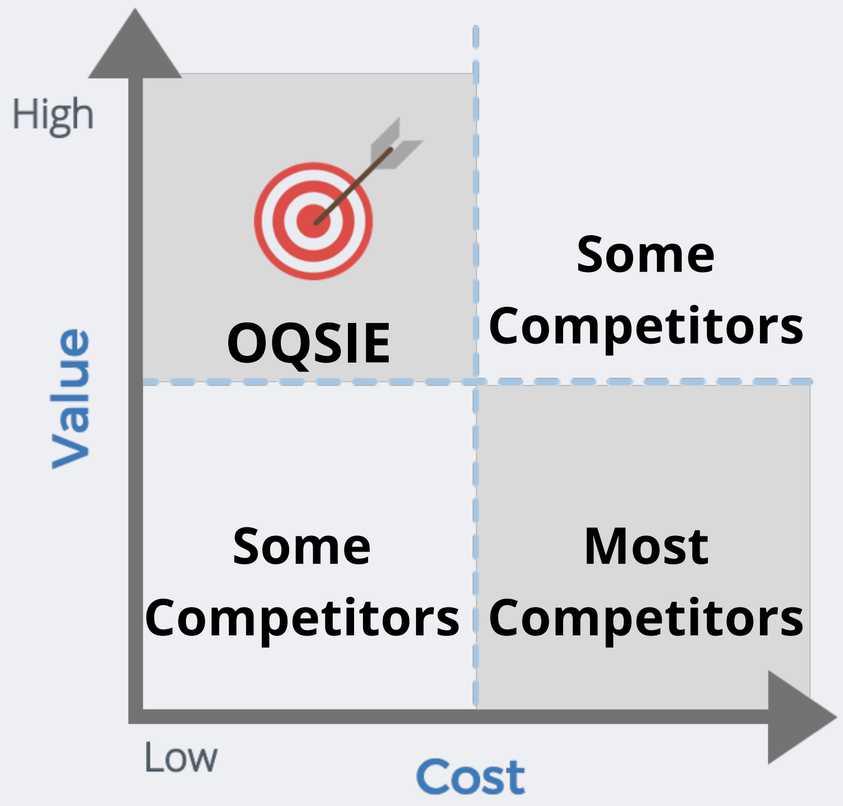
### Client Testimonial

"The OQSIE team guided us to anticipate questions and action expectations in our Warning Letter response. Our response set us up for an effective remediation effort."

***www.oqsie.com***
***www.linkedIn.com/company/oqsie***

## WHY OQSIE?

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




### 1. Our Value Proposition

- High value, low cost
- Highly experienced industry professionals
- Strong framework and advanced tools

### 2. Execution & Sustainability

- Fast and effective resolutions of compliance issues = 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