FAQ for Qualifyo

General Information

Q: What is Qualifyo?

A: Qualifyo is a company specializing in global supply chain auditing and regulatory consulting. Since its inception in 2018, it has served over 120 global clients, conducted more than 1400 audits, and established a presence in over 17 locations.

Q: What services does Qualifyo offer?

A: Qualifyo offers a range of services including GMP audits, gap analysis, training and consulting, mock inspections, and ongoing regulatory support.

Services

Q: What are GMP audits?

A: GMP (Good Manufacturing Practice) audits involve thorough inspections of manufacturing facilities, laboratories, and suppliers to ensure compliance with regulatory requirements and industry best practices.

Q: What is a gap analysis?

A: A gap analysis is a detailed assessment performed by Qualifyo's experts to identify areas of non-compliance and develop tailored action plans to address these deficiencies.

Q: How does Qualifyo conduct mock inspections?

A: Qualifyo's mock inspections simulate real-world regulatory scenarios to prepare your team for actual regulatory inspections, identifying areas for improvement to ensure compliance.

Q: What type of training and consulting does Qualifyo provide?

A: Qualifyo offers customized training programs and consulting services to help clients implement effective quality management systems and achieve regulatory compliance.

Q: What regulatory support does Qualifyo offer?

A: Qualifyo provides ongoing regulatory support and guidance to help clients navigate complex regulatory requirements confidently and achieve compliance.

Way of Working

Q: How does Qualifyo ensure the quality of its audits?

A: Qualifyo follows a standardized process involving detailed planning, execution, and follow-up. This includes a pre-audit checklist, risk assessment, audit agenda preparation, and thorough reporting and review procedures.

Q: What is the typical process for an audit at Qualifyo?

A: The process includes the following steps:

1. Client submits project details.
2. Qualifyo shares and finalizes a CDA.
3. A quotation is provided and agreed upon.
4. An initial invoice is raised.
5. A pre-audit checklist is shared with the client and site.
6. Audit date is confirmed.
7. Risk assessment and auditor allocation are completed.
8. Audit agenda is prepared and shared.
9. The audit is executed.
10. A draft audit report is submitted within 5 calendar days.
11. Client reviews and confirms the report.
12. Final audit report and observations are shared.
13. Follow-up on CAPA (Corrective and Preventive Actions) every 15 days.
14. Final compliance verification and audit close-out letter are issued.

Contact Information

Q: How can I contact Qualifyo?

A: Qualifyo has office locations in India, China, Europe, and the USA. For specific contact details, please refer to the 'Contact Us' section on their website or their provided contact information in documentation.

Q: Where does Qualifyo operate?

A: Qualifyo operates globally, with significant coverage in India, China, and Europe.

About Qualifyo

Q: What makes Qualifyo different from other auditing firms?

A: Qualifyo's key differentiators include extensive experience in regulated industries, commitment to quality assurance, a client-centric approach, a global network of auditors, and strict confidentiality measures.

Q: What is Qualifyo's mission?

A: Qualifyo's mission is to provide rigorous auditing services that ensure the highest levels of quality, safety, and compliance.

Q: What is Qualifyo's vision?

A: Qualifyo aims to set global benchmarks in pharmaceutical auditing, ensuring integrity, compliance, and patient safety.