

Case Study -End to End GxP Audits for Global CRO

Client: Leading Contract Research Organization, North Carolina, USA

Challenges

- Scheduling and completing supplier audits on time and across 22 countries
- Timely follow-up and closure of audit observations
- Availability of qualified GxP auditors globally

Our Solution

- Dedicated Project
 Management Team for efficient communication and coordination with suppliers.
- Global and Proficient auditor team proficient in GxP practices across various regulatory domains.
- Effective Audit Tracking for timely closure of audit observations and CAPA through close collaboration with suppliers.
- RxAMS: RxCloud's proprietary tool automates audit scheduling, communication, and provides insightful analytics.

Value Delivered

- **100% On-Time Delivery:** All audits were completed within the agreed-upon timelines.
- **100% Compliance** with regulatory requirements across different GxP areas.
- 35% Cost Reduction: Client benefited from cost optimization through our Fixed Price Managed Services Model and reduced travel costs.
- End-to-End Ownership right from initiation to closure, ensuring a streamlined and accountable approach.