

STUDY MONITORING & AUDITING SERVICES

Study Monitoring and Laboratory Auditing

The scientific studies that are conducted to identify a product and its environmental and human safety profile comprise the cornerstone of every successful regulatory product application. Most companies find it necessary to outsource their product testing to contract research organizations (CROs). **toXcel** staff have placed and monitored hundreds of scientific studies on behalf of clients in all fields of regulatory compliance testing.

When working with contract laboratories, it is important to ensure that data are reliable, fit-for-purpose, and in compliance with the study protocols, standard operating procedures (SOPs), and regulatory guideline requirements. Our quality professionals conduct comprehensive audits for all types of laboratory studies.

toXcel staff are experienced in GLP and non-GLP laboratory study management. Our quality auditing services include:

- Good Laboratory Practices (GLP) compliance
- Protocol development
- In-process study monitoring (critical phase inspections)
- Facility/site inspections
- Draft/ final report reviews
- Standard Operating Procedure (SOP) reviews
- Assess qualification and training of personnel
- Review raw data records, reports, record/sample retention and archives
- Evaluate compliance with protocol and SOPs
- QA unit assessment
- Laboratory equipment maintenance records
- Animal housing and care
- Historical control data
- Chain of custody records
- Sample collection procedures
- Test substance storage and sample preparation procedure review
- Experimental and analytical documentation
- Security of intellectual property
- Test article stability evaluation

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