

Head – Quality Assurance (Pre-Clinical Toxicology)

Qualifications: M.V.Sc. (Toxicology / Pharmacology) / M. Pharm. (Quality Assurance)

Experience: About 5 years' relevant experience in a Quality Assurance in a GLP-compliant Pre-clinical Testing Facility

Job Description:

- Design and Execute a Quality Assurance Program for the test facility
- Preparation, Review and Maintain copies of Standard Operating Procedures (SOPs)
- Verify study plans for compliance with Principles of GLP
- Conduct internal audits, study audits and routine process audits for pre-clinical studies as per GLP requirements.
- Review study reports
- Be responsible for control and issue of documents
- Day-to-day management of QA activities, including documentation
- Preparedness for GLP audits by external agencies like OECD / US FDA

Expertise and Skills:

- Good understanding of Quality System regulations and requirements and ability to assess and implement improvements to the existing system
- Strong leadership skills and demonstrated success in managing a large Team
- Proficient in the US FDA / OECD GLP guidelines
- Good understanding of validation/qualification requirements; change management; deviation control and management; documentation requirements etc.
- Commitment to excellence in quality
- Superb organization, communication and teamwork skills and strong interpersonal skills to be able to effectively interact within multidisciplinary groups
- Ability to work effectively within cross-disciplinary teams and with vendors.
- Creative problem solver and keen ability to address current and anticipated issues
- Self-starter with high energy level and strong results orientation