



#### **Purpose**

Support “quality data, on time” by performing Quality Assurance (QA) review and QA audits according to Pyxant Labs Inc. Standard Operating Procedures (SOPs), relevant regulatory guidelines, and as directed by the Quality Assurance Manager or Director.

#### **Responsibilities**

- Daily laboratory audits. This includes, but is not limited to, auditing laboratory practices, equipment use calibration and maintenance, personnel training records, computer security and audit trails, sample receipt and tracking, standard, reagent, and sample preparation and storage, and documentation procedures. Prompt reporting of findings to analysts, lab management.
- In-process audits of all ongoing studies, regulated by the FDA, per Good Laboratory Practices (GLP). This includes study audits at all phases of the study, (protocols, methods, forms, sample receipt, SOPs, method validation data and reports, bioanalytical sample analysis data and reports, agricultural sample analysis data and reports, laboratory notebooks, etc.). Prompt reporting of audit findings to clients, analysts, lab management.
- Support department goals by reviewing data for consistency, scientific integrity, accuracy, and completeness.
- Recommend follow-up action by communicating with Lab Ops staff and management to ensure compliance with GLP, OECD and JMHW standards, regulatory guidelines, and Pyxant Labs SOPs.
- Work as a liaison between the QA group, the laboratory personnel and data managers. This includes communicating a consistent quality message and helping to guide and train analysts on all quality related issues.
- Serve as a back up to the QA Director on all Document Control (DC) related issues to ensure SOPs, controlled forms, and the master schedule sheet are accurate and current.
- The QA Auditor has the qualifications and experience to perform audits, sign off on QA statements, and other functions performed by the QA Unit.

Other responsibilities may include support of Quality Systems (QS), which may involve validation review, training, assisting with study archives, or communicating with customers to ensure study-specific requests are integrated into ongoing studies in compliance with applicable regulations.

#### **Qualifications**

- The QA Auditor role requires an appropriate combination of college-level education and technical and regulatory experience related to the work performed at Pyxant Labs.
- The candidate must demonstrate proficiency in effective organization and attention to detail to ensure accordance with Pyxant Labs SOPs and regulatory guidelines.
- Aptitude in Microsoft Office Suite, including MS Word, MS Excel, MS Access, and MS Outlook is required.
- Excellent communication, human interaction, and dispute resolution skills are compulsory.
- All roles within the company demand strong team interaction skills, a high level of independence and initiative in work approach, and ability to communicate effectively.