Job Description

Quality Assurance Manager

The Quality Assurance Managers (QAM) responsibility is to ensure that the Bioarray’s products are fit for purpose, are consistent with and meet both external and internal requirements. This includes legal, regulatory compliance and customer expectations. The role is focused on developing the company’s quality management system, monitoring the performance of the quality system, measuring outcomes against standards, ensure that the quality system is functioning properly, uncovering deviations from specified processes and procedures, advising and implementing changes to the system, and provide training, tools and techniques to enable others to achieve quality standards.

Responsibilities include, but are not limited to the following:

- Client Services oversight
- Information Systems Supervision
- Develop and establish company’s quality procedures, standards and specifications in conjunction with operating staff
- Develop quality assurance plan by conducting hazard analyses; identifying critical control points and preventive measures; establishing critical limits, monitoring procedures, corrective actions, and verification procedures; monitoring sub-contractor QC of supplies.
- Implement a complete Quality Management System (QMS) including comprehensive SOPs for the full process for Bioarray’s products from test requisition through to delivery of the final report to the clinician.
- Ensure that the company’s QMS conforms to customer, internal, regulatory and legal requirements.
- Validate quality processes by establishing product specifications and quality attributes; measuring production; documenting evidence; determining operational and performance qualification; writing and updating quality assurance procedures.
- Implement a CAPA procedure for deviations from the requirements specified in the SOPs for internal and external purposes.
- Prepare quality documentation and reports by collecting, analyzing and summarizing information and trends including failed processes, stability studies, recalls, corrective actions, and re-validations
- Set up and maintain controls, documentation procedures and records
- Make suggestions for changes and improvements and their implementation
- Work with sub-contractors to establish quality requirements for external material suppliers and monitoring process for said suppliers
- Draft and finalize Quality Agreements with sub-contractors
- Develop and finalize supply chain procedures
- Maintain and improve product quality by completing product, company, sub-contractor, system, compliance, and surveillance audits; investigating customer complaints;
- Ensure evaluation of, and reporting on, vendor quality systems
- Report to top management on the performance of the QMS (e.g. results of quality audits, corrective actions), including needs for improvement
- Review and approve adherence to all quality standards of test results prior to release.
- Develop and validate transport materials for transfer/shipping of tissue samples, as well as develop documentation corresponding to the requisition of said sample tissue.