Quality Assurance Manager

Posting Date: 22 Oct 2024
Company: Microbix Biosystems Inc
Department: Quality Assurance
Reports to: Director, Quality Assurance & Compliance
Location: 235 Watline Ave, Mississauga, Ontario

COMPANY OVERVIEW

Microbix develops and commercializes proprietary biological and technological solutions for human health and wellbeing. We manufacture a wide range of critical biological materials for global diagnostics industry, notably antigens used in immunoassays and Quality Assessment and Proficiency (QAPs) testing products.

Microbix 's business of producing high quality viral and bacterial preparations are the results of nearly three decades of experience in the field and as a result of Microbix's expertise, its products have received widespread and longstanding customer acceptance with continuing growth in demand.

Microbix also applies its biological expertise to develop other innovative and proprietary technologies and products.

Microbix is ISO 9001 & 13485 accredited, FDA & Health Canada establishment licensed, Australian TGA registered, and provides CE marked products.

As our business continues to grow, we are currently seeking an experienced and well motivated individual to full-fill the role of our Quality Assurance manager.

Job Requirements

- Manage Quality Management System documentation and support the implementation of an electronic Quality Management System (QMS).
- Prepare quality documentation and reports, analyze QMS processes to identify and evaluate negative trends.
- Develop and improve procedures and processes to meet regulatory requirements (Health Canada, ISO 9001 and ISO 13485, and EU IVDR).
- Record, review, and approve QMS documentation, including batch records and product release.
- Support internal quality audits and external inspections by regulatory agencies and customers.
- Maintain inspection readiness and communicate concerns to Senior Leadership as needed.
- Assess compliance risks and implement mitigation measures.
- Assist in resolving customer complaints and queries.

- Collaborate on continuous improvement initiatives and stay updated on quality management practices.
- Train new and existing personnel on quality standards and practices.
- Assist with validation and qualification of Quality processes and equipment.
- Contribute to Quality Management Reviews (QMR).

Qualification

- Bachelor's degree in science
- At least 7 years of experience in Pharma/Biotech/Medical Device industries
- At least 2 years of management experience to manage team including scheduling and monitoring timely completion of all QA activities
- Experience in eQMS is required

Personal Competencies

- Strong oral and written communication; handles confidential information; frequent internal and external interactions.
- Some autonomy; follows guidelines; analyzes complex data; may make recommendations.
- Requires high concentration and critical thinking.
- Manages policies, procedures, and personnel; demonstrates leadership, negotiation, and organizational skills.
- Involve some budgeting responsibilities.