

MICHAEL ANDERSON

Senior Quality Assurance Specialist

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Distinguished Biotechnology Quality Assurance Manager with over a decade of expertise in ensuring compliance with regulatory standards and enhancing product quality within the biotechnology sector. Demonstrated proficiency in implementing robust quality management systems and fostering a culture of continuous improvement. Proven track record in leading cross-functional teams to achieve operational excellence and streamline processes while maintaining adherence to stringent industry regulations.

WORK EXPERIENCE

Senior Quality Assurance Specialist | GenTech BioSolutions

Jan 2022 – Present

- Led the development and implementation of quality assurance protocols for biopharmaceutical products.
- Conducted thorough audits of manufacturing processes to ensure compliance with FDA regulations.
- Collaborated with R&D to establish quality metrics for new product development.
- Managed CAPA processes to address non-conformities effectively.
- Trained staff on quality standards and regulatory requirements to enhance compliance.
- Utilized statistical process control tools to monitor and improve production quality.

Quality Assurance Analyst | BioHealth Innovations

Jul 2019 – Dec 2021

- Performed quality audits and inspections across various stages of the production cycle.
- Assisted in the preparation of regulatory submissions and documentation.
- Facilitated risk assessments to identify potential quality issues early in the development process.
- Implemented training programs aimed at enhancing employee awareness of quality standards.
- Collaborated with external vendors to ensure adherence to quality agreements.
- Analyzed quality data to identify trends and recommend process improvements.

SKILLS

Quality Assurance

Regulatory Compliance

CAPA Management

Statistical Analysis

Process Improvement

Team Leadership

EDUCATION

Master of Science in Biotechnology

Berkeley

University of California

ACHIEVEMENTS

- Achieved a 30% reduction in product deviations through the implementation of a new quality management system.
- Received the 'Excellence in Quality' award for outstanding contributions to product safety and compliance.
- Spearheaded a cross-departmental initiative that improved audit readiness, resulting in zero major findings during the last regulatory inspection.

LANGUAGES

English

Spanish

French