



# MICHAEL ANDERSON

## Senior Quality Assurance Specialist

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### SUMMARY

Distinguished Biotechnology Quality Assurance Manager with over a decade of experience in ensuring compliance with rigorous industry standards and regulatory requirements. Expertise in implementing quality management systems that enhance operational efficiency and product integrity within biotechnology firms. Proven track record in leading cross-functional teams to uphold quality assurance protocols, thereby fostering a culture of continuous improvement.

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### WORK EXPERIENCE

#### Senior Quality Assurance Specialist BioGen Solutions

Jan 2023 - Present

- Designed and implemented quality assurance protocols to ensure compliance with FDA regulations.
- Conducted internal audits and risk assessments to identify quality gaps.
- Collaborated with R&D teams to integrate quality standards into product development.
- Trained staff on best practices in quality management and compliance.
- Managed product release processes to ensure adherence to timelines and quality standards.
- Developed metrics and KPIs to monitor quality performance across departments.

#### Quality Assurance Analyst GeneTech Innovations

Jan 2020 - Dec 2022

- Executed validation protocols for manufacturing processes and equipment.
  - Reviewed and approved batch records and quality documentation.
  - Led investigations into non-conformances and implemented corrective actions.
  - Participated in vendor audits to ensure compliance with quality expectations.
  - Assisted in the development of training materials for quality assurance processes.
  - Maintained quality assurance databases and documentation systems.
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### EDUCATION

#### Master of Science in Biotechnology, University of California, Berkeley

Sep 2019 - Oct 2020

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### ADDITIONAL INFORMATION

- **Technical Skills:** Quality Assurance, Regulatory Compliance, GMP, Risk Assessment, Auditing, Team Leadership
- **Awards/Activities:** Successfully led a project that resulted in a 30% reduction in quality-related incidents.
- **Awards/Activities:** Received the 'Excellence in Quality Award' for outstanding contributions to quality initiatives.
- **Awards/Activities:** Implemented a quality management system that improved operational efficiency by 40%.
- **Languages:** English, Spanish, French