



MICHAEL ANDERSON

REGULATORY AFFAIRS ASSOCIATE

PROFILE

Results-driven Life Sciences Compliance Specialist with over 6 years of experience in the biotechnology sector. Skilled in interpreting complex regulatory requirements and translating them into actionable compliance strategies. Expertise in conducting internal audits, managing compliance training programs, and preparing comprehensive reports for regulatory submissions. Strong background in molecular biology and laboratory practices, combined with a deep understanding of federal and state regulations.

EXPERIENCE

REGULATORY AFFAIRS ASSOCIATE

BioInnovate Labs

2016 - Present

- Monitored regulatory changes and assessed their impact on product development and compliance.
- Drafted and submitted regulatory documents for new product approvals, achieving a 15% increase in submission success rate.
- Conducted internal audits that identified compliance risks, leading to the development of mitigation strategies.
- Facilitated training sessions for staff on regulatory requirements and compliance practices.
- Collaborated with legal teams to ensure compliance with intellectual property laws.
- Prepared compliance reports for senior management, highlighting key risks and mitigation plans.

LABORATORY COMPLIANCE OFFICER

Genomic Solutions Inc.

2014 - 2016

- Ensured laboratory practices adhered to CLIA and CAP regulations through regular inspections.
- Implemented a quality control system that reduced errors in lab results by 25%.
- Coordinated with laboratory staff to develop and revise SOPs to enhance compliance.
- Conducted compliance training for over 50 employees, improving awareness of regulatory standards.
- Managed document control processes to ensure timely updates of compliance-related documentation.
- Assisted in external audits, resulting in zero findings during the last three inspections.

CONTACT

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SKILLS

- Regulatory Affairs
- Compliance Auditing
- Quality Control
- Training Development
- Documentation Management
- Risk Assessment

LANGUAGES

- English
- Spanish
- French

EDUCATION

MASTER OF SCIENCE IN BIOTECHNOLOGY, UNIVERSITY OF BIOENGINEERING, 2014

ACHIEVEMENTS

- Achieved a significant reduction in compliance-related incidents through proactive training initiatives.
- Received the Compliance Excellence Award for outstanding performance in regulatory submissions.
- Collaborated on a research project that secured funding for compliance-related innovations.