MICHAEL ANDERSON

Regulatory Affairs Associate

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Innovative Biomedical Compliance Specialist with 3 years of experience in the biotechnology field. I have a strong background in regulatory compliance, risk management, and quality assurance. My experience includes working closely with research and development teams to ensure that all products meet the required regulatory standards before market release. I am adept at conducting audits, preparing regulatory submissions, and developing compliance documentation.

WORK EXPERIENCE

Regulatory Affairs Associate | Biotech Global Jan 2022 – Present

- Supported the regulatory team in preparing submissions for new product approvals.
- Conducted audits of compliance documentation and processes.
- Assisted in the development of training materials for regulatory compliance.
- Collaborated with cross-functional teams to ensure regulatory adherence.
- Maintained up-to-date knowledge of regulatory changes impacting products.
- Achieved successful approval for three new biopharmaceutical products.

Quality Assurance Intern | Health Innovations Inc. Jul 2019 – Dec 2021

- Assisted in quality audits of biomedical products.
- Reviewed product specifications to ensure compliance with regulations.
- Participated in the preparation of quality management documentation.
- Conducted training for staff on quality assurance practices.
- Documented findings from audits and provided feedback for improvement.
- Gained hands-on experience in regulatory processes and quality assurance methodologies.

SKILLS

Regulatory compliance | Quality assurance | Auditing | Risk management | Documentation | Team collaboration

EDUCATION

Bachelor of Science in Biochemistry 2019

Stanford University

ACHIEVEMENTS

- Contributed to the successful launch of a new biopharmaceutical product within deadlines.
- Recognized for outstanding performance during internship with a commendation.
- Implemented a tracking system for compliance documentation that improved accuracy by 25%.

LANGUAGES

English | Spanish | French