MA

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SKILLS

- Regulatory Compliance
- Drug Development
- Risk Assessment
- Project Management
- Cross-Functional Collaboration
- Clinical Trials

EDUCATION

DOCTOR OF PHILOSOPHY IN PHARMACEUTICAL SCIENCES - UNIVERSITY OF HEALTH

LANGUAGE

- English
- Spanish
- German

ACHIEVEMENTS

- Successfully led the approval of 10 new drug products within competitive timelines.
- Recognized for excellence in regulatory strategy development with a corporate award.
- Implemented a new training framework for regulatory compliance that improved team efficiency.

Michael Anderson

REGULATORY AFFAIRS DIRECTOR

With over 12 years of experience as a Chemical Regulatory Scientist in the pharmaceuticals sector, I have developed a robust understanding of the complex regulatory environment governing drug development and manufacturing. My expertise includes navigating FDA regulations, ICH guidelines, and global health authority requirements. I have successfully managed regulatory submissions for numerous drug approvals, ensuring compliance with safety and efficacy standards.

EXPERIENCE

REGULATORY AFFAIRS DIRECTOR

PharmaSolutions Inc.

2016 - Present

- Oversaw regulatory submissions for 20+ drug products, achieving a 95% approval rate.
- Led cross-functional teams in the development of regulatory strategies for new products.
- Developed comprehensive regulatory documentation for clinical trials and market applications.
- Conducted risk assessments to ensure compliance with FDA and global regulations.
- Presented regulatory strategies to senior management, influencing product development direction.
- Maintained awareness of evolving regulations to ensure ongoing compliance.

SENIOR REGULATORY SCIENTIST

MediTech Corp.

2014 - 2016

- Managed regulatory submissions for clinical trial applications, ensuring alignment with FDA guidelines.
- Reviewed and approved labeling and advertising materials for compliance.
- Conducted audits of regulatory processes to identify and rectify compliance gaps.
- Collaborated with R&D teams to evaluate product safety and efficacy data.
- Developed training programs for staff on regulatory compliance and best practices.
- Engaged with health authorities during product approvals to address queries and concerns.