MA

Phone: (555) 234-5678

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Address: San Francisco, CA

Website: www.michaelanderson.com

EXPERTISE SKILLS

- Regulatory strategy
- Biologics
- Risk assessment
- Team management
- FDA/EMA interactions
- Compliance training

LANGUAGES

- English
- Spanish
- French

CERTIFICATION

- PhD in Biochemistry, University of Washington, 2010

REFERENCES

John Smith
Senior Manager, Tech Corp
john.smith@email.com

Sarah Johnson
Director, Innovation Labs
sarah.j@email.com

Michael Brown
VP Engineering, Solutions Inc
mbrown@email.com

MICHAEL ANDERSON

SENIOR REGULATORY AFFAIRS MANAGER

Accomplished Biomedical Regulatory Scientist with over 10 years of experience in regulatory affairs within the biotechnology sector. Expertise in leading regulatory strategies for complex biologics and ensuring compliance with both domestic and international regulations. Proven ability to manage multiple projects simultaneously while maintaining high standards of quality and accuracy. Strong background in liaising with regulatory agencies and preparing comprehensive responses to inquiries.

PROFESSIONAL EXPERIENCE

BioGenix Solutions

Mar 2018 - Present

Senior Regulatory Affairs Manager

- Oversaw regulatory submissions for biologics, achieving a 95% approval rate on first submission.
- Developed regulatory strategies that streamlined the approval process by 30%.
- Managed a team of regulatory professionals, enhancing team effectiveness and compliance knowledge.
- Conducted risk assessments for product pipelines, identifying potential regulatory hurdles.
- Liaised with FDA and EMA, ensuring alignment on regulatory expectations.
- Prepared and presented data to regulatory agencies, facilitating constructive feedback and approval timelines.

Innovative Biologics

Dec 2015 - Jan 2018

Regulatory Affairs Specialist

- Assisted in the preparation of BLA submissions, contributing to successful product launches.
- Reviewed scientific data and clinical study reports for regulatory compliance.
- Maintained regulatory files and documentation, ensuring readiness for audits.
- Trained staff on regulatory processes and compliance requirements.
- Collaborated with marketing to ensure product labeling met regulatory standards.
- Participated in internal and external audits, achieving favorable outcomes without observations.

ACHIEVEMENTS

- Successfully led a biologics licensing application that resulted in a new product entry within 18 months.
- Awarded 'Best Regulatory Team' for innovative approaches to expedite submissions.
- Developed a comprehensive training program that improved compliance knowledge across the organization.