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SKILLS

- Digital health
- Telemedicine
- Regulatory strategy
- Risk analysis
- Stakeholder engagement
- Compliance training

EDUCATION

**BACHELOR OF SCIENCE IN HEALTH
INFORMATICS, UNIVERSITY OF
WASHINGTON**

LANGUAGE

- English
- Spanish
- German

ACHIEVEMENTS

- Successfully guided a digital health startup through initial FDA submissions.
- Recognized as a thought leader in digital health regulations at industry conferences.
- Contributed to a project that streamlined regulatory processes, reducing time to market by 20%.

Michael Anderson

REGULATORY AFFAIRS CONSULTANT

Innovative Regulatory Affairs Analyst with a focus on the intersection of technology and regulatory compliance in the healthcare sector. Extensive experience in evaluating regulatory requirements for digital health products and telemedicine applications. Recognized for developing regulatory frameworks that facilitate compliance while promoting innovation. Exceptional analytical skills, allowing for the identification of regulatory risks and the formulation of mitigation strategies.

EXPERIENCE

REGULATORY AFFAIRS CONSULTANT

Digital Health Innovations

2016 - Present

- Evaluated regulatory requirements for various digital health solutions, ensuring compliance with FDA and global standards.
- Developed comprehensive regulatory strategies for telehealth applications.
- Collaborated with product teams to integrate regulatory considerations into the design process.
- Conducted workshops for stakeholders on digital health regulations.
- Maintained up-to-date knowledge of emerging regulatory trends in digital health.
- Provided guidance on regulatory submissions for software as a medical device (SaMD).

REGULATORY AFFAIRS ANALYST

HealthTech Solutions

2014 - 2016

- Assisted in the preparation of regulatory submissions for mobile health applications.
- Conducted risk assessments for digital health products.
- Reviewed marketing materials for compliance with regulatory standards.
- Supported the development of internal regulatory policies and procedures.
- Engaged in cross-functional teams to align product development with regulatory requirements.
- Analyzed regulatory changes impacting digital health initiatives.