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EXPERTISE SKILLS

- Global regulatory strategy
- Market access
- Compliance management
- Risk mitigation
- Training development
- Cross-functional leadership

LANGUAGES

- English
- Spanish
- French

CERTIFICATION

- Master of Science in
Pharmaceutical Regulatory Affairs,
University of Southern California

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

GLOBAL REGULATORY AFFAIRS LEAD

Accomplished Pharmaceutical Regulatory Affairs Specialist with a focus on global regulatory compliance and strategic market access. Extensive experience in developing regulatory strategies that align with business goals while ensuring adherence to international standards. Proven expertise in leading cross-functional teams to facilitate the timely submission of regulatory documents and manage post-approval compliance.

PROFESSIONAL EXPERIENCE

NextGen Pharma

Mar 2018 - Present

Global Regulatory Affairs Lead

- Directed global regulatory strategy for product development and market entry.
- Managed regulatory submissions and responses to agency inquiries across multiple regions.
- Conducted training for teams on international regulatory requirements.
- Developed risk mitigation strategies for regulatory challenges.
- Collaborated with commercial teams to align regulatory and business objectives.
- Monitored global regulatory changes to inform strategic planning.

BioHealth Corp

Dec 2015 - Jan 2018

Regulatory Compliance Specialist

- Ensured compliance with FDA, EMA, and other regulatory agencies.
- Reviewed and approved marketing materials for regulatory compliance.
- Conducted audits to assess compliance with internal policies.
- Provided regulatory guidance to cross-functional teams on product development.
- Assisted in the preparation of post-market surveillance reports.
- Maintained regulatory documentation and tracking systems.

ACHIEVEMENTS

- Successfully led a project that resulted in a 40% reduction in time to market.
- Received the 'Innovation in Regulatory Affairs' award for exceptional project management.
- Contributed to a strategic initiative that improved regulatory compliance metrics by 35%.