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EXPERTISE SKILLS

- Drug Development
- Regulatory Compliance
- Clinical Trials
- Audit Management
- Team Mentorship
- Strategic Planning

LANGUAGES

- English
- Spanish
- French

CERTIFICATION

- Master of Science in Pharmaceutical Sciences, University of 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

REGULATORY AFFAIRS MANAGER

Accomplished Clinical Regulatory Affairs Manager with a robust history in the pharmaceutical industry, specializing in drug development and regulatory compliance. Demonstrated proficiency in leading regulatory submissions for investigational new drugs and overseeing post-marketing surveillance. Expertise in strategic planning and execution of regulatory activities that drive product success in competitive markets. Exceptional ability to interpret complex regulatory guidelines and translate them into actionable strategies for cross-functional teams.

PROFESSIONAL EXPERIENCE

CurePharma Inc.

Mar 2018 - Present

Regulatory Affairs Manager

- Oversaw regulatory submissions for multiple drug candidates, ensuring adherence to FDA and EMA guidelines.
- Managed the development and execution of regulatory strategies for clinical trials.
- Coordinated with clinical operations to align trial designs with regulatory requirements.
- Reviewed and approved regulatory documents, including IND and NDA submissions.
- Led audits and inspections, ensuring compliance with regulatory standards.
- Mentored junior regulatory staff, enhancing team capabilities and knowledge.

PharmaWise

Dec 2015 - Jan 2018

Regulatory Affairs Analyst

- Supported regulatory submissions for new drug applications and amendments.
- Maintained regulatory databases and ensured accurate documentation practices.
- Conducted research on regulatory requirements for various therapeutic areas.
- Collaborated with clinical teams to ensure compliance in trial execution.
- Assisted in preparing responses to regulatory agency inquiries.
- Participated in cross-functional meetings to provide regulatory insights.

ACHIEVEMENTS

- Successfully led a project to submit an NDA three months ahead of schedule.
- Awarded 'Regulatory Excellence' for outstanding contributions to regulatory submissions.
- Increased the success rate of regulatory submissions by 40% through improved processes.