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EXPERTISE SKILLS

- Regulatory strategy
- Medical device compliance
- Quality management systems
- Risk management
- Team leadership
- Post-market surveillance

LANGUAGES

- English
- Spanish
- French

CERTIFICATION

- Master of Science in Biomedical Engineering, Johns Hopkins University

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 DIRECTOR

Accomplished regulatory affairs expert with a robust background in medical devices and a strong commitment to ensuring product safety and efficacy. Over 12 years of experience in regulatory strategy development, submission management, and post-market surveillance. Demonstrated proficiency in navigating the complexities of international regulatory requirements and standards, particularly in the European Union and Asia-Pacific regions.

PROFESSIONAL EXPERIENCE

MedDevice Corp.

Mar 2018 - Present

Regulatory Affairs Director

- Directed regulatory strategy for a portfolio of medical devices.
- Oversaw the submission of 510(k) and PMA applications to the FDA.
- Engaged with global regulatory bodies to secure product approvals.
- Managed post-market surveillance activities to ensure ongoing compliance.
- Led cross-functional teams in regulatory project planning and execution.
- Developed risk management plans in accordance with ISO standards.

Innovate Medical Solutions

Dec 2015 - Jan 2018

Regulatory Affairs Manager

- Coordinated regulatory submissions for new medical device launches.
- Implemented quality management systems to enhance compliance.
- Conducted training sessions on regulatory requirements for product development teams.
- Reviewed and approved labeling and promotional materials for compliance.
- Maintained regulatory databases and documentation systems.
- Facilitated audits and inspections by regulatory authorities.

ACHIEVEMENTS

- Successfully led a project that achieved a 20% reduction in approval timelines.
- Recipient of the Compliance Excellence Award in 2020.
- Authored regulatory guidelines adopted by industry associations.