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EXPERTISE SKILLS

- regulatory strategy
- medical devices
- compliance management
- cross-functional collaboration
- risk management
- training and mentoring

LANGUAGES

- English
- Spanish
- French

CERTIFICATION

- Bachelor of Science in Biomedical Engineering, University of Michigan

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 LEAD

Strategic Regulatory Affairs Executive with over 12 years of experience in the medical device industry, recognized for expertise in regulatory strategy development and implementation. Demonstrated success in navigating the complexities of global regulatory requirements, ensuring compliance for a diverse range of medical devices. Proven ability to lead cross-functional teams through the regulatory submission process, resulting in timely product approvals.

PROFESSIONAL EXPERIENCE

MedTech Innovations

Mar 2018 - Present

Regulatory Affairs Lead

- Led regulatory submissions for Class II and Class III medical devices.
- Collaborated with engineering and quality assurance teams to ensure compliance.
- Developed and implemented regulatory strategies for product development.
- Managed relationships with international regulatory agencies for product approvals.
- Conducted risk assessments to ensure compliance with ISO standards.
- Provided regulatory training and mentorship to junior staff.

Healthcare Solutions Group

Dec 2015 - Jan 2018

Regulatory Affairs Consultant

- Advised clients on regulatory requirements for medical device submissions.
- Conducted comprehensive audits to identify compliance gaps.
- Developed regulatory strategies tailored to client needs and product types.
- Facilitated communication between clients and regulatory authorities.
- Prepared and submitted regulatory documentation for client products.
- Provided ongoing support for post-market surveillance and reporting.

ACHIEVEMENTS

- Instrumental in achieving 95% approval rate on regulatory submissions.
- Recognized as 'Employee of the Year' for outstanding contributions to regulatory affairs.
- Successfully led a project that reduced submission timelines by 40%.