George Smith's Resume

Regulatory Affairs Specialist

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Profile Summary

Dynamic and detail-oriented Regulatory Affairs Specialist with over 5 years of experience in managing regulatory submissions, ensuring compliance with global and national health regulations, and facilitating project approvals within the pharmaceutical sector. Demonstrated expertise in steering cross-functional teams to achieve 20% faster regulatory approval timelines and successful engagement with FDA, EMA, and other health authorities.

Work Experience

Regulatory Affairs Specialist

Pfizer Inc.
1st Jan, 2018 - Present

- Orchestrated 40+ IND/NDA submissions, resulting in a 20% reduction in approval time.
- Developed comprehensive regulatory strategies, enhancing compliance by 30%, assessed by independent audits.
- Collaborated with cross-functional teams, leading to successful product registration in EU, Japan, and Canada.

Regulatory Affairs Associate

Johnson & Johnson
1st Jun, 2015 - 31st Dec, 2017

- Assisted in preparation and review of regulatory submissions to FDA, minimizing errors by 15%.
- Monitored and reported on changes in regulatory guidelines, maintaining 100% compliance.
- Coordinated regulatory meetings, prepared documentation, and liaised with external regulatory bodies.

Education

Harvard University

Master of Science in Regulatory Affairs
1st Sep, 2013 - 31st May, 2015

University of California, Berkeley

Bachelor of Science in Biomedical Sciences
1st Sep, 2009 - 31st May, 2013

Skills

Regulatory Submissions, FDA Regulations, Project Management, Compliance, Cross-Functional Collaboration, Strategic Planning, Risk Management

Notable Projects

Global Regulatory Strategy Initiative

Led a team to develop and implement a global regulatory strategy, improving international compliance alignment across multiple territories and achieving a 25% increase in regulatory process efficiency.

Certifications

Regulatory Affairs Certification (RAC)

Issued by Regulatory Affairs Professionals Society (RAPS), 10th Oct, 2017

Awards

Regulatory Excellence Award

Awarded by Pfizer Inc., 15th March, 2020