Jacqueline Modaff

Regulatory Affairs Manager

jacqueline.modaff@gmail.com
(393) 778-1991
123 Maple St, Concord, NH 03301

Education

Master of Science in Regulatory Affairs at University of New Hampshire, Durham, NH

Aug 2014 - May 2018

Relevant Coursework: Regulatory Strategy, Quality Assurance and Compliance, Risk Management, Clinical Trials, Biostatistics, Medical Device Regulations, Pharmaceutical Law, Ethics, and Global Health Policy.

Links

linkedin.com/in/jacquelinemodaff

Skills

- Compliance
- Risk assessment
- Negotiation
- Documentation
- Policy development
- Communication
- Project management

Languages

- English
- French

Profile

Results-driven Regulatory Affairs Manager with 5 years of experience in ensuring compliance with industry regulations and implementing strategic initiatives for optimal product approval. Demonstrated expertise in managing regulatory submissions, risk assessments, and quality management systems. Strong interpersonal skills with a proven ability to collaborate effectively with cross-functional teams and regulatory agencies. Skilled in streamlining processes to maximize efficiency, while maintaining a strong commitment to quality and safety standards. Dedicated to staying current with evolving regulations and industry trends to ensure ongoing product success and company growth.

Employment History

Regulatory Affairs Manager at Lonza Group, NH

Apr 2023 - Present

- Successfully streamlined the regulatory submission process, reducing approval times by 25% and increasing overall efficiency in the department.
- Spearheaded the development and implementation of a comprehensive regulatory compliance program, resulting in a 50% reduction in non-compliance issues and a 30% decrease in related fines and penalties.
- Led a cross-functional team in the preparation and submission of 10 new product applications within a one-year period, achieving a 100% approval rate and contributing to a 15% increase in annual sales revenue.
- Developed and delivered regulatory training programs for over 200 employees, improving overall organizational understanding of regulatory requirements and fostering a culture of compliance.

Associate Regulatory Affairs Manager at Thermo Fisher Scientific, NH

Aug 2018 - Mar 2023

- Successfully managed the submission of 15+ regulatory applications within one year, resulting in a 100% approval rate and ensuring timely market access for Thermo Fisher Scientific products in various regions.
- Streamlined internal processes for regulatory compliance, reducing the average time taken for dossier preparation by 25% and improving overall efficiency in the regulatory affairs department.
- Led a cross-functional team in the successful completion of a company-wide regulatory audit with zero major findings, demonstrating Thermo Fisher Scientific's commitment to maintaining high standards in product quality and safety.
- Conducted comprehensive regulatory intelligence research, identifying potential changes in regulations across key markets, which enabled the company to proactively adapt strategies and avoid potential compliance risks.

Certificates

Regulatory Affairs Certification (RAC)

Oct 2021