Dorette Quaranto

Regulatory Affairs Specialist

Profile

As a dedicated Regulatory Affairs Specialist with over 2 years of experience, I excelled in ensuring compliance with global regulations and guidelines, while effectively managing multiple projects in a fast-paced environment. I successfully collaborated with cross-functional teams to develop and implement regulatory strategies for product approvals, and skillfully navigated complex regulatory landscapes. My strong analytical and communication skills allowed me to prepare clear and concise documentation, as well as to build and maintain positive relationships with regulatory agencies. Throughout my professional journey, I continuously stayed informed on the latest industry developments and changes, ensuring that my organization's products consistently met the highest standards of safety, efficacy, and quality.

Employment History

Regulatory Affairs Specialist at Oklahoma Medical Research Foundation, OK

Mar 2023 - Present

- Successfully managed the submission of 10+ Investigational New Drug Applications (INDs) and 5 New Drug Applications (NDAs) within a 2-year period, resulting in a 100% approval rate from the FDA.
- Streamlined the regulatory document management system, reducing document retrieval time by 40% and improving overall efficiency of the department.
- Led a cross-functional team in the development and implementation of a comprehensive GxP training program, increasing employee compliance with regulatory requirements by 50%.
- Conducted thorough audits of clinical trial documentation for 15 studies, identifying and addressing critical gaps in compliance, ultimately reducing the risk of regulatory sanctions by 30%.

Associate Regulatory Affairs Specialist at Charles River Laboratories, OK

Jul 2021 - Jan 2023

- Successfully led the preparation and submission of 10+ regulatory applications, resulting in a 100% approval rate and contributing to the company's growth.
- Streamlined the regulatory compliance process by implementing an improved tracking system, reducing the average time for approval by 25% and increasing overall efficiency.
- Coordinated cross-functional teams to ensure timely and accurate completion of 15+ regulatory projects, achieving a 95% on-time completion rate and enhancing collaboration between departments.
- Conducted comprehensive regulatory risk assessments for 20+ new products, effectively mitigating potential risks and ensuring compliance with all applicable regulations.

Education

Bachelor of Science in Regulatory Affairs at University of Oklahoma, Norman, OK

Details

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Links

linkedin.com/in/dorettequaranto

Skills

- Regulatory knowledge
- Analytical skills
- Attention to detail
- Communication skills
- Project management
- Problem-solving abilities
- Time management

Languages

- English
- Urdu

Hobbies

1. Reading industry-related journals and articles
2. Attending workshops and conferences on regulatory policies and updates
3. Collecting and analyzing data on regulatory trends and developments