SILVIA RODOCKER

Regulatory Affairs Associate

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PROFILE

Dedicated Regulatory Affairs Associate with 1 year of experience in managing regulatory compliance and supporting product registrations. Proficient in interpreting and applying industry regulations, liaising with global regulatory bodies, and facilitating timely submissions. Strong commitment to continuous learning and professional development in the dynamic regulatory landscape. Adept at collaborating with cross-functional teams to drive successful product launches and maintain market presence.

LINKS

linkedin.com/in/silviarodocker

SKILLS

- Compliance monitoring
- Risk assessment
- Documentation management
- Policy analysis
- Regulatory intelligence
- Stakeholder communication
- Submission preparation

LANGUAGES

- English
- Indonesian

HOBBIES

EMPLOYMENT HISTORY

Regulatory Affairs Associate at PRA Health Sciences, KS

Mar 2023 - Present

- Successfully managed the regulatory submission process for 5 new drug applications within a year, resulting in a 100% approval rate and contributing to the company's overall growth.
- Streamlined the regulatory document review process by implementing an efficient tracking system, reducing the average review time by 30% and increasing team productivity.
- Led a cross-functional team in the development and execution of a comprehensive regulatory strategy for a major product launch, resulting in a 50% faster approval time compared to previous launches.

Regulatory Affairs Assistant at IQVIA, KS

Jul 2022 - Jan 2023

- Successfully managed the submission of 50+ regulatory documents for clinical trials, resulting in a 95% on-time submission rate and contributing to the timely initiation of studies.
- Streamlined the regulatory affairs process by developing a comprehensive tracking system for submissions, reviews, and approvals, leading to a 20% increase in efficiency and improved communication among team members.
- Assisted in the preparation and review of 30+ Investigational New Drug (IND) applications and 10+ New Drug Applications (NDA), contributing to the approval of 5 new drugs by the FDA within the past year.

EDUCATION

Bachelor of Science in Regulatory Affairs at Kansas State University, Manhattan, KS

Sep 2017 - May 2022

Relevant Coursework: Regulatory Frameworks and Compliance, Risk Management, Quality Assurance and Control, Clinical Research, Biostatistics, Medical Device Regulations, Pharmacovigilance, and Ethics in Regulatory Affairs.

CERTIFICATES

Regulatory Affairs Certification (RAC)

Aug 2021

Certified Regulatory Compliance Manager (CRCM)

Jul 2020