CONTACT PERSON

MIKE FROGGATT

m.froggatt@proclinical.com

PEOPLE WHO APPLIED FOR THIS ALSO APPLIED FOR

Manager, Clinical Life Cycle Management

UNITED STATES - HIGHLY COMPETITIVE SALARY

Regulatory Operations Associate

UNITED KINGDOM - HIGHLY COMPETITIVE SALARY

Regulatory Operations Archivist

UNITED STATES - HIGHLY COMPETITIVE SALARY

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APPLY

Associate Director of Regulatory Affairs Operations

Posted:
06.10.17
Location:
New Jersey - United States
Salary:
Highly Competitive Salary
Reference No:
RA.MF.13923

ProClinical is seeking to fill the newly-opened role of Associate Director of Regulatory Affairs Operations for our client, based in Cranbury, NJ. The ideal individual will assume responsibility for the direction and execution of regulatory submissions to ensure timely and quality creation and lifecycle management of global submissions in accordance with agency and company standards. They will support the integration of the Regulatory Information Management (RIM) system into current business practices and participate in all regulatory operations activities. This role is perfect for an individual that thrives in a fast-paced working environment, and who is committed to flexibility, proactivity, resourcefulness and efficiency in the workplace.

Responsibilities

- Lead assigned projects with manageable risks and resource requirements.
- Develop, implement and oversee maintenance of relevant technologies and infrastructure.
- Interpret, implement, and ensure compliance with relevant regulatory bodies.
- Participate in the development and implementation of standards, templates, and procedures related to electronic regulatory documentation.
- Provide feedback and coach/mentor all relevant staff.
- All other ad-hoc tasks as assigned.

Skills And Requirements

- BS or MS in scientific discipline or equivalent (advanced degree/RAC certification preferred).
- 7+ years' regulatory affairs experience with drugs and/or biologics.
- 5+ years' experience in regulatory operations with relevant experience implementing electronic document management systems.
- Experience in the implementation and usage of electronic document management.

Excellent written, verbal and interpersonal skills.
Awareness of all relevant legal business principles and practices.
Strong attention to detail.
Ability to work individually and in a team environment.
Experience with publishing software (Microsoft Word, Adobe Acrobat, etc.)

To Apply:

Please click on the Apply button. Please include a short note outlining why you are interested in the role and why you think you are suitable.

In case you have difficulty in applying or if you have any questions, please call Mike Froggatt at (+1) 6467689727 or upload your resume on our website - www.proclinical.com.

A full job description is available on request.

ProClinical is a specialist employment agency and recruitment business, providing job opportunities within major pharmaceutical, biopharmaceutical, biotechnology and medical device companies.

APPLY