CONTACT PERSON

PETER DUVALL

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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

Regulatory Affairs Associate

Posted:
03.10.17
Location:
CAMBRIDGE - United Kingdom
Salary:
Highly Competitive Salary
Reference No:
RA.PD.13802

A leading US biopharmaceutical organisation with a solid commercial portfolio of life-saving drugs within a number of therapy areas have a new Regulatory Affairs Associate to join the International Regulatory Affairs team to be based in Cambridge or Stockley Park on a contract basis. The company has a growing pipeline of investigational drugs and approximately 5,000 employees in offices across four continents. This position will report to the Associate Director Regulatory Affairs (Inflammation) and will be responsible for the preparation of regulatory submissions for investigational medicinal products that treat inflammatory diseases:

Job Responsibilities:

- Preparation and/or co-ordination of the regulatory documentation to support Clinical Trial Applications/ amendments and Paediatric Investigational Plans (PIP) in the European Union.
- Interaction with the Regulatory, Clinical Research and Clinical Operations team leads to ensure optimal execution of the agreed regulatory strategy for development medicinal products.
- Represents the International Regulatory function at cross functional submission/ study management team meetings.
- Responsible for maintaining a working knowledge of regulatory requirements and guidelines and for communicating changes in regulatory information to product teams.
- Supports the Associate Director as required.

Skills and Requirements:

- Degree in biological/life sciences, pharmacy or medicine (or international equivalent). An advanced degree is desirable.
- Experience in the preparation/submission of regulatory documentation to support clinical trials applications/amendments in the European Union and good breadth of understanding of European regulations relating to clinical trials.

Experience with working with document management systems (RDMS / SMS).
Experience representing Regulatory Affairs on cross functional teams is desirable.
Resilient profile with the ability to deliver in an ambiguous environment
Ability to engage and manage multiple stakeholders to achieve the objective
Curious with learning agility
Operationally excellent
Organised with systematic approach to prioritisation
Process orientated to achieve the business objective

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 Peter Duvall on +44 203 0789 542 or upload your CV 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.

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