

Senior Regulatory Documentation Scientist

Job ID: 00412474

Job Function

Development

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Experienced

Who We Are

At the Roche Group, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 30 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. The headquarters for Roche pharmaceutical operations in the United States, Genentech has multiple therapies on the market for cancer and other serious illnesses. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset and are dedicated to remaining a great place to work.

The Position

Objectives and Scope of Position:

- Responsible for the preparation of regulatory documents for submission to regulatory authorities within subject area (clinical/safety). This role involves working in close partnership with the medical/scientific content owners in the relevant functions
- Takes accountability for delivering regulatory documents and works effectively and closely with key content owners
- Applies document and project management expertise
- Contributes to the functional excellence of regulatory documentation (process management)

Primary Responsibilities and Accountabilities

- Prepare regulatory documents in accordance with applicable regulatory guidelines/Roche standards/SOPs, ensuring high scientific quality & consistency with other documents where appropriate
- Liaise with document contributors to gather information (including Licensing partners where relevant)
- Plan & create timelines for the production and review of documents ensuring alignment with overall project timelines where appropriate

- Review documents for: organisation/clarity/use of English language/grammar/scientific standards/consistency between textual presentations and listings/tabular or graphical displays
- Manage the review process, including leading/coordinating adjudication of review comments and incorporating review comments
- Participate as a member of key functional/cross functional Team (s) (e.g. Regulatory Area Functional Team, Safety Team etc), ensuring that Teams adequately plan for document deliverables
- Ensure that the document is published in collaboration with Regulatory Operations and that the document is approved by the single accountable signatory

In addition as a Senior Regulatory Documentation Scientist

- Manage the preparation of a suite of regulatory documents e.g. Clinical Dossier, suite of Safety Documents
- Lead Writing Team for preparation of Clinical Dossiers/Safety Reports
- Review documents to ensure adherence to documentation quality standard, regulatory requirements and consistency of messages across all documents for a product/across clinical documents within a dossier
- Prepare specifications for outsourced work (writing/review of documents) and serves as Roche liaison for project purposes
- Plans and creates timelines for the production of assigned documents e.g. Clinical Dossier/Suite of Safety documents. Ensures proper planning and resourcing of all documents assigned to Writing Team including what work or portions of work to be outsourced
- Actively contributes to best practices and continuous improvement within Regulatory Documentation. Represents the group in functional and cross functional initiatives/projects when required

Who You Are

Education/Qualifications:

- PhD, MSc or equivalent in relevant scientific discipline, or healthcare professional
- Post doctoral or previous pharmaceutical experience would be an advantage

Experience/Skills/Knowledge:

- Demonstrated clear, high quality scientific writing style in the English language
- Competence in the preparation of a variety of regulatory documents
- Ability to independently analyze and synthesize data from a broad range of disciplines
- Ability to work effectively in a team environment
- Strong communication and organizational skills
- Strong interpersonal skills
- Excellent knowledge of regulatory documentation guidelines pertinent to subject area i.e. Clinical/Safety
- Commitment to performance measures of time, costs and quality
- Problem solving skills
- Ability to co-ordinate multiple documents/assignments to tight deadlines

Genentech is an Equal Opportunity Employer.