



Scientist, CMC Writer, (m/f)

Date posted: September 27, 2019

Location: Vienna, Austria

About HOOKIPA:

HOOKIPA Pharma Inc. (NASDAQ: HOOK) is a clinical stage biopharmaceutical company developing a new class of immunotherapeutics, targeting infectious diseases and cancers based on its proprietary arenavirus platform that is designed to reprogram the body's immune system.

Position Summary:

HOOKIPA has an open writer position with a focus on process development, quality and clinical topics. The Scientist, CMC Writer (m/f) will join the Regulatory Affairs team in order to develop high-quality, scientifically accurate CMC communications materials for publication and presentation to a variety of audiences. As a Scientist, CMC Writer, you will work collaboratively with the R&D, Manufacturing and Technical Development teams to analyze data, write, review, edit, and submit scientific, manufacturing, other CMC, and regulatory documents for publication. He/she will also work on other technical literature for internal and external use as needed.

As Scientist, CMC Writer you will ideally have a scientific, manufacturing or drug development background, with a strong understanding of virology and oncology areas.

The ideal candidate is a clear and precise writer, as well as detail-oriented, driven, independent, and able to respond quickly to evolving needs. Good analytical and writing skills, ability to work in a fast-paced environment and professionalism are all essential behaviors for this role.

This position within the Regulatory Affairs department will be based in Vienna, Austria .

Main Responsibilities:

- Write and edit manuscripts on manufacturing studies and/or scientific reports including special summaries from raw data for submission to regulatory agencies and/or for in-company use, monographs, comprehensive reviews, scientific exhibits, and other projects as required
- Critically analyze complex data and information and collaborate with R&D, Clinical and Technical Development teams on data analysis, description, and presentation
- Create tables, charts, figures, and other visual display elements for presenting scientific and clinical data
- Ensure efficient and consistent formatting of documents, to maintain quality and ease of review across multiple documents assembled in a regulatory dossier
- Contribute to overall project management and to cross functional working groups as needed to facilitate efficient development and finalization of regulatory documents for submissions

Qualifications:

- An advanced degree (PhD, PharmD, MD) in Virology/Immunology
- A background in molecular biology/genomics or oncology a plus
- Thorough understanding of drug development and manufacturing processes
- Demonstrated skills and experience in writing, editing, reviewing, and formatting manuscripts, abstracts, poster presentations, and slide decks. Must be able to write clearly and concisely, and to explain complex scientific information to the general public, as well as to scientific peers.



- Experience in writing regulatory documents – Knowledge of EMA and FDA guidelines is a plus
- Fluency in written and spoken English.

Skills:

- An independently motivated working style with good problem-solving skills allowing analysis, synthesis, and compilation of data from a broad range of disciplines
- A demonstrated ability to prioritize tasks, work simultaneously on multiple projects, and complete high-quality documents according to timelines
- Good computer and documentation software skills
- An ability to work in a fast-paced, cohesive, collaborative team-oriented work environment

What we offer:

- Strong team with dedicated and passionate scientists
- Excellent working atmosphere
- Opportunities for personal development
- Working in a multinational and multicultural environment

We are required by Austrian law to post a minimum salary. The minimum monthly gross salary for this position is EUR 3.714,- based on fulltime (40 hours per week); depending on experience and qualification salary can be negotiated. In addition, we offer a performance-related bonus payment and participation in our stock option compensation program.

Starting date: as soon as possible

Contact:

If you (m/f) are interested in this challenging position, please send your CV including cover letter and credentials to: **talent@hookipapharma.com**

For more information on HOOKIPA please visit www.hookipapharma.com