# Manager – Quality Management (m/f)

**Date posted:** September 21, 2020
**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.
In 2018, HOOKIPA entered into a collaboration and license agreement with Gilead Sciences, Inc., a world leader in innovative therapies against infectious diseases, to develop arenavirus-based therapies against HIV and Hepatitis B.
The incumbent of the position will be dedicated to the success of the HOOKIPA-Gilead collaboration, from a Quality Management (QM) point of view.

**Position Summary:**
This position is part of the Quality Management (QM) group at HOOKIPA and reports directly to the Senior Manager Quality Control. In addition to all other parts of QM this position has day to day interaction with HOOKIPA key functions, such as External Manufacturing, Project/Portfolio Management, Technical Development and Regulatory Affairs. Most importantly there is a constant interaction with various parts of the Gilead organization as required by the respective project status.
This position focuses on the goals and deliverables of the Gilead cooperation from the QM point of view (Quality Control & Compliance). The incumbent should act as the solely go-to function within HOOKIPA Quality groups and for Gilead CMC contacts.

**Main Responsibilities:**

<u>Technical project management</u>

- Provide overall guidance of all Quality functions relative to their contribution to the Gilead collaboration
- Continuously plan, review, and revise the QM relevant parts of the Gilead project plan (in close cooperation with HOOKIPA Gilead project manager and non-QM functions towards the benefit of the project)
- Closely monitor the development of all applicable parts of the project, identify QM implications and develop/decide on actions as well as appropriate priorities to make the project run smoothly. This includes in particular following responsibilities:
    - supplier qualification
    - CMO/CLO oversight
    - sample prioritization and testing
    - results evaluation and presentation (Results will trigger project planning and steering within QM)
- Liaise between Quality and Regulatory relative to the Gilead cooperation, provide regulatory writing for QM-owned CMC parts of clinical trial applications (IB, IND, IMPD etc.)
- Liase between the HOOKIPA Quality Groups, External Manufacturing and Project Management to assure project progress and required product release cycle times
- Contribute to continuous improvements of HOOKIPA's Quality systems

General project leadership

- Focus on project progress and success by providing all quality-related input necessary
- Drive input based on Quality requirements according to the ICH/EU/AMBO, i.e. keeping up-to-date with most recent project developments and implementing appropriate measures accordingly
- Own specific Quality systems within HOOKIPA, provide SOP training to the rest of the project team members and run self-inspection of day-to-day practice aiming at continuous improvement
- Manage the QM side of the project timelines and budget as needed
- Ensure intercultural awareness between the project team members

**Qualifications & Skills:**

- University Studies, degree in a Life Science area like Pharmacy or Biochemistry
- Substantial experience in managing research cooperation projects with a specific Quality Management focus (ideally experience within clinical development, clinical research and clinical trial environment in the biotech area)
- Particular knowledge of recombinant virus vector technology a strong plus
- Hands-on knowledge of EU GMP regulation
- Fluency in English, both spoken and written

**What we offer:**

- Strong team with dedicated and passionate scientists
- State of the art infrastructure
- 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 3.802,- 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 a cover letter (summarizing your qualification and experiences) as well as your credentials to: **talent@hookipapharma.com**

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