

HYLORIS PHARMACEUTICALS SA

Quality Assurance Officer

We are currently looking for a Quality Assurance Officer. The successful candidate will be responsible for ensuring any Quality Assurance activity in a start-up environment, focused largely on reformulated or repurposed value-added medicines in a broad variety of therapy areas and will support the Director QA & RA in a key role to set-up a quality system for Hyloris' global operation.

Job description

As Quality Assurance Officer, you will:

- Assure continuous compliance with quality and industry regulatory requirements, including oversight of external documents (such as protocols & reports from subcontractors & suppliers, clinical datasets, scientific publications, etc...)
- Interpret and implement quality assurance standards and procedures applicable to the company's work environment
- Draft, publish and roll-out quality assurance policies and procedures
- Keep track of vendor / supplier qualification.
- Investigate customer complaints and non-conformance issues
- Collect and compile data related to quality and perform descriptive statistics over time-course
- Analyze data to identify areas for improvement in the quality system
- Develop, recommend, and monitor corrective and preventive actions (CAPA)
- Prepare reports to communicate outcomes of quality activities
- Review the implementation and efficiency of quality and inspection systems, including key performance indicators
- Document internal audits and other quality assurance activities
- Identify training needs and organize training interventions to meet quality standards
- Organize risk management activities, independently and with project teams
- Responsible for document management systems

Your professional profile

- Minimum Qualification: Bsc medical, pharmaceutical or life sciences or quality management
 - Minimum Experience: 3+ years industrial experience in (pharmaceutical) quality assurance
 - Languages: English (written and verbal) – French is an asset
 - Computer proficiency is mandatory
 - Certifications is an advantage including Quality Auditor, Quality Engineer, Quality Improvement Associate, Six Sigma
 - Familiarity with GMP, GLP, GCP, and ICH guidelines is required
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Your abilities

- Demonstrates strong work ethics, and excellent written and verbal communication skills
- Strong problem-solving skills with an aptitude for providing solutions
- Eye for detail especially regarding consistency of instructions across several documents
- Ability to balance a sense of urgency with adherence to quality
- Be proactive and results-oriented with a focus on business
- Strong interpersonal skills, a collaborative and trust enabling work style, building partnerships among key stakeholders
- Organizational aptitude to be a part of an outstanding team
- Adaptability, flexibility, independence, and resourcefulness to both lead a big vision strategy while also being willing to roll-up-sleeves and multi-task to thrive in a start-up environment dedicated to growth
- To have essential professional attributes include a detailed-oriented analytical thinking, a team-player attitude, respect and understanding for cultural differences in different countries, and efficient utilization of time and resources

About Our Company

Hyloris is a specialty biopharma company identifying and unlocking hidden potential in existing medications for the benefit of patients and the healthcare system. We apply our knowhow and technological innovations to existing pharmaceuticals and have built a broad proprietary pipeline with the potential to offer significant advantages over currently available alternatives. We currently have two, partnered commercial-stage products, Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid analgesic for the treatment of pain. Our development strategy primarily focuses on the FDA's 505(b)2 regulatory pathway, which is specifically designed for pharmaceuticals for which safety and efficacy of the molecule has already been established. This pathway can reduce the clinical burden required to bring a product to market, and significantly shorten the development timelines and reduce costs and risks. Hyloris is based in Liège, Belgium. For more information, visit www.hyloris.com.

Our values

Our talented staff work in accordance with our company values:

- We are proud of our entrepreneurial culture and foster open communication, mutual respect, professionalism and efficient decision-making and we believe that our multicultural organisation is one of our most important competitive advantages.
- We believe that timely and well considered decisions as a response to emerging opportunities and ideas is the key to our success.
- We believe that the success of the company lies in the competence, dedication, and motivation of each of our employees.
- We believe that freedom returns flexibility and empowerment returns commitment.

For more information about our company, please visit www.hyloris.com. Motivation letter and CV can be sent to koenraad.vanderelst@hyloris.com.
