

HYLORIS PHARMACEUTICALS SA

Manager Regulatory Strategy

We are currently looking for a Manager Regulatory Strategy. The successful candidate will contribute to regulatory strategy in a start-up environment and coordinate regulatory submissions across different stages and therapeutic areas, focused largely on reformulated or repurposed value-added medicines.

Job description

As Manager Regulatory Strategy, you will:

- Support the leadership team during interactions with FDA and other relevant regulatory agencies
- Manage regulatory submission requirements and deadlines
- Manage company systems to ensure accurate documentation of all regulatory submissions
- Coordinate cross-functionally to assist with the organization of regulatory applications and reports
- Participate in technical discussions, presenting, compiling, and reporting relevant strategies and making recommendations
- Conduct regulatory research and literature searches and author submission packages (including but not limited to meeting requests and packages, IND/NDA sections, PSPs, ODDs)
- Collaborate with vendors to submit applications and reports to applicable regulatory agencies within established timelines and with high-quality standards
- Support the implementation of new processes and SOPs

Your professional profile

- Minimum Qualification: PhD medical or life sciences
- Minimum Experience: 5+ years industrial experience in regulatory affairs
- Languages: English (written and verbal) – French is an asset.
- Computer proficiency is mandatory.
- Experience with FDA regulations and guidelines on drug development is required.
- Direct experience with FDA meetings and 505(b)(2) development programs required.
- Familiarity with GLP, GCP, and ICH guidelines required.
- Experience with ex-US regulatory health authorities an asset.
- Experience with regulatory submissions software an asset.

Your abilities

- Demonstrates strong work ethics, and effective written and verbal communication skills.
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- Strong problem-solving skills with an aptitude for providing solutions.
- Ability to balance a sense of urgency with adherence to quality.
- Excellent written and verbal communication.
- Be proactive and results-oriented with a focus on business.
- Strong interpersonal skills, a collaborative and trust enabling working 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 growing environment.
- To have essential professional attributes including 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.
