

# HYLORIS PHARMACEUTICALS SA

## Regulatory Officer

We are currently looking for a Regulatory Officer. The successful candidate will be responsible for execution of regulatory applications of various types of pharmaceutical applications.

### Job description

As Regulatory Officer, you will:

- Provide regulatory operations support in a start-up environment
- Manage regulatory submissions across different stages of the development path
- Manage and publish medicinal product dossiers
- Collaborate with vendors to submit applications and reports to applicable regulatory agencies within established timelines and high-quality standards
- Keep track of regulatory procedures and organize responses to information requests and commitments given to health authorities
- Manage and publish medicinal product dossiers
- Focus on development of reformulated or repurposed value-added medicines in a broad variety of therapeutic areas
- Participate in technical discussions, project meetings and reviews
- Collaborate with Hyloris' multidisciplinary team and outside partners
- Publish and author submission packages (including, but not limited to, Scientific Advice, CTA, MAA)

### Your professional profile

- Minimum Qualification: Master medical, pharmaceutical or life sciences
- Minimum Experience: 3+ years industrial experience in regulatory affairs
- Languages: English (written and verbal) – French is an asset
- Computer proficiency is mandatory
- Experience with European & FDA regulations & guidelines on drug development is required
- Direct experience with publishing of submission packages is required
- Familiarity with GMP, GLP, GCP, and ICH guidelines is required
- Experience with regulatory submissions software an asset

### Your abilities

- Demonstrates strong work ethics, and effective written and verbal communication skills
  - 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
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- Meticulous attention to detail regarding publishing of submission packages
- Be proactive and results-oriented with a focus on business needs
- 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 start-up environment dedicated to growth
- To have essential professional attributes include analytical thinking, team-player attitude, mutual respect and understanding for cultural differences in a global team and environment 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](http://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](http://www.hyloris.com). Motivation letter and CV can be sent to [koenraad.vanderelst@hyloris.com](mailto:koenraad.vanderelst@hyloris.com).

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