Krystal Biotech

Pharmacien Responsable

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About Krystal Bio: At Krystal Biotech, we bring together the brightest and most eager minds to relentlessly pursue the discovery, development, manufacturing, and commercialization of genetic medicines to treat diseases with high unmet medical needs. Founded in 2016, Krystal is distinguished in three powerful ways: science and technology using our patented gene therapy platform, innovative manufacturing supported by our commercial scale facilities, and a unique commercialization model that focuses on the patient's end-to-end experience.
Krystal received U.S. FDA approval for the first and only redosable gene therapy treatment, VYJUVEK®, for the treatment of Dystrophic Epidermolysis Bullosa (DEB). Krystal continues to leverage our proprietary platform to rapidly advance a robust pipeline of investigational genetic medicines in respiratory, oncology, dermatology, and ophthalmology.
Krystal is headquartered in Pittsburgh, PA, which is home to our two state-of-the-art CGMP manufacturing facilities with teams around the world and satellite offices in Switzerland, Germany, and Japan. We are a company built and run by people who care, are fearless in the face of a challenge, love the work they do, and practice the highest level of scientific integrity. As we grow, we are seeking team members that embody these values.

Role Overview: The Responsible Pharmacist ensures that all pharmaceutical activities comply with French and European regulations.
They are legally accountable to the French Health Authorities (ANSM) for the quality, safety, and compliance of biological medicinal products.

Key Responsibilities:

- Ensure compliance with the French Public Health Code
- Guarantee adherence to GxP (GMP, GDP, GVP)
- Act as the primary contact with ANSM
- Set up the exploitant status in France
- Oversee compliance of Marketing Authorizations and regulatory dossiers
- Ensure appropriate licenses are maintained (MAH, manufacturer, importer)
- Oversee or delegate batch release activities (in coordination with the Qualified Person if applicable)

- Maintain the Pharmaceutical Quality System (QMS)
- Approve key quality procedures
- Supervise deviations, CAPAs, change controls, and OOS investigations
- Oversee pharmacovigilance systems (in coordination with PV responsible person)
- Ensure proper reporting of adverse events
- Approve promotional and scientific materials
- Ensure compliance with GDP (Good Distribution Practices)
- Oversee storage, distribution, and import/export activities
- Manage product recalls and quality complaints
- Lead preparation for ANSM inspections and partner audits
- Ensure implementation of corrective and preventive actions
- Support, as needed, some activities related to other European countries

Qualifications:

- Doctor of Pharmacy
- Mandatory registration with the French Order of Pharmacists (Section B or C depending on activity)
- Significant experience in pharma/biotech industry
- Background in Quality, Manufacturing, or Regulatory Affairs
- Experience in rare disease
- Experience with regulatory inspections (ANSM/EMA)

Key Skills:

- Strong knowledge of French and EU pharmaceutical regulations
- Expertise in GxP (GMP, GDP, GVP)
- Scientific rigor and ethical mindset
- Ability to operate in innovative biotech environments
- Excellent communication with authorities and stakeholders
- Native French speaker with good working proficiency in English

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