Apprentice Regulatory Affairs, Global Regulatory Affairs Development Strategy

Reports to: **Senior Specialist Regulatory Affairs**
Location: **Paris - Levallois-Perret**

Alexion, Astrazeneca Rare Disease, is a global biopharmaceutical company focused on serving patients and families affected by rare diseases and devastating conditions through the discovery, development and commercialization of life-changing medicines. As a leader in rare diseases for more than 25 years, Alexion has developed and commercializes two approved complement inhibitors to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), as well as the first and only approved complement inhibitor to treat anti-acetylcholine receptor (AchR) antibody-positive generalized myasthenia gravis (gMG) and neuromyelitis optica spectrum disorder (NMOSD). Alexion also has two highly innovative enzyme replacement therapies for patients with life-threatening and ultra-rare metabolic disorders, hypophosphatasia (HPP) and lysosomal acid lipase deficiency (LAL-D) as well as the first and only approved Factor Xa inhibitor reversal agent. In addition, the company is developing several mid-to-late-stage therapies, including a copper-binding agent for Wilson disease, an anti-neonatal Fc receptor (FcRn) antibody for rare Immunoglobulin G (IgG)-mediated diseases and an oral Factor D inhibitor as well as several early-stage therapies, including one for light chain (AL) amyloidosis, a second oral Factor D inhibitor and a third complement inhibitor. Alexion focuses its research efforts on novel molecules and targets in the complement cascade and its development efforts on hematology, nephrology, neurology, metabolic disorders, cardiology, ophthalmology and acute care. Headquartered in Boston, Massachusetts, Alexion has offices around the globe and serves patients in more than 50 countries. This press release and further information about Alexion can be found at: www.alexion.com.

Position Summary

- During this apprenticeship in the Global regulatory affairs – Development Strategy (GRA-DS) department, you will have the opportunity to support various regulatory activities of Alexion- products in clinical stages in rare diseases indications.

Principal Responsibilities

Your main responsibilities will include but are not limited to:

- Preparation and submission of Clinical Trial Applications to worldwide Competent Authorities
- Support the answer to questions from Competent Authorities
- Participation to Clinical Trial Team meeting
- Preparation of Pediatric Investigation Plan, Orphan Drug Designation or Scientific Advice applications
- Regulatory intelligence
- Keep regulatory database up to date

Qualifications

- Have performed a first internship in the Industry
- Have basic knowledge and interest in clinical development
- Dynamic and able to build working relationship and collaborate with others, good team player,
- English both written and oral

Education

- PharmD : Pharmaceuticals studies
- Master's Degree : Regulatory Affairs

Competencies

- IT : microsoft pack office

AstraZeneca embraces diversity and equality of opportunity. We are committed to building an inclusive and diverse team representing all backgrounds, with as wide a range of perspectives as possible, and harnessing industry-leading skills. We believe that the more inclusive we are, the better our work will be. We welcome and consider applications to join our team from all qualified candidates, regardless of their characteristics. We comply with all applicable laws and regulations on non-discrimination in employment (and recruitment), as well as work authorization and employment eligibility verification requirements.