

Aston Life Sciences is the proud leading company in Consulting, Recruitment and Executive Search for Life Sciences industry in Switzerland. Part of Vulcain Engineering Group (+ 1'700 employees worldwide) through its Life Sciences branch Consultys, we are based in Switzerland and serve Eastern and Western Europe as well as North America. Life Sciences is our passion and we are committed to successfully support our clients in their quest to improve patient's health all around the world.

For one of the global leaders in the Pharmaceutical industry located in the Zürich area, we are looking for a:

Regulatory Affairs Manager (1-year contract)/ Pharmaceutical *Zürich area*

Your role: As Regulatory Affairs Manager, you will be part of the Global Regulatory and Quality organization within Pharmaceutical R&D department for Oncology products. The main mission will be to develop regulatory strategy and lead regulatory projects with cross-functional teams related to post authorization activities. Possibility to be directly hired by the company at the end of this 1-year contract.

Your tasks:

- Participate with the EU Regulatory team to develop Regulatory strategy for clinical and non-clinical related post authorization activities for Oncology
- Manage projects with cross-functional teams to deliver clinical and non-clinical life cycle regulatory activities such as: Type II variations, PASS, PAMs, PSURs for Oncology
- Lead interactions with the local operating companies and global cross-functional teams in relation to pre- and post-launch regulatory activities
- Provide Regulatory consultative advice and support to Early Access Programs
- Collaborate on operational activities with the EMA (European Medicines Agency) for centrally approved products

Your profile:

- Bachelor, Master Degree or similar diploma in a Scientific discipline
- From 5 years of Regulatory Affairs experience in Pharma or Biotech environment
- Strong Regulatory experience for Oncology drug development and life-cycle management
- Documented post-authorization experience with the European Medicines Agency for centrally approved products
- Proven experience of working in a global environment in Pharma or Biotech environment
- Demonstrated track record to work in a cross-matrix organization
- Very good oral and written communication skills in English is a must
- Ability to prioritize and manage changing workload and meet deadlines
- Attention to details with communication and influencing skills to advise internal partners and negotiate with external stakeholders

Start date: 17 February 2020

Place of work: Zürich area