Debiopharm is a private, Swiss-based biopharmaceutical company. Mainly focused in oncology and bacterial infections, the company develops innovative therapies that target high unmet medical needs with an ambition to improve patient quality of life. Debiopharm Research & Manufacturing S.A., based in Martigny, is a pharmaceutical research, development and production facility, inspected and registered with the main regulatory authorities. The Company is a world leader in polylactic-co-glycolic acid (PLGA)-based injectable, sustained-release technology.

For his **Regulatory Affairs** Department, Debiopharm Research & Manufacturing in Martigny is looking for a

REGULATORY AFFAIRS MANAGER, 100%

Your Mission :

Manage all post marketing regulatory activities of chemical pharmaceutical drug products including renewals, CMC variations, update of Labeling, extension of indications.

Your Responsibilities :

- Maintenance of registration files for all post-approval activities.
- To author, review and lead high quality documents for regulatory submissions.
- Prepare response to questions raised by competent regulatory agencies.
- Provide expert content guidance for quality portions of the CTD, ensuring compliance of documentation to internal company standards and external regulatory guidelines.
- Coordinate with partners' regional regulatory teams for global strategy.
- Define, develop and lead regulatory strategies for post-marketing activities.
- Assess internal change controls.
- Maintenance and update of the Product Information.
- Internal Regulatory contact for Pharmacovigilance and Marketing and Business.
- Keep up to date Regulatory Information Management System.
- Maintain policy & regulatory intelligence.
- Provide regulatory strategies for projects as RA representative in cross-functional teams.

Your Profile :

- Degree in Science (e.g. Chemistry, Pharmacy) or equivalent.
- Min 3 years' experience in Pharmaceutical regulatory affairs for sterile parenteral chemical drugs, ideally prolonged-release formulation.
- Maintenance, Renewal, Update Labeling, Extension of indications.
- Good knowledge of ICH Quality standards, European and US pharmacopoeias, International CMC Guidances, including ASEAN.
- Previous experience in meeting with Health agencies.
- Strong attention to details and organizational skills required.
- Good written and oral communication, technical writing and editing skills.
- Ability to handle different topics and willingness to learn.
- Demonstrate good interpersonal skills, ability to work with others in an international team environment, effective interactions in cross department teams.
- Orientation for work result details, with emphasis on accuracy and completeness.
- Fluent in French and English.

If you fit this profile please send your application by our website : **www.debiopharm.com/careers**