

# REGULATORY AFFAIRS SPECIALIST

Geneva, Switzerland

## Company description

Labatec Pharma is a Swiss pharmaceuticals company backed by more than 50 years' experience in proposing high-quality products to its home market. Our strategy is to continuously extend our drugs portfolio, focus on injectable generics for the hospital market, as well as grow multi-market.

## Purpose and scope

Manage the submission and approval of applications for new products and variations in Switzerland for products under responsibility and ensure regulatory compliance.

Support regulatory activities in export markets.

## Key responsibilities and accountabilities

- Assist in the development of regulatory strategies for product acquisition (due diligence activities), technical changes and maintenance for drug products, medical devices and food supplements.
- Manage submission and approval of applications for marketing authorizations in Switzerland
- Manage the maintenance of existing MAs (CMC variations, product information/labeling updates, renewals...) in Switzerland.
- Supports applications for new MAs, variations and renewals in export markets (in close collaboration with local team).
- Prepare/update and review internal regulatory SOPs.
- Assist in answering to medical information requests.
- Assist in reviewing and approving promotional materials for Switzerland.
- Assist in preparing product's reimbursement dossiers for Switzerland.
- Assist the Local Safety Officer in pharmacovigilance activities for Switzerland.

## Education / Languages

- Degree in a Life Science, higher degree preferable (PharmD, PhD, MSc)
- Excellent spoken and written English and French; Intermediate level spoken and written German (highly appreciated).

## Professional skills and experience

- 2-5 years of relevant regulatory affairs experience
- Good knowledge of European regulation and preferably of the Swiss regulation (experience with Swissmedic highly appreciated)
- eCTD experience
- Knowledge of Pharmacovigilance requirements
- Pragmatic, focus on results and solutions
- Must be flexible and adaptable to changing project priorities and work assignments

Please send your application to [careers@labatec.ch](mailto:careers@labatec.ch)