

REGULATORY AFFAIRS OFFICER



Lisbon, Portugal

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 Portugal for products under responsibility and ensure regulatory compliance.

Support regulatory activities in export markets and in Switzerland.

Key responsibilities and accountabilities

- Assist in the development of regulatory and pricing strategies for product acquisition (due diligence activities), technical changes and maintenance for drug products in Portugal.
- Manage submission and approval of applications for marketing authorizations in Portugal.
- Support applications for new MAs, variations and renewals in export markets (in close collaboration with local team).
- Help with the registration and maintenance of MAs in Switzerland.
- Prepare/update and review internal regulatory SOPs.
- Work in close collaboration with the QPPV in pharmacovigilance activities for Portugal.
- 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. Basic knowledge in French (highly appreciated).

Professional skills and experience

- 2-5 years of relevant regulatory affairs experience
- Experience in preparation and submission of new applications/variations in Portugal
- Experience with regulatory agency interactions and preparation of documents for regulatory agency interactions
- eCTD experience
- Knowledge of Pharmacovigilance requirements
- Pragmatic, focus on results and solutions

Please send your application to careers@labatec.ch