

We provide you with expert and comprehensive support in quality, pharmacovigilance, regulatory affairs and more.

You can concentrate on your core business.

QUALITY MANAGEMENT

- Assumption of the function of the technically responsible person (RP) / responsible person for narcotics (vP)
- · Supervision of the quality management system
- Carrying out audits (external / internal) and inspections by authorities (incl. preparation and follow-up)
- Evaluation of product quality reviews
- · Assistance with training management

PHARMACOVIGILANCE

- Assuming the role of person responsible for pharmacovigilance
- Monitoring and reporting of adverse effects and quality defects

REGULATORY AFFAIRS

- · Advice on authorisation strategies
- Adaptation of the EU dossier to the requirements of Switzerland (Module 1)
- Implementation of registration procedures from 'pre-submission' to 'post approval'
- Life cycle management (variations, renewals)
- Adaptation of packaging texts and medicinal product information texts

SETTING UP A BRANCH OFFICE

 Support with administrative tasks for the establishment of a company branch in Switzerland incl. company headquarters at Alloga

