PharmaServices

Our modules

Quality management

- Assuming the role of responsible specialist or their deputy in accordance with Swiss law
- Assuming the role of responsible person for narcotics or their deputy in accordance with Swiss law
- Creating and maintaining a quality management system
- Conducting and supervising audits, self-inspections and/or inspections by authorities
- Assisting with the preparation and follow-up of audits and inspections
- Product quality review tests
- Creating and implementing training courses

Pharmacovigilance

- Assuming the role of person responsible for pharmacovigilance
- Dealing with undesirable effects, quality defects and medical enquiries, and forwarding them on.
- Submitting periodic safety update reports (PSUR)

Regulatory affairs

- Life cycle management (variations, renewals)
- Managing registration procedures from pre-submission to market approval and post-approval
- Preparing electronic dossiers (eCTD, eDok)
- Adapting EU dossiers to Swiss requirements
- Advice on marketing authorisation strategies

Assuming responsibility for medical devices

- As an importer
- As an authorised representative (CH-REP) and/or as a person responsible for regulatory compliance (PRRC)

Health insurance approval

- Strategic consulting
- Preparing new applications for admission and changes to the specialities list
- Preparing requests for price increases (PEG)
- Support in reviewing admission conditions every 3 years

Setting up a branch office

- Supporting administrative tasks to establish a branch office in Switzerland, including the registered office at Alloga
- Opportunity to share use of Alloga's infrastructure (workspaces, reception, meeting room, canteen)
- Assuming the role of authorisation holder for companies that do not have a Swissmedic operating licence

We provide you with expert and comprehensive support in quality and regulatory matters.

How you can benefit from PharmaServices

- ✓ At Alloga, you can look forward to dealing with a highly qualified team with wide-ranging expertise and plenty of experience.
- ✓ We will provide you with professional advice and show you how we can best support you with our range of services. Direct communication and short response times make us flexible and efficient.
- ✓ You can concentrate on your core business while we provide you with the resources you need to ensure comprehensive quality management.
- ✓ On request, we can also support you in the following areas:
  - Registration matters
  - Importing medical devices or providing a CH-REP
  - Helping pharmaceutical companies operating abroad to gain a foothold in Switzerland
  - Establishing a company headquarters at the Alloga premises and sharing use of the infrastructure

Do you have any other quality requirements or would you like to receive a quote? We would be happy to make time for you and work with you to evaluate possible solutions.

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