Gesundheitswesen | Market Access & Medical | Firmenseminare

Regulatory Affairs intensive

Advanced insights into regulatory affairs requirements and processes in the Swiss pharma environment

In the practice-oriented seminar Regulatory Affairs intensive, you will gain in-depth insights into regulatory requirements and processes within the Swiss healthcare market. You will learn to confidently understand and apply regulatory foundations as well as current developments. In addition, you will train how to competently navigate approval processes and regulatory authority requirements, in particular with Swissmedic and the FOPH (Federal Office of Public Health).

Another focus is on identifying and proactively managing interfaces with Market Access, Quality, Clinical, Medical Affairs and Marketing. You will develop practical strategies for preparing dossiers and for effective communication with stakeholders. Furthermore, you will place Regulatory Affairs in an international context and take into account the specific characteristics of the Swiss market.

By the end of the seminar, you will be able to apply your knowledge directly in practice and handle regulatory challenges in a professional and confident manner.

Learning objectives

The focus is on collaborative reflection, discussion and building on experience at eye level.

- You discuss regulatory challenges in the Swiss environment at an advanced level and confidently put them into context
- You develop complex regulatory and lifecycle strategies and critically assess them, gaining greater confidence in handling approvals and variations
- You confidently manage interactions with authorities and develop an enhanced understanding of regulatory authority communication
- You recognize typical challenges at interfaces with Market Access, Quality, Clinical, Medical Affairs, and Marketing and are able to develop solution approaches
- You further develop experiences, best practices, and current challenges through peer exchange

Content

- Regulatory Affairs in overview
- Legal basis (HMG / AMZV)
- National and international approval processes
- Swissmedic perspectives
- Workshop «market entry switzerland»
- Label Customisation & Lifecycle Management, Product Information & Labelling Switzerland
- RA – Medical – Marketing – Market Access – Pharmacovigilance (PV) - QA – Supply Chain – Compliance
- Approval process and procedure for the meeting with Swissmedic
- CTD & eCTD with focus Swissmedic
- Inspection Readiness
- Trends in Regulatory Affairs

Practical relevance

Regulatory Affairs plays a key role in market access within the pharmaceutical industry. This seminar provides hands-on knowledge of Swissmedic and FOPH requirements, dossier preparation and interface management. In this way, you help ensure efficient approvals, reduce risks and contribute to overall business success.

At the same time, we actively encourage peer-to-peer exchange: participants are given space to share their own experiences, learn from one another, and build professional networks on an equal footing. This not only supports fast and well-founded approvals, minimises risks, and strengthens business performance - it also creates a valuable, collaborative learning environment.

Target group

- Advanced Regulatory affairs professionals (not suitable for beginners)
- Senior RA specialists or professionals with several years of experience
- Professionals actively working with Swissmedic or international regulatory authorities
- Professionals who wish to discuss complex topics and learn from one another
- Participants seeking peer-to-peer exchange and practical discussions

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Datum
Mittwoch, 28. Oktober 2026
Donnerstag, 29. Oktober 2026

Zeit
jeweils 09.00 - 17.30

Sprache
English

Art der Veranstaltung
Seminar

Ort
shqa
Hirschmattstrasse 1, 6003 Luzern
Lageplan

Das shqa Büro liegt im 1. Stockwerk

Kosten pro Person (exkl. MwSt.)
CHF 1'960 .– (für shqa Mitglieder)
CHF 2'960 .– (für Nichtmitglieder)
In diesen Kosten inbegriffen sind: Seminarpräsentation und Teilnahmebestätigung

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