



Regulatory Affairs Specialist (f/m/d) – Germany & Switzerland

Job No. R3610499, Munich, Germany
Chemietarif Bayern (Entgeltgruppe 10-12)

About us

GE Healthcare is a leading global medical technology and digital solutions innovator. Our mission is to improve lives in the moments that matter. Unlock your ambition, turn ideas into world-changing realities, and join an organization where every voice makes a difference, and every difference builds a healthier world.

Your responsibilities

Germany:

You will support all maintenance and life-cycle activities for pharmaceutical products within national and international practices (MRP, DCP, CP):

- Preparation, update, review of regulatory texts (SmPC, PIL, Labelling) and artwork
- Review of advertising material
- Communication and coordination with stakeholders to ensure the necessary measures for maintaining regulatory compliance of the existing drug approvals (Life Cycle Management)
- Support in update/preparation of SOPs

Switzerland:

You will provide Pre- and post-market support:

- Conduct research on new submission requirements and options, monitor and communicate about upcoming challenges in the Swiss market
- Assist in regulatory projects, track processes incl. timely entries in regulatory databases and systems as well as compliant document archiving
- Support in compiling SL-applications to the BAG
- Prepare, update, and review Swiss product labelling (SmPC, basic text, labels) to ensure conformity with current applicable regulatory requirements

Your profile

- University degree in life sciences (pharmacy, chemistry, biology or related discipline)
- Proven professional experience in the field regulatory affairs (RA) with pharmaceutical products
- RA experience in Germany as well as in Switzerland
- Experience in national and international practices (MRP, DCP, centralized procedures)
- Profound knowledge of the requirements for marketing authorization applications as well as the appliance and interpretation of relevant guidelines
- Experience of review of Marketing Material in Germany (HWG, UWG, FSA); experience as Information Officer acc. § 74a AMG is an asset
- Experience in Health Authority negotiations
- Fluency in German and English

We look forward to receiving your [online application](#) or on [GE Careers](#) by searching for the following job number **R3610499**!

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