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Regulatory Affairs Manager - (Swiss Submissions, home-based) (m/w/d)

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Company: IQVIA

Location: Brussels

Category: other-general

The Manager, Regulatory Affairs International supports ambitious geographical expansion plans. The position will support registration of existing portfolio products into new territories and to register several of development projects into the international region. This role is key to driving both the Regulatory strategy and execution.• Provide Regulatory Consulting for ODS Applications, New Marketing Authorisation Applications, as well as Swiss variation and PSUR submissions.
Key Responsibilities/Scope of the Job
Manage client's product portfolio

Prepare the Swiss submissions based on applications submitted in EU or elsewhere including all documents

needed for inclusion in module 1 of the eCTD. Perform a quality check on the documentation for suitability for submission to Swissmedic (validation according to Swissmedic requirements).

Create/update the Swiss Product Information (Information for Professionals and Patient Information as applicable) based on the SmPC approved in the EU or elsewhere.

Prepare module 1 documents (forms, locally required documents etc.) based on the documentation provided by Company (e.g., module 1 from the EU submission). Indicate sufficient hyperlinking for Swissmedic purposes.

Perform/Support submissions activities to Swissmedic through the appropriate electronic gateway and support client during the entire regulatory process.

Establish and maintain contact with the national regulatory authorities (Swissmedic) on behalf of client

Assist client's in national regulatory affairs issues and provide advice on national-specific requirements related to clients product(s)

Monitor national Regulatory Affairs legislation and continuously inform client of new or changed national requirements that affect client's products

Advise client on current Swissmedic requirements for packaging materials.

Co-ordinate end to end local activities including artwork and proof reading

aRMM submissions, adaptation, and maintenance (translation)

Update product information to relevant local HA databases

Position Qualifications
Education/Learning Experience/Work Experience
A University Degree in Life Sciences is required with 5 to 7 years of industry experience, of which at least 3 years of experience within Regulatory Affairs (registration, development, maintenance)

Experience of regulatory requirements in countries outside the US and Europe

Very good knowledge in written and oral English is required, knowledge of any other languages would be an asset

Experience from leading projects and cross-functional teams

German language on B2/C1 level

Personal Attributes
A strong team player, with the ability to work effectively in a team setting and interact with people of different cultural, seniority and functional backgrounds

Highly self-motivated and able to drive activities

Excellent communication skills

The suitable candidate should demonstrate the values; Care for our patients, for our colleagues and for our company, Ambition, Urgency, Ownership and Partnership

Ensure exemplary behavior, ethics and transparency within the Company and with regulatory agencies

#LI-Remote
IQVIA is a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry. We believe in pushing the boundaries of human science and data science to make the biggest impact possible – to help our customers create a healthier world. Learn more at

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