

## Sr. Regulatory Affairs Specialist

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Company: Abbott

Location: Wavre

Category: other-general

For our Diabetes Care division, we are recruiting a Senior Regulatory Specialist for Benelux. The Senior Regulatory Specialist is responsible for managing an efficient program to ensure that all regulatory activities for Abbott Diabetes Care products are achieved to an agreed schedule.

### Role and Responsibilities:

Formulate, develop and manage a program to enable all EMEAP registrations, when applicable, are completed efficiently and to an agreed schedule.

Manage a roll out program for existing products and new launches.

Work with the Regulatory Management team, Regulatory Affairs colleagues, and cross-functional team to develop and implement strategies that will ensure the timely introduction of products onto the international market.

Manage the creation and development of Technical files and/or submission documentation for Abbott Diabetes Care devices in accordance with regulatory requirements, including MDR 2017/745 & IVDR 2017/746.

Provide guidance to Regulatory colleagues in coordinating the preparation of regulatory submissions.

### Your Profile:

Educated to university degree level or equivalent preferably in a Scientific discipline e.g. Chemistry, life Sciences, Biology.

Experience of working within the requirements of ISO 13485, the Medical Devices Directive (93/42/EEC), Medical Device Regulation 2017/745, and/or the IVD Directive (98/79/EC), IVDR 2017/746.

Experience of working with local Regulatory requirements if applicable (Belgium, Luxemburg, The Netherlands)

Ability to establish excellent working relationships with regional and global internal stakeholders and navigate complex matrix environments.

Strong communication skills (verbal and written).

English, French required. Dutch is a strong asset.

Abbott offers an attractive salary package combined with good opportunities to learn and develop. If you recognize yourself in this profile and you would like to know more, please apply online.

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