



(Junior) Manager (m/f/d) Medical Device Vigilance »

Within Fresenius Medical Care, the QREM Department (Quality, Regulatory Affairs & Management Systems) has the key responsibility to ensure that the company maintains and receives its marketing authorizations (e.g. CE-marks or drug registrations). Having identified legal requirements and regulations for the company, QREM works with different departments guiding them and ensuring that regulatory compliance and regulatory prerequisites for medical devices & drugs are met. Within the company, QREM holds different regulatory functions and one lies within Drug Regulatory Affairs & Product Safety.

Your assignments

As a "**(Junior) Manager (m/f/d) Medical Device Vigilance**" you will make an important contribution to the safety of our medical devices. You will record and document medical device risks and will identify and document product safety indicators, create post market surveillance & periodic safety update reports and process product incidents.

Your task will also include recording and documenting of risks concerning medical devices. While reporting medical device incidents to the authorities, you will compile risks of medical devices for clinical evaluation and will draft product safety indicators.

Process optimization for vigilance of medical devices and maintenance of security databases will be part of your responsibility.

Your profile

If you have a graduate degree in technical or scientific studies or equivalent qualification with relevant experience in a similar function then you would be on the right track. We would surely appreciate your application if you have professional expertise in EU medical devices law (incl. MEDDEV guidelines) and experience in Management System Standards (ISO 13485, ISO 14971).

If you enjoy using your analytical, evaluation and decision-making skills then this position would be worth your while.

On a personal level, you would convince us if you are keen on demonstrating your strong communication and conflict management competence and if you are capable of handling confidential information and of interacting across all levels of business functions. In this role as a "**(Junior) Manager (m/f/d) Medical Device Vigilance**", we expect you to have high language proficiency in German and English (written and spoken) to interact within our international working environment.

Your contact

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