QMD Services
Quality | Medical | Devices

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Because patient safety matters

Product Reviewer (Full time) (m/w/d)

Job description:

As part of your mission as a product reviewer, you will be responsible for carrying out evaluations as part of the CE marking conformity assessment procedures in the field of in-vitro diagnostic devices.

You will be responsible for reviewing the technical documentation of the manufacturers independently or as a team of reviewers with the goal of verifying whether the devices meet the requirements of the regulation IVDR 2017/746 and other relevant standards. You have to write technical reports and to support the entire certification project. Ultimately your work will determine whether a device has been demonstrated to be safe and effective, meets the intended use, and can be recommended for CE certification to the notified body.

Essential Functions:

- Conduct CE product review assessments in the framework of the applicable European Regulations (CE) for a wide range of in-vitro diagnostic medical devices for different risk classes depending on the area of expertise.
- Coordinate with other product reviewers, clinical specialists, and the project managers to meet the review timelines, provide quality review reports and ensure the consistency of the information via the consolidation of the review/assessment.
- Ensure active regulatory monitoring and communication within the team of new requirements identified in your specific areas of in-vitro diagnostic medical device expertise.

Required Education and Experience:

- Successfully completed studies (bachelor/master/diploma) in the field of medicine or equivalent qualification in relevant studies, such as medical technology, pharmacy, engineering or other relevant sciences.
- Professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing or research.
- Independent work, correct and precise way of working
- Fluent English skills as well as experienced handling of MS Office applications
- knowledge of IVDR as well as related harmonised standards/state of art standards, CS and MDCG guidance documents
- Experience with a notified body or comparable is desirable