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**Because patient safety matters**

# Specialists in laboratory medicine (full time, remote/hybrid/office) (m/w/d)

**Job description:**

As part of your mission as IVDR internal clinician, you will be responsible for carrying out CE marking conformity assessment procedures in the field of in-vitro diagnostic devices in compliance with IVDR (RE (EU) 2017/746).

You are responsible for reviewing the technical documentation of the manufacturers independently or in a team. You will write performance assessment reports, check post market performance follow-up, work with EURL and support the entire certification project.

You will work in an international team, residing in the EU or UK is preferred, the team language is English.

**Essential Functions:**

- Conduct CE product performance 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 internal clinicians, product reviewers, clinical specialists, and the project managers to meet 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 human medical studies (MD/PhD/diploma)
- Board-certified specialist in laboratory medicine
- 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 is preferable
- Experience with a notified body or comparable is desirable

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