



TECHNOPATH
CLINICAL DIAGNOSTICS

Title: **Labelling Administrator**

Reporting to: **Labelling Team Lead**

Role and Responsibilities

- Conducting validation and verification activities to support the introduction of an electronic system to generate 'Instructions for Use'.
- Generation, reviewing and release of 'Customer facing documentation' (i.e. Instruction for Use, XML generation, webpage maintenance etc.).
 1. Instructions for use
 2. XML files
 3. Rilibäk Guidelines
 4. Kit & Vial Labelling
- Control, distribution and administration of labelling documentation, which support Technopath's quality management systems.
- Support Labelling team in ensuring that relevant labelling requirement standards are met at Technopath.
- Process and approve labelling related document change requests.
- Support tasks to deliver for CE marking activities as required to IVD directive & IVD Regulation.
- Provide support to Technopath Manufacturing QA, R&D Quality and Quality Systems areas from a quality perspective as required.
- Other duties as required to support Technopath quality systems.
- Demonstrate an understanding of the application of the Quality Policy through daily activities. Maintain vigilance to ensure adherence to the Quality Policy and system procedures by promptly reporting noncompliance issues to management.
- Performs other related duties as assigned by management.
- Support the Technical Library activities and review on a daily basis.
- Support the Labelling Specialist in preparing Labelling documentation on time.

Qualifications

- Minimum Level 5 qualification in a relevant Science, Pharmaceutical, Engineering or Quality Assurance discipline.
- or
- 1+ years industry experience working in a regulated medical product environment would be advantageous.
 - Good knowledge of FDA 21CFR820, ISO13485, IVDD98/79/EC, IVDD2017/746/EU, In Vitro Diagnostic Medical Device Regulation EU/2017/746 and international regulatory requirements.
 - Strong interpersonal skills and the ability to communicate well - verbally and in writing - with others.
 - Excellent attention to detail and ability to prioritise.
 - An ability to manage a number of jobs at the same time.
 - Knowledge of InDesign advantageous.

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