



TECHNOPATH
CLINICAL DIAGNOSTICS

Title:

Regulatory Affairs Specialist (Maternity Leave cover)

Reporting to: Regulatory Affairs & Quality Systems Manager

Role and Responsibilities:

- Execute and complete tasks and deliverables for CE marking activities as required to IVD directive.
- Provide updates and maintain status of product registration and notifications.
- Provide documentation and certifications upon request.
- Provide documentation and submit for product registration outside the European Union.
- Maintain a list and original (where necessary) of all current, relevant EU standards and Directives, 21 Code of Federal Regulation (CFR) and FDA Guidance Documents.
- Ensure that Technopath is aware of relevant standards and its application.
- Provide, as required, regulatory input and approval for changes and classification of changes to all documents impacting the QMS.
- Assisting in preparing and maintenance of Technical Files for product registration and submissions to EU and International Competent Authorities and / or Regulatory Agencies.
- Provide the required information to EU and International Competent Authorities for product registration and submission as required.
- Input in to Post Market Surveillance and Risk Management processes.
- 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.
- Ensure compliance with all documented Quality system requirements, as per FDA QSR's and ISO 13485 during day to day.
- Conduct internal quality system and supplier quality audits.
- Maintain a good level of housekeeping in designated areas, and observe all Health and Safety at work requirements.
- Other duties as required to support Technopath quality systems.

Qualifications:

- Minimum of degree qualification in a relevant Science, Engineering or Quality Assurance discipline.
- 3+ years industry experience working in a Quality Assurance regulated medical product environment.
- Thorough knowledge of FDA 21CFR820, ISO13485, IVDD98/79/EC and international regulatory requirements.
- Familiar with ISO 14971.
- Strong interpersonal skills and the ability to communicate well - verbally and in writing - with others.
- Excellent attention to detail and ability to prioritise.
- B.Sc. in Science/Engineering/QA or related discipline.
- A minimum of 3 years practical experience required in a quality function.
- Strong initiative and troubleshooting skills required.

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Technopath Life Sciences Park, Fort Henry, Ballina, Co. Tipperary V94 FF1P, Ireland.
www.technopathcd.com

Please forward your
CV to to our Human
Resources department:
hr@technopathcd.com