TECHNOPATH
CLINICAL DIAGNOSTICS

Title: **Supplier Quality Specialist**

Reporting to: **QS Manager**

Role and Responsibilities

- Manage process for control of Economic Operators to TCD (Suppliers / Distributors / Importers / Authorized Reps).
- Liaise with the Purchasing & Business Development groups to identify new Economic Operators as needed. Review suitability of new Economic Operators in accordance to established quality system requirements and approve for use if all require criteria have been achieved.
- Collaborate with Purchasing and Legal to ensure the development and implementation of effective quality agreements with Economic Operators.
- Monitor existing Economic Operators' performance on a routine basis.
- Communicate with Economic Operators regularly. Establish and develop good working relationships with Technopath Economic Operators.
- Support the assessment of non-conforming raw materials received from suppliers. Liaise with Quality Systems to ensure the effective completion of Supplier Corrective Actions (SCAR's)
- Conduct Economic Operator quality control audits as required to ensure vendors and their supplies remain in compliance with company requirements and regulatory standards.
- Incoming Quality Assurance: Maintain raw material specifications (file/update), complete check of raw material certificates of analysis, perform visual inspections.
- Coordinate, execute and lead the auditing program by conducting internal audits as well as supplier quality audits as the site Lead Auditor.
- Support and participate in external Audits (HPRA, Notified Body Audit, Customer Audits)
- Provide support to Non-Conformance, CAPA, Change Controls and Documentation Control activities as required.
- Update, review and approval of quality documentation such as SOPs, Material control records, Manufacturing Documentation etc.
- Support the Implementation, maintenance and continuously improve applied quality system (FDA CFR 820 and ISO 9001 & 13485) at Technopath Manufacturing.
- Perform other duties as required to support Technopath Manufacturing Quality Systems (QA, RA, Quality Support)

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

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- Operate within the company's standard operating procedures and review, maintain and create appropriate procedures.
- Maintain a good level of housekeeping in designated areas, and observe all Health and Safety at work requirements.
- Perform other related duties as required.

Qualifications

- B.Sc. in Science/Engineering/QA or related discipline.
- Lead Auditor training.
- A minimum of 3 years practical experience required in a quality function.
- Strong initiative and troubleshooting skills required
- Thorough knowledge of FDA 21CFR820, ISO13485, IVDD98/79/EC, IVDR (EU) 2017/746 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.
- 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