



TECHNOPATH
CLINICAL DIAGNOSTICS

Title: **Design Quality Assurance Engineer**

Reporting to: **Design Control & Labelling QA Manager**

Role and Responsibilities

- Responsible for supporting the Design Control process and ensuring that Design History Files comply with Technopath Clinical Diagnostic (TCD) policies/procedures and applicable regulatory requirements.
- Act as the Quality representative on Design Control projects from project initiation through to product launch to ensure compliance to applicable procedures and standards.
- Manage and lead the change control process by liaising with impacted areas to ensure timely and compliant implementation and completion.
- Work in collaboration with R&D, Labelling, Operations, Validation, Business Development and Supply chain on design control and change control projects.
- Review and approve all process validation documentation inclusive of plans, protocols and reports ensuring compliance to applicable procedures and standards.
- Responsible for creation and maintenance of Risk Management Files for each product.
- Facilitate process and design failure mode and effects analysis meetings.
- Responsible for maintaining Design Control and R&D procedures to ensure compliance to regulatory or standard requirements.
- Liaise with external customers on change requests.
- Provide training and guidance to staff on the requirements of the design control and change control process in TCD.
- As required perform internal audits to ensure compliance of TCDs quality management system to the requirements of ISO13485, MDSAP and FDA.
- Perform other related duties as prescribed by the Design Control and Labelling QA Manager or VP of Quality and Regulatory.

Qualifications

- BSc in Science/Engineering/QA or related discipline with a minimum of 3 years practical experience required in a quality function.
- Knowledge desirable in relation to risk management; ideally in the IVD or Medical Device industry.
- Strong initiative and troubleshooting skills required.
- Excellent communication and interpersonal skills.
- Excellent attention to detail and ability to plan and prioritise.

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Technopath is part of LGC Clinical Diagnostics.

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