



TECHNOPATH
CLINICAL DIAGNOSTICS

Title:

Quality Specialist (Change Control & R/D QA)

Reporting to: VP of Quality & Regulatory Affairs

Role and Responsibilities:

Change Control:

- Manage and lead the change control process by liaising with impacted areas to ensure timely and compliant implementation.
 - Liaising with internal and external customer change requests
- Guide and support change control initiators throughout the process.
- Provide support to Change Controls and Documentation Control activities
- Update, review and approval of quality documentation such as Validation Documentation, Design Documentation, SOPs, Manufacturing Documentation etc.

R&D Quality Assurance:

- Assist in the development of design and process verification and validation test plans. Ensure verification/validation results demonstrate compliance to applicable standards.
- Ensure a successful transfer of new/modified products to production. Review production processes for quality of validation through IQ/OQ and PQ activities.
- Review Design History Files and Technical Files for conformance to applicable requirements.
- Responsible for creating and maintaining Risk Management files for each product
- Responsible for ensuring that Design Control / R&D procedures are maintained and updated meeting regulatory requirements.
- Responsible for co-ordination of Post Market Surveillance process

Training:

- Maintain the Technopath Training system (Training Files, Organisational Charts, Job descriptions etc.)

General duties:

- Conduct internal quality system and supplier quality audits.
- 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.
- Provides back-up support to other group members in the performance of job duties as required
- Maintain a good level of housekeeping in designated areas, and observe all Health and Safety at work requirements.
- Supports/participates in the organization's Continuous Improvement Policy
- Perform other related duties as required

Qualifications:

- 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
- 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.

Multichem®

THE QUALITY CONTROL COMPANY



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Please forward your
CV to to our Human
Resources department:
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