



Senior Engineer – Quality Assurance (Q.A.)

Position / Title

Senior Engineer / Medical Devices

Department / Area

Quality Assurance

Reports to

Team Lead - Q.A.

Language

English (required/essential) / German (at least B2 level)

Education

Bachelor of Science or Engineering (Mechanical / Biomedical) / Master's degree preferred.

Experience

Minimum 2 years in quality engineering role in post market surveillance or complaint handling.

Primary Tasks and Responsibilities

Complaint handling

- Receiving & registration of customer complaints
- Maintenance of complaints log / register
- Complaint investigation
- Report writing & updating customers on complaint outcomes
- Follow-up on closing of complaint actions
- Complaint data analysis

Non Conformance handling

- Review and approval on NCR requests
- Maintaining the NCR log / register
- Scheduling NCR review board meetings
- Participation in NC investigation meetings
- Follow up on closing of NCRs
- NCR data analysis

Adverse Event & Incident Reporting / Regulatory Notification

- Collect information on adverse events
- Perform investigations
- Prepare Incident / Adverse Event Reporting reports
- Submit Incident / Adverse Event reports & supporting documents to regulatory authorities
- Act as Deputy Safety Officer (as per MPG for products)
- To maintain Adverse Event, Incident, Reporting & Recall register / log
- Create Periodic safety update reports



Primary Tasks and Responsibilities (cont'd)

Certificate of Conformance/Analysis/Sterility support

- Support on issuance of Certificate of conformance/Analysis/Sterility

Skills / Competencies

- Prior quality engineering experience in the medical device
- Effective troubleshooting and problem solving skills.
- Experience in the use of statistical tools e.g. MiniTab, SPC etc.)
- Good Communication and presentation skills

Working conditions

Permanent / Full time (40 hrs / week) – Winsen, Germany.

Any specific skill requirements

Work permit within the European Union.

Herr Surendra Singh Thakur, Team Lead - Q.A.

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