PR/095857 | QMS Engineer - Medical Device

募集職種

人材紹介会社
JAC Recruitment Vietnam Co., Ltd

求人ID
1599154

業種
医療機器

雇用形態
正社員

勤務地
ベトナム

給与
経験考慮の上、応相談

更新日
2026年06月26日 11:02

応募必要条件

職務経験
3年以上

キャリアレベル
中途経験者レベル

英語レベル
流暢

日本語レベル
無し

最終学歴
短大卒： 準学士号

現在のビザ
日本での就労許可は必要ありません

募集要項

Key Responsibilities

- Develop, implement, and maintain the Quality Management System (QMS) in full compliance with ISO 13485:2016 and all applicable international, regulatory, and customer requirements.
- Lead QMS-related training sessions at the Vietnam facility; ensure ongoing compliance with company and regulatory standards through effective system implementation and maintenance.
- Continuously review and improve the QMS to ensure its effective application remains consistent with product and process requirements.
- Maintain QMS documentation and oversee document control activities, including training, distribution, archiving, obsolescence management, and version tracking.
- Plan, lead, and organise internal, external, and customer audits; manage pre- and post-audit coordination across relevant departments.

- Lead follow-up on audit findings and quality issues; develop and implement corrective action plans and verify effectiveness through to closure.
- Conduct regular cross-departmental QMS inspections to identify potential issues proactively; communicate and coordinate with relevant teams to resolve known and emerging risks.
- Participate in management reviews; assist in the preparation, execution, and tracking of management review outcomes.
- Organise and deliver training programmes; promote a culture of quality awareness in line with the company's quality policy and objectives.
- Manage and monitor cleanroom environmental conditions; prepare monthly reports and trend analysis.
- Support monthly quality objective and KPI reviews; prepare quality performance metrics and KPI reports on a monthly basis.
- Perform any other duties as assigned.

Requirements

- Education — Diploma or above in a relevant discipline
- Experience — Minimum 3 years of experience in quality assurance and/or regulatory affairs within a medical device manufacturing environment
- Technical Knowledge — Qualified ISO 13485:2016 internal auditor; familiarity with ISO 14971:2019, cleanroom standards, and relevant medical device regulations
- Skills — Effective communication and interpersonal skills; ability to collaborate productively with multi-functional teams across different levels of the organisation
- Language — Proficient in English, Chinese (Mandarin), and Vietnamese

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会社説明