
SSMR MR Quality Engineer (DCU) 质量工程师

Responsibilities:

1. Professional complaint handling to satisfy the customer and meet the national regulation
专业地反处理抱怨以提升客户满意度和满足法规要求;
2. Do risk assessment for safety-relevant complaints and stipulation of countermeasures
对安全相关的抱怨和对策约定的风险评估;
3. Work with SHS region unit for Adverse Event and Field Safety Corrective Action reporting
与西门子医疗区域部门合作处理不良事件和场地安全更新的上报;
4. Define and follow-up the error-analysis and solutions for hardware and software topics via the involvement of the responsible development departments or suppliers
与相关部门或供应商合作制定与跟进硬件和软件的错误分析和解决方案;
5. Review start-up reports and safety related test reports and escalate if necessary/
评审启动报告和安全相关的测试报告, 并在必要时将问题升级;
6. Statistical analysis of post marketing relevance data for early warning and improvement of product quality
对上市后相关数据进行统计分析, 以预警和改进产品质量。

Qualifications and Experiences:

1. Medical device product knowledge/医疗器械产品知识
2. 3+ years working experience/至少 3 年以上工作经验
3. Procedure & standards understanding (ISO9001, ISO13485, ISO14971,QSR, etc.)/程序和标准的理解
4. Knowledge of quality methods like 8D,5Why,Fishbone,etc/熟悉质量工具如 8D,5Why,鱼骨图等方法
5. Statistical methods and data analysis capability is preferred /培训能力
6. Fluent in English (spoken and written)/流利的英文 (听说读写)
7. Effective communication and coach skill/有效的沟通和指导技巧