



# ISO13485 医疗器械质量管理体系审核员

## ISO 13485 MEDICAL DEVICES AUDITOR

### | 岗位职责

1. 执行公司安排的审核任务，及时向相关人员反馈审核工作中出现的各种问题，并积极配合解决问题；
2. 在审核工作中坚持审核原则，遵守审核员的行为规范和公司的各项规定，注意自己的言行，维护公司利益和形象；
3. 及时完成审核资料的准备、与客户在审核前的沟通、督促客户整改不符合项、根据认证决定工作人员的意见修改和完善审核资料等工作；
4. 及时完成公司安排的技术文件的编制工作；
5. 积极参加公司安排的现场见证工作；
6. 在审核中了解客户需求并向相关部门反馈；
7. 积极参加公司安排的有关培训工作；
8. 提供与审核相关的工作及公司其他各项工作的建议；
9. 主动学习，持续提高自身的专业素质和审核技能，为受审核方提供有价值的意见和建议，不断提升审核工作质量；

### | Job responsibilities

1. To perform tasks arranged by the company, feedback problems in audit work in time to crews and cooperate to solve problems actively.
2. To stick to audit principles, obey conduct guidelines for auditors and company rules and maintain company's image and interests.
3. To prepare audit materials promptly, communicate with clients before audit, urge clients to rectify nonconformity, amend and perfect audit materials according to opinions from certification crews.
4. To compile technical documents arranged by the company promptly.
5. To participate in on site witnessing work.



6. To clarify clients' needs and report them to the company.
7. To attend job training arranged by the company actively.
8. To provide suggestions on audit and other works.
9. To improve professional skills and provide valuable advice for clients so as to escalate the quality of audit.

#### | 任职要求

1. 本科及以上学历；
2. 具备 ISO13485 审核员资质，并专职从事 ISO13485 审核工作 1 年以上；
3. 良好的沟通能力、及良好的英语书写、沟通水平，具备计算机基本操作能力；
4. 具备独立在压力下开展工作的能力；
5. 能满足经常性出差需要。

#### | Requirements

1. Bachelor degree or above.
2. Qualification of ISO13485 auditor and 1 year' s working experience or above related with ISO13485 audit.
3. Good communication skills, good command of both spoken and written English, and good computer skills.
4. Able to work independently under the pressure.
5. Accept frequent business trip.

#### | 联系方式：

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