

# 医疗器械质量管理体系认证

# ISO 13485

风险管理 | 法规合规 | 质量控制 | 文件化和可追溯



# 认证收益

- 加速生产流程与设备分配:提高生产效率,缩短产品上市时间,抢占市场先机。
- 增强市场竞争力与买家信任:通过国际认可的质量管理体系,树立企业品牌形象,赢得更多国内外客户的信赖与合作。
- 推动流程系统性优化: 建立并持续改进内部管理体系,减少浪费,提升整体运营效率。
- 确保供应链持续优化监控:加强对供应商的管理与监督,确保原材料及零部件质量,降低供应链风险。
- 探索并实施高效运营策略:引入先进管理理念与工具,不断创新运营模式,降低成本,提升利润空间。
- **质量管理改进**:帮助企业建立完善的质量管理体系,包括质量策划、质量控制、质量保证和质量改进等环节。

### 认证流程

### 了解需求

确认企业认证的需求和 应用场景。

### 报价及申请

根据企业情况提供报 价,收集申请表和资 质文件。

### 申请及合同评审

核实企业信息,确认专业 类别、审核天数,并安排 审核员。

### 一阶段审核

确认企业资质及认证信息,判断是否符合二阶 段审核条件。

\*若有不符合项,需整改 并验证通过后才能进入 二阶段审核

### 年度审核

每年进行一次审核, 确保持续符合标准, 三年后进行再认证审 核,以更新保持最新 有效周期。

### 报告评定及发证

根据评定结果,作出 认证决定,颁发认证 证书。



### 二阶段审核

进一步验证企业体系与 标准的符合性。 \*若有不符合项,需整改

\*若有不符合项,需整改并验证通过后才能继续 后续环节。

### 联系我们

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## 我们的优势

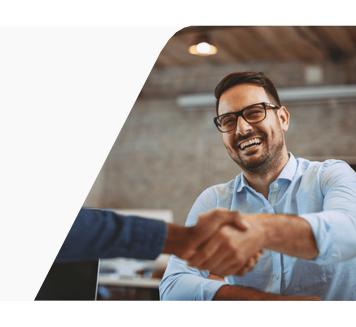
Amtivo集团获得国际认可机构UKAS(英国皇家认可委员会),ANAB(美国国家标准协会和美国质量协会),以及INAB(爱尔兰国家认可委员会)等认可,Amtivo凯瑞克依集团资源能够在全球范围内开展UKAS认证业务,拥有以下独特优势

- **国际背景与本地化服务**:依托Amtivo集团在全球40多个国家的资源,结合对中国本地市场的深入理解,为企业提供量身定制的解决方案,确保认证服务既符合国际标准又贴合实际需求。
- 专业团队与丰富经验:拥有一支经验丰富的专业审核团队,认证过程科学、高效、公正,帮助企业顺利完成认证。
- 高客户推荐率: 多家知名企业建立了长期合作关系,服务质量获得广泛认可。94%的客户表示愿意推荐我们的服务。

# 欢迎联络我们获得报价

Amtivo凯瑞克作为认证行业的专业机构,提供ISO 13485医疗器械质量管理体系认证服务,帮助企业确保其产品在生产、存储、分发、安装等各环节都符合用户和法律标准。

通过取得ISO 13485认证,Amtivo凯瑞克帮助企业改进质量管理,提高效率和安全性,让中企业能更好地进入更大的市场。





# 联系我们



# Medical Device Quality Management System Certification

# ISO 13485



### What Are the Benefits

- Accelerate Production Processes and Equipment Allocation: Enhance production efficiency, reduce time-to-market, and gain a competitive edge.
- Strengthen Market Competitiveness and Buyer Confidence: Build a strong brand image through an internationally recognized quality management system, earning trust and fostering partnerships with domestic and international clients.
- **Drive Systematic Process Optimization**: Establish and continuously improve internal management systems to minimize waste and improve overall operational efficiency.
- Ensure Continuous Supply Chain Monitoring and Optimization: Strengthen supplier management and oversight to guarantee the quality of raw materials and components, reducing supply chain risks.
- Explore and Implement Efficient Operational Strategies: Adopt advanced management principles and tools, innovate operational models, reduce costs, and maximize profit margins.
- Quality Management Enhancement: Support businesses in establishing a comprehensive quality management system, including
  quality planning, control, assurance, and improvement.

# **Certification Journey**

### **Understand Requirements**

Clarify the company's specific needs and use cases

### **Quotation and Application**

Provide a tailored quote and gather the necessary forms and documents.

# Application and Contract Review

Verify company details, confirm category, audit duration, and schedule auditors.

### Stage 1 Audit

Assess the company's qualifications and certification details to determine whether it meets the requirements for the Stage 2 audit.

### **Annual Audits:**

Annual audits ensure compliance, with a recertification audit required every three years.

# Report Assessment and Certification

Based on the audit findings, a certification decision will be made, and the certification will be awarded.



### Stage 2 Audit

Conduct a deeper assessment to confirm the company's system aligns with the standard. Note: Any non-conformities identified in Stage 1 must be rectified and verified before proceeding to Stage 2. Similarly, any issues found in Stage 2 must be resolved and validated before moving on to subsequent steps.



# Risk Management Regulatory Compliance Quality Control Documentation and Traceability



# **Why You Should Choose Amtivo**

Amtivo Group is proud to hold accreditation from internationally respected bodies such as **UKAS** (United Kingdom Accreditation Service), **ANAB** (American National Standards Institute and American Society for Quality), and **INAB** (Irish National Accreditation Board). With the support of the Group's extensive resources, Amtivo China is equipped to deliver UKAS-accredited certification services worldwide,

- **Global Expertise with Localized Services**: Drawing on Amtivo Group's presence in over 40 countries worldwide and a deep understanding of the Chinese market, we provide tailored solutions that ensure certification services meet international standards while aligning with practical needs.
- **Professional Team with Extensive Experience**: Our team of experienced auditors ensures a scientific, efficient, and impartial certification process, helping businesses achieve certification smoothly.
- **High Customer Recommendation Rate**: Many renowned companies have established long-term partnerships with us, reflecting the high quality of our services. 94% of clients have expressed willingness to recommend our services.

### Contact us to Get a Quote

Amtivo China, as a professional certification body, offers ISO 13485 Medical Device Quality Management System certification services. This certification ensures that a company's products meet user and regulatory requirements across all stages, including production, storage, distribution, and installation.

By achieving ISO 13485 certification, Amtivo China supports businesses in enhancing their quality management, improving efficiency and safety, and gaining better access to larger and more competitive markets.





Contact us