Romano Security Consulting Limited

ISO 13485 Consultancy
Service Description

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ISO 13485 Introduction

ISO 13485:2016 is an internationally agreed standard that specifies and sets out the requirements for a quality management system (QMS) specific to the medical devices industry.

ISO 13485 is designed to be used by organisations involved in the design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities e.g. technical support.

ISO 13485 can be applied throughout the entire life cycle of a medical device, from initial conception to production and post-production, including final decommission and disposal. It also covers aspects such as storage, distribution, installation and servicing, and the provision of associated services.

An ISO 13485 compliant QMS has several key elements or milestones. Romano Security Consulting recommend a structured and pragmatic approach to implementing ISO 13485 and the key elements below can inform this approach:

- Scoping, planning and budgeting
- Securing and maintaining senior management and board commitment
- Conducting a gap analysis
- Identify interested parties, legal, regulatory and contractual requirements
- Designing a suitable risk management framework
- Conducting a risk assessment and producing a risk treatment plan
- Reviewing, identifying and implementing the controls to mitigate risks
- Development of a Medical Device File
- Developing internal competence, accountability and assigning responsibilities
- Developing ISO 13485 QMS documentation, policies, procedures and records
- Developing process documentation
- Conducting regular QMS staff awareness training
- Measuring, monitoring and reviewing the QMS
- Internal auditing of the QMS
- UKAS accredited ISO 13485 certification audit

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Romano Security Consulting ISO 13485 Consultancy Service Description

Romano Security Consulting delivers ISO 13485 Quality Management System (QMS) consultancy to help organisations who provide medical devices, design, implement, and manage an effective QMS. We support the full certification lifecycle from scoping and implementation through to ISO 13485 certification.

Romano Security Consulting have the skills and experience to assist in the implementation and ongoing management of your ISO 13485 QMS, having successfully implemented and managed numerous QMS's and ISMS's over the last 15 years for organisations of all types, shapes, and sizes, from small businesses all the way up to government departments and multinational corporations.

Romano Security Consulting provide various levels of consultancy support for organisations who are looking to implement an ISO 13485 QMS and gain ISO 13485 certification or who already have an ISO 13485 QMS embedded within the organisation and are looking for some support to maintain their ISO 13485 certification.

Romano Security Consulting ISO 13485 Consultancy Services:

ISO 13485 Certification Support

End to end, advice, guidance, and consultancy support covering all of the required ISO 13485 elements from scoping all the way through to ISO 13485 certification for businesses of all types, sectors and sizes.

Specific ISO 13485 Milestone Consultancy Support

If you require consultancy support at various stages of your ISO 13485 implementation or certification project e.g. risk assessment, staff training, QMS documentation creation, internal audits, project management.

ISO 13485 Gap Analysis

If you need to measure your current level of compliance against ISO 13485 then our ISO 13485 Gap Analysis is a great starting point. We'll work with you through the ISO 13485 QMS sections to identify any gaps and provide you with a detailed report on where those gaps are and provide you with a detailed roadmap on how to close the gaps.

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ISO 13485 Internal Audit

If you need assurance prior to your certification audit or you don't have the resources, skills and experience in house to conduct ongoing ISO 13485 internal audits, we can provide an internal audit resource and detailed audit report to highlight any non-compliance.

ISO 13485 Managed Service

If you are looking for a dedicated ISO 13485 resource to pro-actively manage, monitor, and maintain an already established and certified ISO 13485 QMS at regular intervals, then let us be that helping hand and keep your ISMS up to date and your risks managed.

Contact Romano Security Consulting

For further details or a quote please contact us on the details below

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