FULL-SCALE SUPPORT
FROM ONE SOURCE

Quality Management for the Medical Device Industry

Quality management in accordance with
ISO 13485, MDR and country-specific standards

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SCC
WE CARE FOR YOUR SUCCESS

THE FAST WAY TO A QMS

All companies manufacturing or placing medical devices on the market under their own name must implement and maintain a quality management system (QMS), in addition to many other legal requirements. Throughout the EU, EN ISO 13485 (“Medical devices – Quality management systems – Requirements for regulatory purposes”) is the only relevant harmonised standard for establishing a quality management system for the actors of the medical device market.

The QMS must also follow the quality management requirements stated in the European Medical Devices Regulation MDR (EU) 2017/745.

Are you looking for a partner who will help you quickly and professionally set up a lean QMS and show you how to “live” it, or simply brings your existing QMS to a high-quality level? Then SCC is exactly the right choice for you.

With our expertise in quality management, we can establish a highly efficient QMS for your company, which is the basis for successful ISO 13485 certification and thus for marketing a medical product.

A well-running, compliant and “lived” QMS that fits the scope of your operations and products provides enormous added value by ensuring smooth processes as well as the high quality of your medical devices.

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OUR QM EXPERTS SUPPORT YOU IN

- Writing your QM manual (QMM) in compliance with standards and MDR, or checking and improving it, or simply streamlining it, so that it efficiently reflects your processes and their interactions
- Defining and formulating your quality policy, your quality planning and your quality goals with you, as well as identifying key performance indicators (KPIs) that enable you to measure and evaluate your processes and identify potential weak points
- Supporting you with re-designing or improving processes, documenting them in procedural instructions (e.g. document control, development, production, supplier control, CAPA, change control, post market surveillance, including complaint management & vigilance, internal audit, management review, etc.), and achieving the goal of smooth quality management, which is the basis for the high quality of your products and services
- Carrying out gap analyses or research into standards, helping you to define and implement suitable measures in order to effectively close identified gaps
- Guiding you through the tasks in EUDAMED, where you are obliged to register as a manufacturer (economic operator), enter the required information depending on the requirements for your product and the availability of the respective module in the European database, and upload documents

DEVELOPMENT OF MEDICAL DEVICES

The development of your QMS starts with the product development process of your medical device. Proper planning throughout the development process, up to first-in-human and post-market surveillance should therefore be fully ensured.

If you have a great idea for a medical device and need a partner to turn it into a market-approved product, SCC is the right choice for you!

On the way from the initial idea to the final product, there are important questions involving different fields of expertise to be answered.

We guide you through the entire development process, supporting you with the preparation of the required documentation and paving the way for your success.

Producers need to document each step of the development process to demonstrate the compliance of their:

- Design History File
- Device Master Record
- Device History Record

Your development process can only be successful if it is performed under a well-implemented QMS providing you with guidance throughout all development steps. Your success is our goal.

INTERNATIONALLY COMPLIANT QMS

Are you a manufacturer of medical devices considering to place them on international markets?

The quality management system approach is gaining increasing significance within the industry. To enhance consistency, efficiency and effectiveness of day-to-day operations, many companies are looking for a single QMS model covering all processes related to their medical devices while also ensuring compliance in all their target markets.

Regardless of your target market and required QMS, e.g. certified according to ISO 13485, 21CFR part 820 (FDA) or MDSAP (Medical Device Single Audit Program), SCC will help you prepare, implement, maintain and improve your QMS.

WITH SCC, YOU GET EVERYTHING YOU NEED FROM A SINGLE SOURCE

- Implementation of lean processes for a successful ISO 13485 audit
- Quick market access for your products
- Faster product development and documentation in accordance with standards
- Accelerated production through efficient processes
- Consistent high quality of your products through establishment of a measurement, control and documentation system, along with an integrated, robust QMS

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OUR SERVICES IN DETAIL

- Offering you templates for the quality management manual, for all QMS processes, including form templates or individual adjustments to your QMS templates
- Providing trainings on all aspects of the QMS in accordance with EN ISO 13485 and MDR, including the relevant local laws and regulations
- Creating and maintaining your quality management manual (QMH), including procedural and work instructions
- Providing support in change management (change control), including any standards research if required
- Assisting with the development of your medical device, in terms of planning, evaluation, modification, transfer, etc., including documentation
- Helping you assess the applicability of standards, e.g. the applicability of ISO 17664 for your medical device (“Reprocessing of healthcare products – Information to be provided by the medical device manufacturer for the reprocessing of medical devices”). If required, we support you with a validation of the reprocessing to meet the requirements of MDR Annex I, Chapter III, 23.4 n.
- Defining and developing quality indicators for your processes and products
- Providing support in the validation of your QM and production processes, including planning, evaluation, changes, etc. and their documentation
- Assisting with the elimination of deviations, including CAPA documentation, complaint management, vigi-lance and reporting of serious incidents & “field corrective actions” in line with the statutory reporting deadlines
- Helping you with the selection of applicable product- and process-related laws, harmonised standards, ordinances, guidelines, directives, etc.
- Carrying out internal audits, analysing non-conformities, developing action plans, including assistance in closing non-conformities
- Supporting lateral entrants with the implementation of ISO 13485 requirements in addition to their already established QMS (ISO 9001)
- Advising importers and dealers on the requirements of MDR Article 16, Paragraph 3
- Providing support in EUDAMED
- And other services on request

YOUR BENEFITS

- You save your resources.
- With us, you have a partner with hands-on expertise in all areas of the medical device sector. This means you will have only one contact person for any quality, regulatory and scientific topic of your concern.
- Our experts professionally adapt the QM system to your needs, helping you avoid a discrepancy between the regulatory-required and lived processes.
- While guiding you through the QM process, we also consider the international requirements of your sales markets (e.g. preparation for FDA audits, MDSAP, etc.).

Please visit our website
for more information or
contact one of our experts at
https://www.scc-medical-devices.com/quality-management-iso-13485

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