From innovation to effective and safe products

Our Medical Device Services for Manufacturers

Regulatory and strategic support
for successful market access and in-market compliance

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SCC
WE CARE FOR YOUR SUCCESS

MEDICAL DEVICE SERVICES FOR MANUFACTURERS REGULATORY AND STRATEGIC SUPPORT FOR SUCCESSFUL MARKET ACCESS AND IN-MARKET COMPLIANCE

The medical device industry is challenged by frequent changes and increasingly tighter regulations. With SCC, you have a competent partner who takes care of all your scientific and regulatory needs.

OUR EXPERTISE

With more than 10 years' experience in the medical device industry, we perfectly understand the needs and challenges of your business.

We have more than 30 years' experience in highly regulated products, pharma pre-clinical services, biocide dossiers, REACH registration services and cosmetics regulations. This provides a solid basis for a versatile consulting service in the area of medical devices.

With our extensive network reaching far beyond the medical devices industry, you will benefit from our knowledge of other industries, products and regulations. For example, we also have a deep understanding of borderline products between medical devices and cosmetics, biocidal products and pharmaceuticals.

We can support you with all services you need for your medical device approval, such as quality management, risk management, biological evaluation, including in-depth evaluations for substances of concern, professional literature search, clinical evaluation, qualification and validation of your equipment, methods and products, as well as a general data gap analysis with respect to the European Medical Device Regulation MDR (EU) 2017/745.

MDR (EU) 2017/745

Starting 26 May 2021, compliance with the new MDR is a minimum requirement for CE marking, approval and placing your medical devices on the EU market.

If you are manufacturing or supplying a medical device to the EU, you need to meet new obligations set out in the MDR, such as:

- Correctly classifying your product against the new risk classification criteria (Annex VIII of the MDR)
- Complying with the updated general safety and performance requirements, including technical documentation, labelling and instructions for use requirements (Annex I of the MDR)
- Meeting the stricter requirements for clinical evaluations (Article 61 and Annex XIV of the MDR).

We can guide you through the requirements of the regulation, ensuring a smooth implementation, assessment and approval of your product:

- We offer training to show you how to implement the MDR in your company, helping you to adopt the required procedures in line with ISO 13485.
- In close collaboration with you, we perform a gap analysis and develop tailor-made concepts aimed at (re-)establishing conformity.

Please visit our website for more information:
https://www.scc-gmbh.de/medical-devices-overview
or contact one of our experts:
scc@scc-gmbh.de

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QUALITY MANAGEMENT

Regulatory requirements already apply during product development. Depending on the risk and target markets, quality management systems, in accordance with ISO 13485 or other specific regional or national requirements, need to be implemented and defined processes need to be written and followed.

If you are looking for strategic, scientific and regulatory advice on the implementation of R&D, production, quality control and other quality-related procedures in your company, then SCC is your best choice.

RISK MANAGEMENT

Manufacturers are required to establish, implement, document and maintain a risk management system. Any risks that may be associated with the use of product, need to be acceptable when weighed against the benefits to the patient. Any risk needs to be reduced as far as possible, without adversely affecting the benefit-risk ratio.

The risk assessment procedure for medical devices is defined by ISO 14971. The requirements defined in ISO 14971 are complex and many questions can arise during a risk assessment when performed by medical and technical experts.

We help you to implement a risk management system in line with ISO 14971 and moderate the risk assessments of your medical devices to ensure that this process is compliant as well as cost-effective and time-efficient.

BIOCOMPATIBILITY

Evaluations carried out to determine the biological risks of medical devices are defined in the international standard series ISO 10993 and product-specific standards.

According to Appendix B.2.2 of ISO 10993-1:2018, risk management activities must be planned in advance. With biological evaluation being a risk management activity, a Biological Evaluation Plan (BEP) is required. It is emphasised that simply planning to conduct testing against all of the aspects of biocompatibility identified in Annex A does not meet the requirements of ISO 14971 and ISO 10993-1.

SCC assists you with or carries out complete biological evaluations, including preparing the BEP based on available chemical and physical data, selecting and monitoring laboratory tests (chemical characterisations and biological tests) and preparing a comprehensive Biological Evaluation Report (BER).

In addition, SCC has profound knowledge in dealing with specific substances of concern, either with respect to human health or the environment.

For more information, ask for our information sheets on biological evaluation and substances of concern.

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CLINICAL EVALUATION

In the EU, technical documentation and clinical evaluation form the central part of any medical device conformity assessment. With the introduction of the new MDR (EU) 2017/745, the rules for planning and preparing of clinical evaluations have been tightened.

We provide tailor-made services, designed to meet the individual needs of our customers:

- Preparing or updating literature searches and clinical evaluation plans and reports, based on the data available for your medical device.
- Providing expert support and guidance during your own literature search and the clinical evaluation process.
- Supporting you in processing deviations identified by your notified body.

For more information, ask for our information sheet on clinical evaluation.

QUALIFICATION AND VALIDATION

Qualification and validation are essential quality management tools for medical device manufacturers. Their implementation, however, can cause uncertainty.

We help you successfully integrate qualification and validation methods in your quality management system and identify equipment and processes that are subject to mandatory qualification or validation or may benefit from validation activities for quality reasons or due to strategic considerations.

We cooperate with your production and quality management experts to design, update and implement a customised validation plan based on the specific requirements of your business.

OUR SERVICES

- Comprehensive consulting services for product development and compliance with MDR (EU) 2017/745
- Thorough gap analysis and tailor-made strategic advice to close the identified gaps
- Risk management implementation and moderation of risk assessments in line with ISO 14971
- Full-service biological evaluation of medical devices in accordance with ISO 10993-1
- Support with human health and environmental concerns in relation to medical devices
- Professional literature search and supply service for clinical evaluations and further needs
- Clinical evaluation following Article 61 and Annex XIV MDR (EU) 2017/745 and all applicable guidelines
- Qualification and validation of your production and quality control equipment and methods
- Support with respect to labelling and information provided
- Planning post market surveillance (PMS).

YOUR BENIFITS

- When working with us, you benefit from our profound knowledge of quality- and admission-related standards and regulations.
- We prepare a detailed gap-analysis, allowing you to plan your budget and approval time.
- We guide you through all processes required for the successful approval of medical devices and prepare the documents required.
- We offer you guidance on borderline products and give independent advice on your best regulatory approval strategy.