Our Medical Device Services for Manufacturers

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

FROM INNOVATION TO EFFECTIVE AND SAFE PRODUCTS

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SCC
WE CARE FOR YOUR SUCCESS

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 20 years experience in the medical device industry, we perfectly understand the needs and challenges of your business.

SCC has 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.

QUALITY MANAGEMENT

Regulatory requirements already apply during product development. Depending on the risk and target markets, quality management systems, in accordance with ISO 13485 and/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 assistance to set up a quality management system and strategic, scientific and regulatory advice on the implementation of quality-related processes, e.g. in R&D, production, quality control in your company, then SCC is your best choice.

For more information, ask for our information sheet on Quality Management.

MDR (EU) 2017/745

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

If you select SCC, you will benefit from getting all expert services related to MDR implementation from a single partner, depending on your needs.

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, including UDI, 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 trainings 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.
- Are you already registered in EUDAMED and do you have received your Single Registration Number (SRN)? We guide you through this process.
- If you need guidance for implementing the Person Responsible for Regulatory Compliance (PRRC) according MDR (EU) Article 15, and in all related tasks, such as process descriptions, SCC is the right contact partner who can support you.

TECHNICAL DOCUMENTATION

A comprehensive Technical Documentation in accordance with the required country specific regulations and laws is the key for getting the intended market approval.

If you need to plan and act for market approval, or if you are looking in general for your right partner in full or partly preparation of the Technical Documentation, in accordant trainings, receiving templates, or if you need support for your received deviations during an audit, then SCC is your best choice.

We provide all services, designed to meet the needs of your product(s).

Whether Risk Classification, Risk Management, Biological Evaluation, Usability, according IEC 62366, or other standards, Clinical Evaluation, or all other required documents, we can prepare each of them or can guide you through each process that must be fulfilled for the conformity assessment.

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.

SCC assists you with or carries out complete biological evaluations by writing professional biological evaluation plans, selecting and monitoring laboratory tests, and preparing final expert reports.

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.

CLINICAL EVALUATION

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 including literature search and preparation of clinical evaluation plans and reports.

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.

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 validation activities for quality reasons or due to strategic considerations.

OUR SERVICES

Comprehensive consulting services and international market access strategies

- Globally compliant quality management systems (ISO 13485, 21 CFR part 820, etc.)
- MDR (EU) 2017/745 compliance
- 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 BENEFITS

- 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 necessary documents.
- We offer you guidance on borderline products and give independent advice on your best regulatory approval strategy.

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

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