

DISCOVER
OUR SEGMENT

MEDICAL DEVICES



SCC

WE CARE FOR YOUR SUCCESS





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Our focus

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

SCC has a long-established expertise in chemicals and highly sensitive chemical products. With more than 10 years of experience in the medical device industry, we can help you with the implementation of the ISO 13485 QM system in the field of R&D activities and the conformity assessment of your products and their ingredients. SCC can assist you in the biological evaluation of your products as defined by ISO 10993 as well as in literature search and clinical evaluations. Further, we are well-versed in the qualification and validation of your equipment, methods and products. SCC can also help you to adopt the new European Medical Device Regulation MDR (EU) 2017/745 in your company and inform you about prospective obligations.

Our expertise

With our substantial experience in the medical device industry, we perfectly understand the needs and challenges of your business. SCC's long-standing experience in compliance checks of highly regulated products, pharma pre-clinical services, biocide dossiers, REACH registration services and cosmetics regulations support provides a solid basis for a versatile consulting service in the area of medical devices. Our extensive network reaches far across the medical devices industry and you will also benefit from our knowledge in adjacent industries. When working with us, our clients profit from:

- Profound knowledge of quality- and admission-relevant standards and regulations
- Development and successful implementation of waiving strategies by selection of applicable studies
- In-depth experience in dealing with toxicity and other health or environment concerns related to your products

We keep our knowledge up to date by staying in close touch with scientific experts from academic, commercial and regulatory fields.

Our services

Comprehensive consulting services for product development and in-market compliance with MDR (EU) 2017/745.

Individual gap analysis against MDR (EU) 2017/745 requirements and recommendations how to overcome gap findings.

R&D support: ISO 13485 procedure definitions, support in selecting funding programmes.

Risk management implementation and moderation of risk assessments in line with **ISO 14971**.

Assisting in **biological evaluation** of medical devices according to **ISO 10993** (risk assessment, study selection, organisation and evaluation).

Literature search and supply service, e.g. for clinical evaluations following MEDDEV 2.7/1 revision 4 Annex A4 and A5.

Clinical evaluation following Article 61 and Annex XIV MDR (EU) 2017/745 and MEDDEV 2.7/1 revision 4.

Qualification and validation of your production and quality control equipment and methods.

International approval of your medical devices.

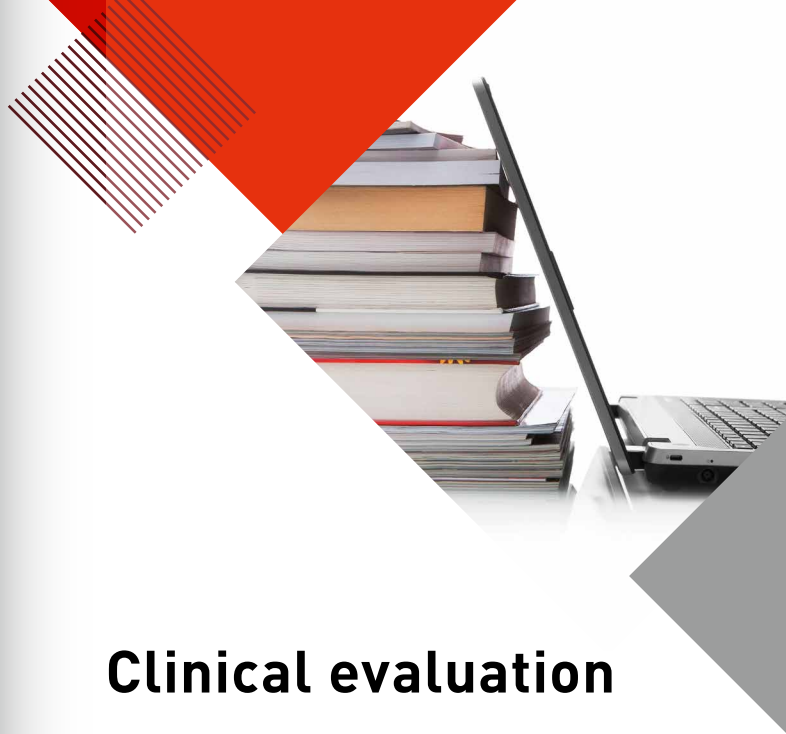


Biological evaluation

Evaluations carried out to determine the biological risks of medical devices are defined in ISO 10993 and product-specific standards, whereas the selection of applicable tests is device-dependent.

Your benefits:

- We have been working with numerous national and international testing laboratories and know which ones can best meet your needs.
- With good knowledge of the impact of various substances, we carefully select the tests to be performed. This strategy not only helps to save costs, but also avoid unnecessary animal testing.
- As early as the development phase, we can draw important conclusions based on cost-effective pre-examinations, which help you prevent aberrations.
- In many cases, risk analysis can be supported by computer simulations. Rely on the expertise of our regulatory science team, helping you to draw the precise conclusions you need for your risk assessment by applying commonly available data combined with suitable models.



Clinical evaluation

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

We offer specific services designed to meet the individual needs of our customers by either providing support during the evaluation process or preparing a clinical evaluation report or its update.

Your benefits:

- Equipped with recent and individually customised literature, you can get an idea of your device's ranking on the global market and the key factors relevant for the medical practice.
- Our up-to-date clinical evaluation helps you to save time and speed up the conformity assessment procedure with your notified body.
- With literature evidence prepared by our experts, you can save costs by avoiding unnecessary clinical investigations or PMCF studies.



Qualification and validation

Alongside verification, qualification and validation are essential quality management tools for medical device manufacturers. However, there is often uncertainty regarding their implementation, particularly among small producers.

Questions frequently arise as to the exact circumstances in which these tools should be applied, and how the processes surrounding qualification and/or validation work in practice.

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

We cooperate with production and quality management experts in your company to work out a customised validation plan based on the specific requirements of your business. If required, we can advise you on how to implement your quality management system and help you prepare the relevant implementation documents.

International approval

We work together with you to develop the best market entry strategy for your medical devices in your target markets:

- For conformity assessments, we help you design your studies to ensure broad international acceptance.
- We maintain an overview of developments in potential markets for your medical devices to help you recognise potential regulatory hurdles in advance and get your products and documents fit for future challenges.
- We develop strategies for cost-efficient market access for your medical devices.

Cultural and language barriers, combined with a lack of experience in dealing with national authorities in target countries, can make market entry a real challenge. But SCC can help you.

Backed up by our international network of experienced partners, we pave the way for a smooth regulatory process in various fast-growing markets with our portfolio of services:

- Communicating with national authorities in target countries on behalf of customers
- Providing technical translation services
- Staying on guard to protect customers' sensitive data by ensuring that only registration-relevant information is shared with the respective authorities in target countries
- Keeping our customers up-to-date, giving them necessary insights to ensure compliance with the latest regulatory developments in target countries

Who we are

SCC – Scientific Consulting Company – was founded in 1989 by Dr Friedbert Pistel. Since then, we have risen to become one of Europe's largest privately owned and independent scientific consulting companies, supporting global customers in the regulatory affairs business.

Our headquarters are located in Germany in the culturally rich Rhein-Nahe region, less than one hour's drive from Frankfurt Airport.

We have a second German office in Berlin, opened in 2014, and in 2018 also established SCC Japan in Tokyo, after 10 years of running a liaison office in Japan.

At SCC, you will find an open-minded, innovative entrepreneurial spirit backed by the expertise and commitment of a strong team. This winning combination has played a significant role in the rapid development of the company. We offer our customers high quality, flexibility, reliability and versatility, coupled with vast knowledge and a wealth of experience. Their success is what drives us forward.

Bad Kreuznach
Berlin

Tokyo

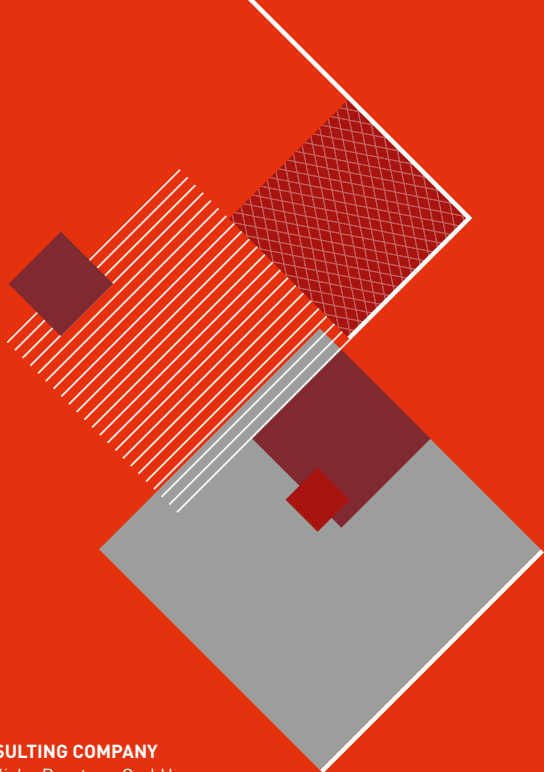
85%
with a university
degree

in
19
different
disciplines

from
10
nations

130
SCC employees





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