Substances of Concern in Medical Devices

Helping you overcome challenges with carcinogenic, mutagenic and reprotoxic (CMR) substances, nanomaterials and other critical substances

ENSURING YOUR PRODUCTS ARE SAFE AND FIT FOR THE FUTURE!

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SCC
WE CARE FOR YOUR SUCCESS

Medical devices are intended to improve health, even though materials used for the manufacturing of medical devices can contain – whether intended or not – substances or materials considered as nanomaterials or with the potential to cause adverse events, so-called substances of concern.

OUR EXPERTISE

Since 1989, SCC has been specialised in assessing biological risks and finding the best solution for its customers. Our backbone is our scientific expertise bundled in the Regulatory Science department. Experts from various regulatory disciplines, such as chemists, physicists, food chemists, biologists, geo-ecologists, toxicologists, ecotoxicologists and environmental fate specialists, work together under one roof.

BIOCOMPATIBILITY

The international standards for assessing the biocompatibility of medical devices are known as the ISO 10993 series, with ISO 10993-1 describing the requirements for evaluation and testing within a risk management process and applicable to all medical devices.

This standard stipulates that for every medical device, the information on the chemical composition including potential impurities must be available and “leachables” should be evaluated by means of a chemical characterisation in line with ISO 10993-18.

Such chemical analysis shows the presence of any substance or material that may be absorbed by the patient and should be included in your risk assessment.

This procedure helps you to eliminate unnecessary biological tests and focus on identified risks.

But what should you do, if specific substances of concern are present in your product?

SUBSTANCES OF CONCERN

Materials containing substances with carcinogenic, mutagenic and reprotoxic (CMR) properties are increasingly coming into focus. There is growing political concern regarding the presence and use of endocrine disruptive substances (ED).

Two general regulatory requirements are important to be considered for medical devices:

- REACH EU Regulation No.1907/2006 (Registration, Evaluation, Authorisation and Restriction of Chemicals)
- RoHS Directive (Restriction of Hazardous Substances in Electrical and Electronic Equipment). RoHS Directive 2011/65/EU, published in 2011, is known as RoHS-Recast or RoHS 2. It includes a CE-marking directive, with RoHS compliance being required for CE marking of products, and now Directive 2015/863, known as RoHS 3. RoHS 3 adds four additional restricted substances (phthalates) to the list of six.

As REACH and RoHS are in force, medical devices produced or imported in the EU must comply with this legislation. Unlike RoHS, REACH applies to everything – from raw materials to finished goods, while RoHS is a product-specific vertical legislation which focuses on hazardous substances in electrical and electronic equipment (EEE).

The CE mark is the legal designation that the manufacturer’s product has met the requirements of all relevant medical device directives, regulations and laws, including REACH and RoHS. This implicates that your conformity assessment process must include both regulatory requirements and be part of your EC Declaration of Conformity. In addition, the medical device specific guideline of phthalates needs to be considered, too.

MONITORING SERVICES FOR YOUR RAW MATERIAL INVENTORY

As manufacturer of medical devices, you need to be up to date with new developments in REACH, RoHS or other similar requirements. The EU list of substances of very high concern (SVHC) is growing every 6 months.

Sounds complicated? It does not have to be.

SCC has profound skills in monitoring the regulatory status of chemicals. We check your substance inventory against the latest scientific information and regulatory changes on a regular basis, such as REACH and RoHS.

We keep you informed on the most important developments via substance inventory status update services, and we also prepare the required reports.

OUR SUBSTANCES OF CONCERN SERVICES

Our experts can help you with:

- Estimating the likely regulatory costs based on a data gap analysis, identifying missing studies and finding waiving opportunities through detailed and systematic database and literature searches
- Regular monitoring of your raw material inventory in relation to new findings and regulatory changes
- Developing tailor-made compliance strategies to meet your needs
- Generating *in silico* data and performing knowledge- and statistics-based QSAR models to predict the activity, properties and toxicity of new or incomplete characterised substances based on the knowledge of their chemical structure
- Planning, contracting and monitoring of laboratory studies using specialised laboratories
- Application of EU guidelines on the benefit-risk assessment of the presence of phthalates
- Establishing allowable limits for leachable substances in accordance with ISO 10993-17 by our experienced toxicologists
- Dealing with specific requests to expert panels and competent authorities

As a result of our assessment, you will receive a detailed report signed by our certified and registered toxicologists, which is accepted by competent authorities and notified bodies.

NANOMATERIALS

Based on the new classification rule 19 in the EU Medical Device Regulation 2017/745, many medical devices need to be classified in higher risk classes if they contain nanomaterials.

The current EU definition leads to ambiguity and causes testing difficulties when determining whether medical devices contain or consist of nanoparticles.

In addition, the potential for internal exposure is not clearly defined within the MDR, leading to additional uncertainty.

How can you identify the presence of nanomaterials if there are no clear methods for their characterisation?

OUR SOLUTIONS FOR NANOMATERIALS

By choosing our services, you will benefit from our expertise in nanomaterials, focused on:

- Characterisation of nanomaterials according to the latest standards and guidelines
- Application of the nanomaterial definition and preparation of assessments to avoid higher classifications and additional tests
- Professional handling of questions regarding internal exposure
- Preparation of literature-based internal exposure assessments for your specific borderline products

First-hand experience in selecting biological tests and monitoring services to handle the specific complexity of the test execution.

TESTING OF NANOMATERIALS

If nanomaterials are present, biological testing should be performed in line with the recent technical report ISO/TR 10993-22, published in 2017. However, by far not all labs have managed to implement new test methods and several methods defined within other ISO 10993 standards need to be adapted in order to be suitable for nanomaterial testing.

How can you handle nanomaterials without approved test methods and sufficient guidance?

YOUR BENEFITS

In choosing SCC, you will benefit from:

- Full-service support with respect to all issues concerning biocompatibility and environmental concerns relating to medical devices
- Access to our special tools and experience with databases and literature research
- Using advanced in silico methods to close existing data gaps
- Our knowledge of the impact of various substances, when selecting the required tests. This strategy helps not only to save time and costs, but also avoid unnecessary animal testing
- Our long years experience of working with national and international testing laboratories and knowing which ones can best fit your needs
- Ensuring safety of your products by providing notified bodies and competent authorities with convincing expert reports prepared by SCC

Whatever your needs are, SCC helps to ensure your medical devices are fit for the future.

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

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