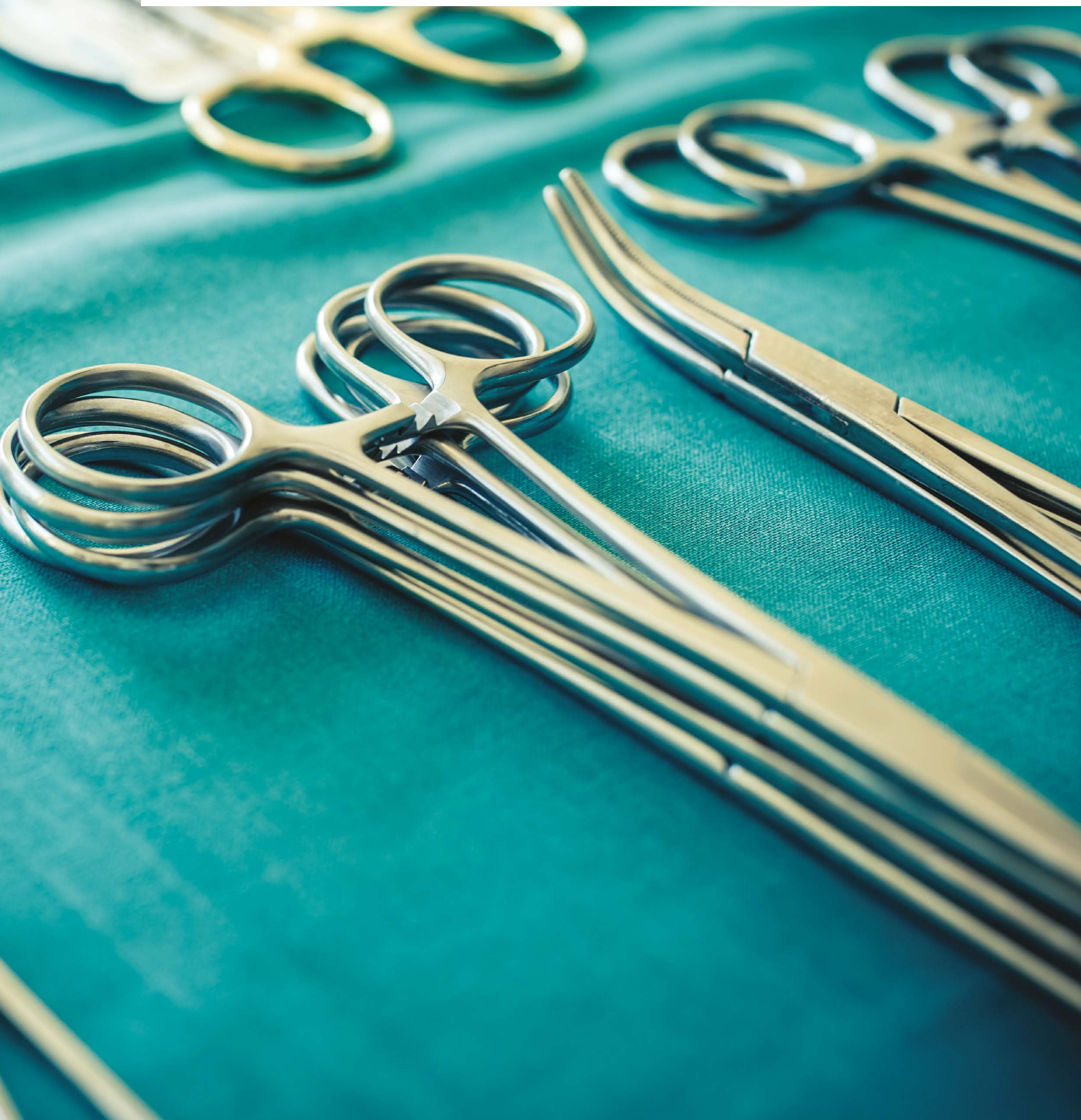
MEDICAL DEVICE SERVICES
CLINICAL AFFAIRS



With proven expertise in the field of clinical affairs, we ensure regulatory compliance for the creation and update of your clinical evaluation, helping accelerate the market entry and certification of your medical device. We can also provide clinical study planning and investigation services. From planning your clinical study to its implementation and evaluation, we can support you with individual services or a full-service package. We can also review and update your post-market surveillance data, and conduct individual literature searches for your documentation according to your requirements, e.g. in the form of biological safety reports under ISO 10993-1 and ISO 14971.

CLINICAL EVALUATION

The clinical evaluation plan and report need to be provided for all medical devices and be updated at regular intervals depending on their classification to keep the newest status. Evidence of safety, performance and clinical benefit is based on clinical data that could be obtained from various sources. Legal requirements are implemented with the validity of the Regulation (EU) 2017/745 and the relevant MDCG guidelines. The guideline MEDDEV 2.7/1 Revision 4 offers additional orientation on the content and implementation of the clinical evaluation.

Our clinical evaluation services include:

- Creating and updating clinical evaluations according to the Regulation (EU) 2017/745, relevant MDCG guidelines, MEDDEV 2.7/1 Revision 4, NMPA or Therapeutic Goods Administration requirements
- Evaluating clinical data regarding sufficiency
- Conducting literature reviews
- Gap analysis
- Implementing the relevant processes and forms
- Evaluating marketing claims
- Database research of clinical experience data
- Risk-benefit assessment
- Trainings and workshops

BIOLOGICAL SAFETY EVALUATION

The overall assessment of biological safety begins with establishing a biological evaluation plan (BEP). Its implementation in a biological evaluation is an essential part of the technical documentation that highlights the safety of your medical device. This is required by ISO 14971:2019 and is specified in terms of content by ISO 10993-1:2018.

We have many years of experience in ISO 14971 and the ISO 10993 series of standards and can provide you with experts with appropriate knowledge. Our specialists have a scientific background with laboratory experience, which guarantees a professional analysis and evaluation of preclinical data. Do not risk any security gaps or development obstacles for your medical device, let us advise you without obligation.

Our services in the field of biological safety evaluation include:

- Conducting and updating biological safety assessments in accordance with ISO 10993-1:2018
- Assessing the collected preclinical data regarding the biological safety of the medical device
- Database research for a scientifically-sound assessment of the biological safety of the medical device
- Creating a biological evaluation plan (BEP) and report (BER)
- Performing tests in collaboration with GLP and ISO 17025:2017 certified and accredited laboratories
- Literature research of preclinical data and preparation of the biological evaluation)
- Training with training certificate

CLINICAL INVESTIGATION AND PMCF STUDIES

Do you already know which aspects should be considered in your clinical investigation or other types of clinical studies (e.g. PMCF studies)? Please contact us and talk with our experts about your clinical data and possible clinical study planning. In addition, we offer a seminar on this topic, in which all relevant points are discussed extensively.

Our clinical investigation services include:

- Project management
  - Defining and coordinating work packages
  - Communicating with involved stakeholders
- Legal and regulatory framework
  - Insurance
  - Approval process via BfArM/PEI and ethics committee
  - Submission and communication to relevant authorities and the ethics committee
  - Implementing procedural instructions and creating forms
- Preparing clinical investigations/studies
  - Developing the study design, including consideration of biometric aspects
  - Developing (electronic) case report forms
  - Preparing and reviewing required documents (e.g. clinical investigation plan, investigator brochure, patient information and consent)
  - Selecting study sites
- Executing and completing the clinical study/ investigation
  - Continuous data management
  - Continuous monitoring
  - Statistical data evaluation
  - Final report

POST-MARKET SURVEILLANCE (PMS)/POST-MARKET CLINICAL FOLLOW-UP (PMCF)

To ensure safety and efficiency of the medical device after it is placed on the market, the Regulation (EU) 2017/745 requires post-market surveillance. This includes all activities medical device manufacturers must undertake, in collaboration with their economic operators, to establish a process for the proactive collection and revision of clinical experience of their medical devices and the requirement to keep this information up to date.

Our services in the area of PMS and PMCF include:

- Implementation of PMS and PMCF processes
  - Evaluating the actual state
  - Identifying and evaluating interfaces
  - Updating or preparing the processes regarding the Regulation (EU) 2017/745
- Preparing PMS and PMCF activities
  - Creation or reviewing the PMS and/or PMCF plan
  - Executing and completing PMS and PMCF activities
- Supporting the collection and evaluation of clinical data or continuous independent collection and evaluation of clinical data
- Submitting to and communicating with the ethics committee in conducting PMCF studies
- Developing the PMCF study design
- Continuously monitoring databases and registers
- Conducting the literature search
- Statistical data evaluation
- Final report in the form of a post-market clinical evaluation report
- Seminars or workshops on post-market surveillance

NSF TRAINING

We provide seminars, on-site training and workshops on the latest updates on the Medical Device Regulation (EU) 2017/745, harmonized standards and guidelines. Contacts us for further details.

BENEFITS OF THE GLOBAL NSF FAMILY

- Independent, global public health organization with a mission of **protecting and improving human health** and a commitment to high standards
- Expanded global access to provide **scalable solutions anywhere in the world**
- **Increased capabilities** to include consulting, auditing, training and education and testing services
- **Innovating solutions** for the growing medical devices, pharmaceutical and biotech markets

OUR COMPANY

NSF provides leading consulting and professional services to the global medical device sector. Our portfolio covers consulting, management of complex projects and interim management. NSF is working as an active member in standardization groups for ISO 13485, ISO 14971, IEC 62366, IEC 60601, IEC 62304 and IEC 82304-1. By co-creating standards, we are able to strengthen your company's position against the competition. It is our business to meet customers' specific needs and to offer ideal solutions. Together we form the future of biomedical engineering by identifying new opportunities and handling critical challenges.

NSF I MEDICAL DEVICES

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