BEST IN CLASS FOR INTERNATIONAL REGULATORY COMPLIANCE

MANAGEMENT | DEVELOPMENT | CONSULTING

NSF provides leading global consulting services in biomedical engineering. Our expertise and long-standing customer relationships help us shape the future of medical technology by identifying new opportunities and addressing and managing critical challenges.

MEDICAL DEVICE REGULATION (EU) 2017/745

We can identify the best transition strategy for your organization based on your product portfolio, certification cycles, target markets, and your notified body and authorities.

We can perform a systematic and independent evaluation of your technical documentation, documented procedures and processes to help you understand what steps you must take to meet the different requirements of the Medical Device Regulation.

IN VITRO DIAGNOSTIC REGULATION (EU) 2017/746

Do you need support with the implementation of the new regulatory requirements for in vitro diagnostic medical devices? Use our experience, knowledge and global network for your business' success in meeting the new requirements.

QUALITY MANAGEMENT

We help you implement relevant requirements from ISO 9001, ISO 13485 and 21 CFR 820 QSR for medical device manufacturers, suppliers or contractors. We analyze your required procedures and transfer the results into standard operating procedures, templates and checklists. Our goal is to involve your employees in the implementation process, to coach and to motivate them to accomplish a successful certification of your organization.

REGULATORY AFFAIRS

We can guide you on regulatory affairs questions like What is the correct submission strategy? Should I certify my software as a stand-alone medical device? What country-specific particularities do I have to consider? We support your decision-making process for conformity assessment, safety and performance requirements (CE-marking), technical documentation, premarket submissions (510(k), PMA, IDE), etc.

RISK MANAGEMENT

We support you in implementing the requirements of ISO 14971 in an individual and practical risk management process. We explain the difference between FMEA and FMECA according to IEC 60812 and risk assessment and control according to ISO 14971.

INTERIM MANAGEMENT

NSF is the leading provider of experienced managers, consultants and engineers in the health care industry. These qualified management resources are available on a temporary basis to organizations that require an immediate, short-term and successful solution.

CRISIS MANAGEMENT

Our crisis management supports you in getting your company back on the road to success.
Top management is crucial – especially in entrepreneurial or exceptional circumstances. We provide expertise in complaints, vigilance reporting, field corrections, removals, recalls, audit findings, 483s, medical device tracking and reporting, etc.

PROJECT MANAGEMENT

Our specialists and project engineers provide support and consulting during all project phases on tasks including project planning, risk management, controlling and documentation. In collaboration with our clients, we select the most efficient development and submission strategy for your medical device portfolio.

HAMBURG ACADEMY

Our Hamburg Academy provides an interdisciplinary platform for responsible organizations and medical device manufacturers for a dialog between all stakeholders in the health care sector.

Benefit from our practical experience and expertise in education and participate in a lively discussion with our experts. Our well-known seminars are the result of a close relationship with the notified body MEDCERT, the specialists in the certification of medical devices and quality management systems. In general, we offer seminars in German and English including:

- Risk management
- Quality management
- Clinical evaluation
- Medical device regulation
- Usability
- Medical device software
- Technical documentation
- Many more

Would you like to continue your education while working? Need flexible scheduling with online on-demand or live instruction? Then start now with NSF's online training and benefit from top-notch courses with top trainers.

SEMINARS

Our national and international seminars and workshops cover the latest topics and relevant standards in the health care sector – a meeting platform for decision makers in the medical device industry. Learn about our seminar program and benefit from the possibility to discuss relevant topics in the medical sector with other seminar attendees and our experts.

ON-SITE TRAINING AND WORKSHOPS

Learn the latest updates on Medical Device Regulation (EU) 2017/745, harmonized standards and guidelines. We can prepare an individual training program for you, tailored to your needs and products. Benefit from our practical experience and educational competence.

SYMPOSIA, CONGRESSES

We plan and conduct congresses for experts from the industry, economy, science, research and authorities.

WHAT PEOPLE ARE SAYING

Very good practical relevance; involvement of all stakeholders, exciting discussions.
Andreas Denk, Dornier MedTech

DEVELOPMENT OF MEDICAL DEVICE SOFTWARE

We help you implement a software life cycle process according to IEC 62304 and IEC 82304-1. We also provide software development and compilation of technical documentation including software risk management and usability files. Our test engineers validate your software as a medical device and process software on-site or in our test lab according to state-of-the-art requirements.

TECHFILE FACTORY

Annexes II and III of MDR 2017/745 & IVDR 2017/746 contain detailed requirements for technical documentation for all classes of medical devices. Now is the time to bring "old" medical device technical files to the level of new MDR/IVDR requirements including Annex I (General Safety and Performance Requirements). Our TechFile Factory service upgrades existing technical files for a medical device. Our experts separate existing technical files into several parts, and then review, improve, rewrite, restructure and editorially assemble them into an MDR/IVDR compliant technical file.

USABILITY

IEC 62366-1 demands detailed requirements in terms of usability for medical devices. Utilize our expert knowledge at the beginning of your feasibility phase. The usability process begins here and not at the final development stage!

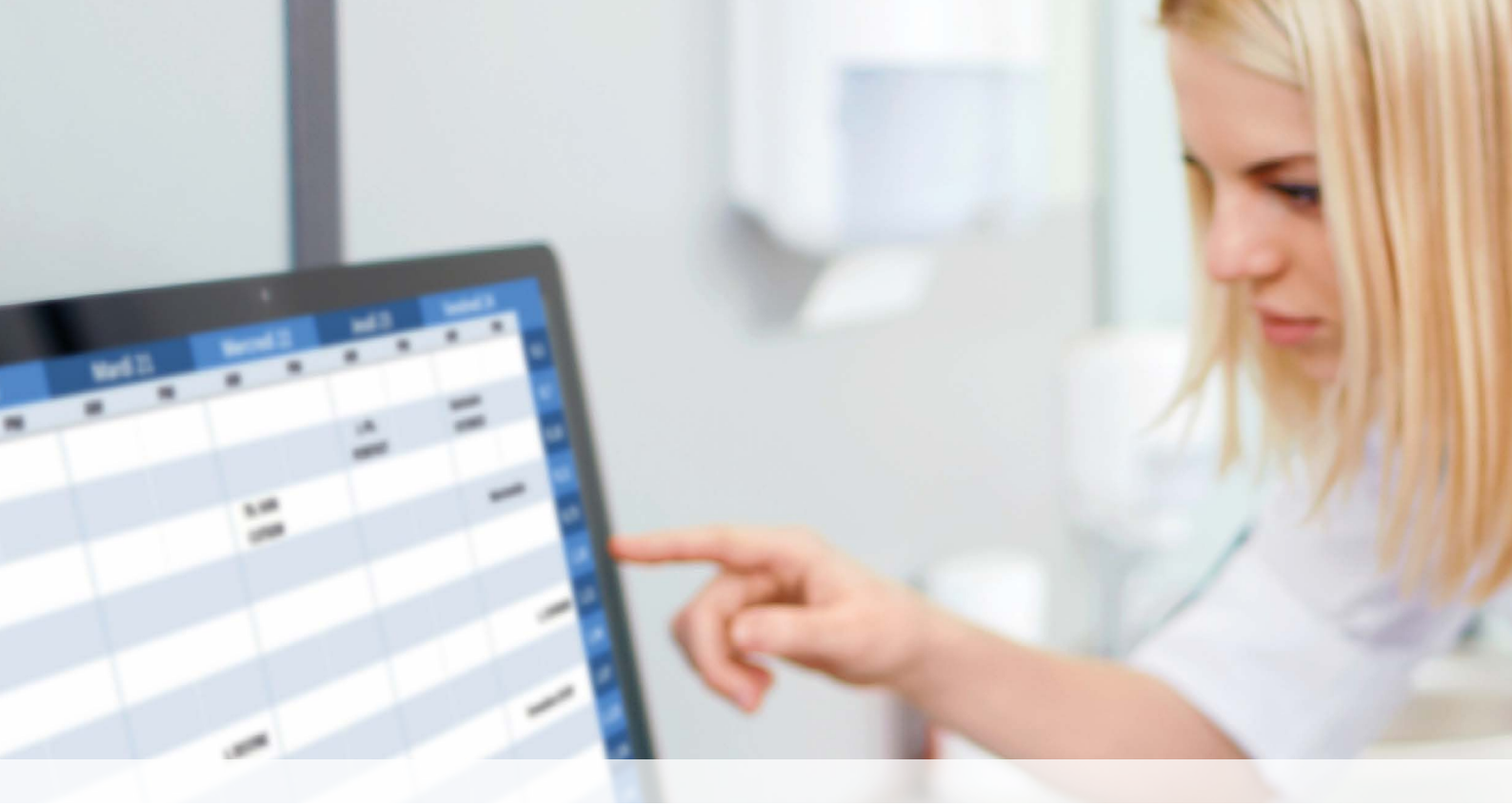
POST-MARKET SURVEILLANCE

To ensure the safety and performance of medical devices on the market, the Medical Device Regulation (EU) 2017/745 requires medical device manufacturers to perform post-market surveillance. This includes activities in collaboration with other economic operators to establish a process for proactive data collection and review of clinical data of medical devices and the requirement to keep this information up to date.

NSF has broad experience in the collection and analysis of clinical data with regard to the benefit-risk ratio and the documentation in corresponding reports.

CLINICAL EVALUATION

Are your clinical evaluations up to date? Take advantage of our expertise and let us help you create or update your clinical evaluation report. You can also attend one of our seminars for comprehensive training and expert advice. This way you gain valuable competitive advantages and accelerate your market access.



CLINICAL STUDIES

We can assist with many different types of studies and clinical investigations, including meeting regulatory requirements in the European market as defined by ISO 14155 and the Medical Device Regulation (EU) 2017/745. We also offer training that provides a deep dive into all aspects of clinical studies. Please contact us about your specific clinical data and clinical study planning needs.

PROCESS VALIDATION

We provide analysis, optimization and validation of your processes in accordance with national and international requirements, such as ISO 13485, 21 CFR 820 QSR or GAMP 5. We analyze your production processes by well-proven process management methods and techniques (process-FMEA/ -FMECA, data analysis) and assist you with your validation activities (retro-/prospective) of PC-software used in production, development or quality management systems.

SURVEYS & ASSESSMENTS

We analyze your marketed devices using post-market surveillance, customer inquiries, competitor surveillance and analysis of complaints. We evaluate technical solutions by risk assessment and clinical evaluation, and we define product-specific reporting criteria and possible corrections, corrective or preventive actions (C/CA/PA). We also offer international standardization activities and trend consulting for medical device manufacturers: Which requirements for medical devices will change soon? What is currently considered state of the art and what new trends are emerging in the market? Which harmonized standards have to be fulfilled for medical devices? NSF provides you with up to date first-hand information on how to be continuously successful in the market.

AUDITS & INSPECTIONS

We provide independent internal audits in accordance with ISO 19011 guidelines for quality management systems, as well as pre-audits as training and preparation for upcoming audits and inspections (ISO audits, FDA inspections, MDSAP audits and supplier audits). Our certified lead auditors (IRCA, RAB-QSA) take over the assessment and maintenance of your quality management system.

An audit can also be carried out remotely for all content and processes that can be reviewed in reasonable technical depth without the physical presence of an auditor, such as operational activities, medical devices and services, and the associated risks. Our auditors, consultants and technical experts support you in the implementation of your audit programs or in the preparation, implementation and follow-up of remote audits by your notified body or competent authorities.

Participation in a remote audit can be done via PC, tablet or even smartphone. The only requirements are an internet connection and a standard internet browser. No special software is required for the participants.

TRUSTEE SERVICE (OEM/PLM)

Prior to the MDR/IVDR it was possible to market medical devices as a private label manufacturer (PLM) without disclosing the original equipment manufacturer (OEM) and without access to the technical file. This is no longer possible under the IVDR. Now the PLM must have control over the full technical documentation of the medical device. NSF offers you a service that enables the controlled exchange of the technical documentation between the OEM and PLM without disclosing critical intellectual property to the PLM. Please contact us to find a customized solution suited to your needs.

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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