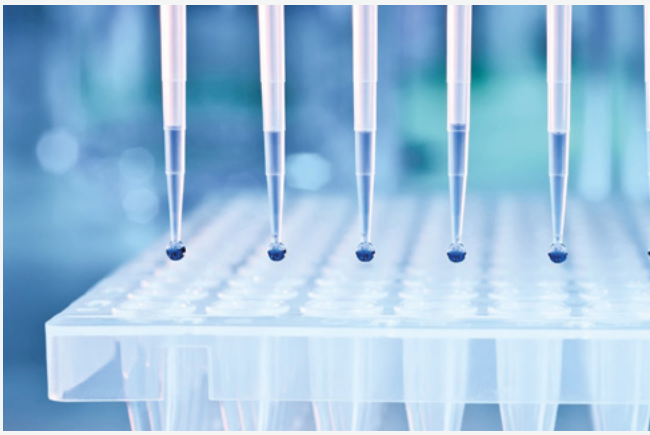
# SERVICES FOR IVD MEDICAL DEVICES

**We accelerate your pathway to certification and market entry. With our renowned and proven expertise in clinical affairs, post-market surveillance and quality management, we ensure your IVD product is compliant with Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). From creating performance evaluations and planning post-market surveillance activities to analyzing technical files and supporting your product life cycle: our experts help you with individually tailored services to address your current and future regulatory needs.**

## PERFORMANCE EVALUATION & PERFORMANCE STUDIES

The IVDR requires manufacturers to conduct and regularly update a performance evaluation of their IVD product to receive and maintain CE marking. With a structured and concise performance evaluation, you can provide evidence of scientific validity, analytical performance and clinical performance that demonstrates the benefit, safety and clinical utility of your IVD product.



Do you already know which aspects should be considered in your performance study? We also support you in planning, design and execution of performance studies and provide extensive training by our subject matter experts.

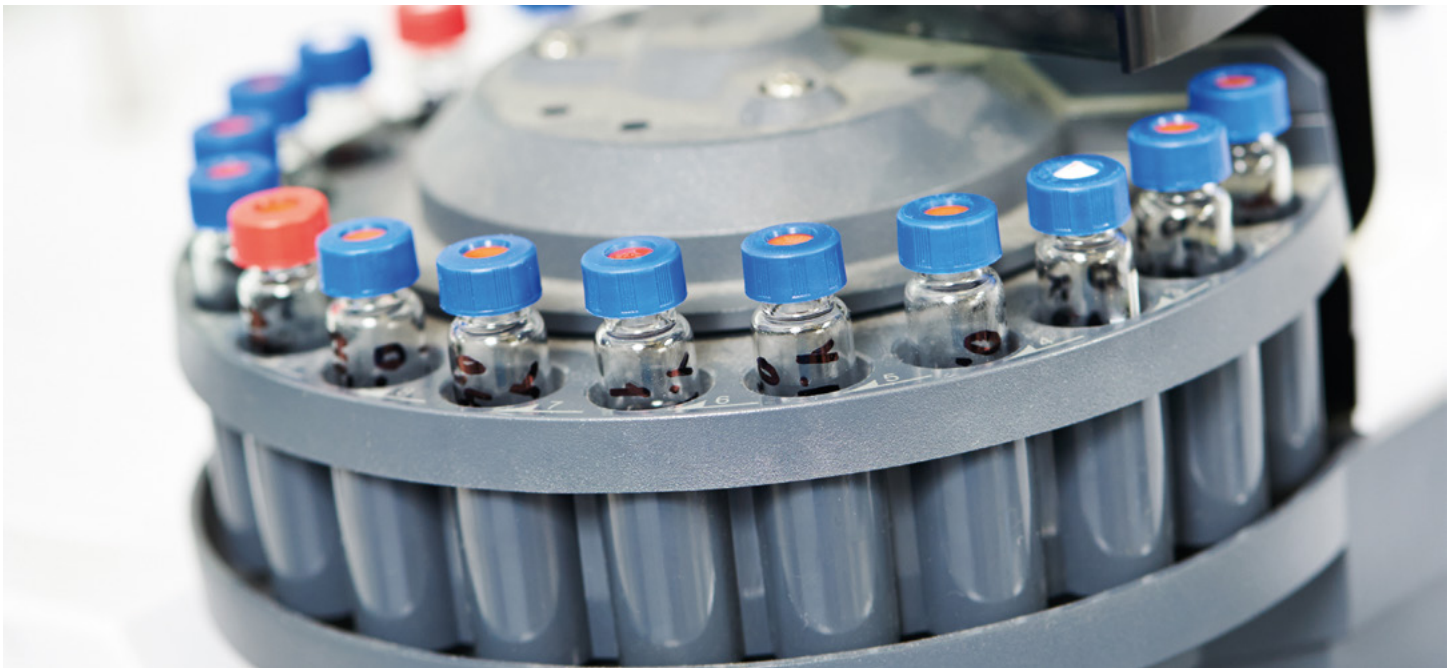
Take full advantage of our performance evaluation services:

- Creation and update of plans and reports for performance evaluation according to IVDR
- Evaluation of performance data to meet regulatory demands
- Conduct of in-depth literature reviews to gather scientific, analytical and clinical evidence
- Gap analyses of your performance data
- Evaluation of your marketing claims
- Research for clinical experience data
- Benefit-risk analysis
- Development, planning and design of performance studies (including selecting study sites and creating case report forms)
- Preparation and review of performance study documents (e.g. study plan, investigator brochure, patient information and consent)
- Conduct and completion of performance studies (including data management, monitoring, statistical evaluation and final reporting)
- Trainings and workshops on clinical affairs and performance studies

# RISK MANAGEMENT & POST MARKET SURVEILLANCE (PMS)

Proper risk management is the basis for effective post-market surveillance: we support you in implementing the requirements of ISO 14971 in an individual and practical risk management process. We also help you in applying usability engineering (IEC 62366-1) and electrical safety (IEC 61010) to reduce risk with safe design and protective measures.

As part of your product registration, the IVDR requires you to establish a post-market strategy to monitor the performance and safety of your product. We help you implement effective PMS to ensure clinical performance data is proactively collected, revised and updated, but also to execute CAPAs/FSCAs and communicate field safety notices in case of complaints.



Ensure effective risk management for your IVD device with our services:

> Implementation of the IVDR and ISO 14971 requirements into your risk management system

> Implementation of usability engineering (IEC 62366-1) and electrical safety (IEC 61010) for IVD devices

> Creation and review of plans for PMS and PMPF

> Support with execution and completion of PMS and PMPF activities (e.g. surveys, clinical performance studies, continuous review of scientific literature or authority databases)

> Development of PMPF study designs

> Statistical data evaluation

> Creation of PMS report, periodic safety update report and PMPF evaluation report

> Trainings and workshops such as:

- FMEA/FMECA in accordance with IEC 60812
- Risk assessment and control in accordance with EN ISO 14971
- Post-market surveillance

# TECHFILE FACTORY & QUALITY MANAGEMENT SERVICES

The IVDR requires full disclosure on design, production and quality testing by manufacturers. This makes it crucial to update existing technical files to meet the new structure and content demanded by IVDR Annexes II and III. Also, it is important to comply with the new general safety and performance requirements of Annex I. Another new key requirement is to create and maintain a robust, adaptive and effective quality management system. Yet, evaluating existing files and closing gaps in the technical documentation and quality management system can require high resource investments from your organization.

Benefit from our TechFile Factory and Quality Management Services to make sure your technical documentation and quality management system meets the regulatory demands:

- Gap analysis of technical documentation and quality management systems considering relevant documents and records
- Implementation of software lifecycle processes according to IEC 62304 and IEC 82304-1 including software development and compilation of technical documentation
- Implementation of the Unique Device Identification (UDI) system for IVD devices in accordance with IMDRF UDI Guidance IMDRF/UDI WG/N48 Final:2019
- Outline of inconsistencies and nonconformities and strategy development to ensure compliance
- Rewriting and compilation of documentation for the assembly of compliant technical documentation
- Strategic consultancy to identify the least burdensome approach
- Planning and implementation of quality management systems addressing European and international requirements (e.g. MDSAP)
- Implementation of relevant requirements from Annex I, II and III of Regulation (EU) 2017/746, ISO 13485, RDC 16/2013 and 21 CFR Part 820 QSR (quality system regulation)
- Communication with notified bodies and regulatory authorities
- Trainings and workshops on technical documentation and quality management systems

## TRAINING

We provide seminars, training and workshops, both on-site and online, about the latest updates on the IVDR as well as relevant standards and guidelines. Contact us for further details.

For more information, visit **www.nsf-prosystem.org** or contact **info-medicaldevices@nsf.org**.

NSF International provides worldwide leading consulting and professional services to the IVD sector. The sustainability of our successful projects is the foundation of our longstanding customer relationships. Together with our customers we form the future of in vitro diagnostics by pointing out new opportunities as well as handling critical challenges. Our portfolio covers consulting, management of complex projects and interim management. It is our business to meet your special needs and to offer ideal solutions. NSF is working as an active member in standardization groups: 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.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