



IN VITRO DIAGNOSTIC SERVICES

CONSULTING, AUDITING AND TRAINING
THROUGHOUT THE PRODUCT LIFECYCLE



NSF International works with in vitro diagnostic companies of all sizes, providing customized end-to-end services throughout the product lifecycle. From concept through to distribution, our expert services enable:

- > Efficient clinical trial conduct
- > Risk appropriate regulatory compliance
- > Implementation of effective and lean quality management systems
- > Maximized contributions of existing staff
- > The highest levels of product quality and safety
- > Improved competitive advantage and speed to market

Our team comprises of former regulators from the EU, USA, Australia and Japan, as well as internationally recognized industry and technical experts. We combine global regulatory knowledge with industry best practices to provide you with customized technical, quality, compliance and regulatory services.

CONSULTING

PROVIDING SPECIALIST IVD KNOWLEDGE AND EXPERT ADVICE

With the EU In Vitro Diagnostic Medical Device Regulation (EU 2017/746) coming into force in May 2022, manufacturers have a tight timeframe for achieving compliance. NSF offers a comprehensive range of consultancy services to assist with this and many other related challenges:

- > Product risk classification
- > Performance evaluations
- > Postmarket surveillance and clinical follow-up activities
- > Regulatory compliance
- > Product range rationalization, regulatory strategy, and market access consulting
- > Identifying and contracting a suitable notified body
- > Quality engineering and validation
- > Quality management system harmonization, simplification and improvement
- > Developing and implementing compliant, cost-effective quality systems
- > Design, qualification and validation of facilities, equipment, computerized systems and processes
- > Advice on legal and regulatory concerns
- > Supply chain requirements
- > Responding to regulatory inspection reports and remediation activities
- > Simplifying quality processes, SOPs and batch records
- > Product-specific technical and testing issues
- > Benchmarking against best industry practices – beyond the regulations
- > Technical file development and review

We also offer full clinical trial services. We help IVD, biotech, medical device and pharmaceutical companies conduct scientifically sound clinical trials and navigate complex regulatory environments in a wide range of therapeutic indications, including, but not limited to, oncology, central nervous system, wound healing, infectious disease, cardiovascular and urology. Comprehensive services are available in project management, regulatory affairs, clinical operations, biostatistics, data management, medical monitoring, safety, pharmacovigilance, and general consulting.



AUDITING

TAKING A CLOSE LOOK AT YOUR FACILITIES AND OPERATIONS' STANDARDS

NSF performs assessment against a wide range of domestic and international medical device, pharmaceutical and combination product regulations and international standards, including Good Manufacturing Practice, Good Distribution Practice, Good Pharmacovigilance Practice, Good Clinical Practice, Good Laboratory Practice, U.S. and international regulations quality systems (21 CFR Part 820, ISO 13485) and the international Medical Device Single Audit Program (MDSAP).

AUDITS

Our assessment processes can be tailored to your specific needs, including:

- > Due diligence
- > Compliance – assessment of activities against standards
- > Inspection readiness (pre-certification)
- > Supply chain robustness
- > Internal audit processes

Outputs can also include recommendations on efficiently reaching compliance.

As well as IVD manufacturers, we audit active pharmaceutical ingredients, excipients, medicinal product manufacturers, distributors, medical device manufacturers, combination product manufacturers, investigational medicinal product manufacturers, QC laboratories, affiliates, contract manufacturers, suppliers, computerized systems and more.

TRAINING AND EDUCATION PROGRAMS

PROVIDING CUSTOMIZED ON-SITE TRAINING, PUBLIC COURSES AND eLEARNING

We offer education that changes behaviors, improves performance and “future proofs” organizations. NSF public courses can be tailored and run on-site.

Examples of course topics include:

- > 21 CFR Part 820, ISO 13485, CAMDCAS and MDSAP medical device quality management systems
- > ISO 14971:2019 risk management
- > Strategic planning for new EU IVD and medical device regulations (IVDR & MDR)
- > Postmarket performance follow-up for IVDs
- > CQI/IRCA medical device lead auditor training, based on ISO 13485:2016 and MDSAP
- > Internal auditor training
- > Performance evaluation
- > CAPA and root cause investigations
- > Pharmaceutical Good Manufacturing Practice, including clinical trials
- > Regulatory issues and regulatory affairs
- > Sterile and biotech products manufacture
- > Human error prevention
- > Changing behavior
- > Master data management and data integrity
- > Process validation
- > Deviation and CAPA management
- > Good Distribution Practice



CONTACT US

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