



Total Product Lifecycle Solutions for the Medical and In Vitro Diagnostics Industry

Recognised experts providing regulatory and quality training, consultancy and auditing services to meet all of your business needs

www.nsf.org



About Us

A QA/RA customised service provider that stands out from the crowd

The NSF Health Sciences Medical Devices team consists of leading subject matter experts in medical devices and in vitro diagnostics who provide professional services tailored to meet the unique and specific demands of international clients.

Our Expertise in Brief

We offer consultancy services covering:

- > Global regulatory science
- > Design, development and implementation of quality systems
- > Quality and regulatory remediation
- > Professional training & education
- > Auditing

Our People

Our team consist of highly qualified and internationally acclaimed QA/RA experts with regulatory backgrounds or experience in the medical device industry. We are committed to providing the highest quality services based on sound science, risk assessment and common-sense pragmatic solutions to help you achieve your goals.



Services

Training and Education

A unique approach to expert-led training and education. NSF provides highly interactive courses that use your real-life scenarios to create a dynamic learning environment. Our courses ensure that the key QA/RA training requirements of your business are met, whilst introducing the latest QA/RA intelligence, techniques and tools.

A full spectrum of training courses is available at www.nsf.org/info/medicaldevices or email eudevices@nsf.org or call us on +44 (0) 1143 600868.

Consulting

The global regulatory environment is becoming increasingly complex. Balancing the demands of maintaining base business, whilst introducing new products and staying on top of regulatory intelligence can be a challenge.

This is where the NSF Health Sciences Medical Devices and IVD team can seamlessly step in to help companies both large and small. NSF provides technical and scientific resources throughout the product life cycle. We support all aspects of new product introduction and product maintenance. Our team of experts can cover most types of medical and IVD devices and combination products.

Our breakdown of consulting services:

- > Global regulatory intelligence
- > Regulatory strategies
- > Submission guidance and preparation
- > Co-ordinating and leading agency interactions
- > White paper authoring for internal company use and publications
- > Scientific and clinical evaluations
- > Implementation and remediation of quality systems

Auditing

The medical and in vitro diagnostic device industry is subjected to frequent and globally orientated audits.

Auditing has become a fundamental aspect of doing international business.

The NSF Health Sciences Medical Devices and IVD team is comprised of recognized subject matter experts. They can provide a comprehensive range of state-of-the-art auditing services to support your company. We cover all aspects of the quality system including design, implementation and remediation, and can provide tailored mentoring and coaching of staff as required, leaving your organization with the skill sets for success.



Medical Device Qualified Person (QP)

In September 2013 NSF Health Sciences launched the Medical Device Qualified Person (QP) program in collaboration with Sheffield Hallam University.

NSF is the first organization to recognize the future demands of the changing regulatory and quality landscape. Proposed revisions of the medical and IVD directives advocate that businesses have a QP in key QA/RA roles.

NSF offers a comprehensive, flexible modular study program that leads to certification, diploma or MSc qualifications. It is endorsed by the Chartered Quality Institute and taught by leading experts.

Additional training courses are also available on demand throughout the year. These typically address the latest hot topics for QA/RA professionals and also provide essential core training for staff who are new to the profession.

Courses may be run at a designated location or brought in house to suit company requirements.



**Sheffield
Hallam
University**



Our Global Presence



NSF Health Sciences Locations

NORTH AMERICA

- > Ann Arbor, MI
- > Bristol, CT
- > Washington, DC

EUROPE

- > Geneva, Switzerland
- > Sheffield, UK
- > York, UK

LATIN AMERICA

- > Lima, Peru

ASIA

- > Shanghai, China

For more information about NSF Health Sciences Medical Devices, contact: eudevices@nsf.org, visit www.nsf.org/info/medicaldevices or call **+44 (0) 1143 600 868**.