

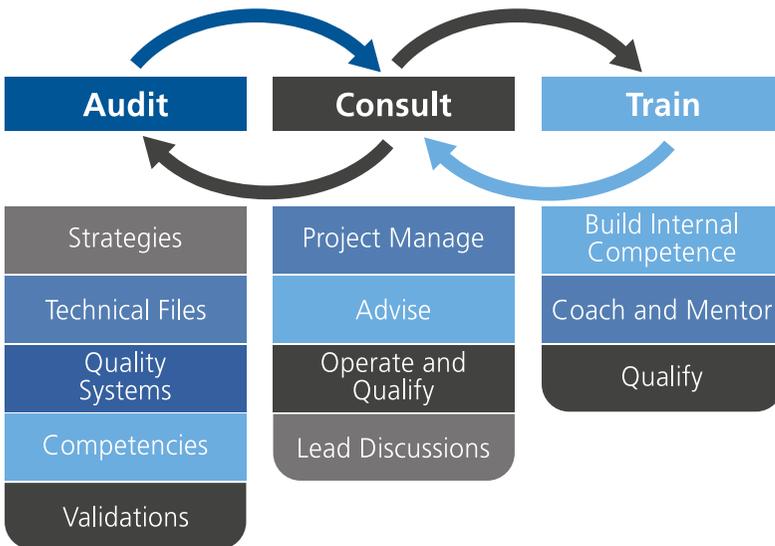


Health Sciences
Medical
Devices

THE MEDICAL DEVICE CONSULTING,
AUDITING AND TRAINING EXPERTS

Auditing

Global medical device organisations are seen as one of the most audited industries today, being subject to both internal audits and multiple external audits from a wide range of regulatory agencies. Being aware of this, and the ever-increasing requirements being placed upon stakeholders in the global medical device market by regulatory, social and economic changes, the NSF Health Sciences Medical Devices team provides a comprehensive range of auditing services to support you, whatever your place in the market.



Our Auditing Services

Recognising the varying degrees of support an organisation requires during the product lifecycle, we offer a range of services to meet your needs both internally and for external compliance, including quality systems requirements, local and international regulations, market and clinician expectations and ever-increasing patient expectations.

- Pre-audits and assessments against global regulations, including EU, USA FDA, Japan, China, Canada and Australia
- 'Health check' audits, enacting the role of a notified body to provide a gap analysis of your organisation's compliance and capability to meet external requirements
- Auditing of design dossiers and technical files for US 510K, CE mark and other market submissions
- 'Health check' audits against best practices in design control, validation, risk management, CAPA, process and supplier control
- Due diligence audits to assist all parties with acquisition decisions
- Auditing the capability of your supply chain to meet your specifications and requirements
- Auditing and benchmarking your organisation against QA/regulatory/market requirements
- Auditing of manufacturing- and technology-related validations, measurement systems, computer software, cleaning, sterilisation and packaging validations
- Audit of design-related validation projects, pre- and post-implementation, testing, scientific and analytical validations
- Full audit solution management and preparation of audit strategies
- Development of your organisation's internal audit capabilities through training and coaching

Areas of Expertise

Product Competencies

Orthopaedic and dental implants and materials
IVD reagents and devices
Cardiovascular devices, including implants
Electromedical devices
Drug/device combinations
Active implants, including pacemakers

Essential Requirement Competencies

Microbiology and sterilisation
Ergonomics and useability
Advanced Technology Medical Products (ATMPs)
Animal tissues
Human blood derivatives
Biocompatibility and toxicology

Audit Training Courses

NSF also runs medical device auditor training courses at introductory, internal auditor and lead auditor levels. For more information, please refer to the included promotional material on Training and Education or email EUdevices@nsf.org.