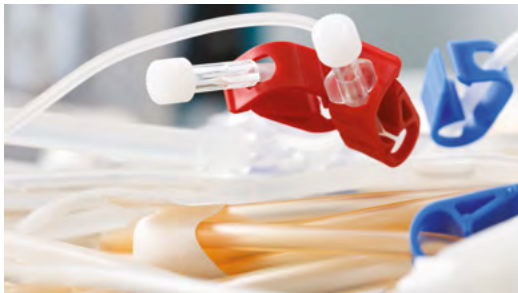
HEALTH SCIENCES SERVICES

SOLUTIONS FOR THE PHARMACEUTICAL, MEDICAL DEVICE AND IN VITRO DIAGNOSTIC INDUSTRIES



NSF International partners with pharmaceutical, medical device and in vitro diagnostic companies, large and small, to provide highly customized end-to-end services throughout the product lifecycle. From early development to commercial manufacture and distribution, our expert services help you to:

- Ensure regulatory compliance
- Implement effective quality management systems
- Maximize the contribution of your people
- Assure the highest levels of product quality and safety
- Improve your competitive edge in the marketplace

Our team is made up of former FDA and EU regulators as well as industry experts. We combine global regulatory knowledge with industry best practices to provide our clients with customized quality, compliance and regulatory services.

CONSULTING

PROVIDING SPECIALIST KNOWLEDGE, EXPERT ADVICE

Contact NSF to be proactive and drive improvements, or for guidance addressing specific regulatory or technical concerns. Our expert team offers the following services:

- Compliance and remediation consulting
- Regulatory strategy and market access consulting
- Quality engineering and validation consulting
- Quality management system improvement consulting
- Development and implementation of cost-effective and compliant pharmaceutical and medical device quality systems
- Advice on design, qualification and validation of new facilities, equipment, computerized systems and processes
- Advice on legal and regulatory concerns
- Assistance responding to regulatory inspection reports
- Simplification of quality processes, SOPs and batch records
- Advice on specific technical problems
- Benchmarking against best industry practices – beyond the regulations
- Product testing advice
- MDR and IVDR compliance
- Technical file development and review

AUDITING

TAKING A CLOSE LOOK AT YOUR FACILITIES AND OPERATIONS

STANDARDS

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

AUDITS

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

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

- Due diligence audits
- Compliance auditing – assessment of activities against standards
- Inspection readiness audits
- Audits of your suppliers
- Audits of your internal audit processes

Outputs can include efficiently reaching compliance.

TRAINING AND EDUCATION PROGRAMS

PROVIDING YOU WITH CUSTOMIZED ON-SITE TRAINING, PUBLIC COURSES AND eLEARNING

We offer education programs that will change behaviors, improve performance and "future proof" organizations. NSF public courses can be tailored and run on-site.

Examples of NSF health sciences course topics include:

- ISO 13485 medical device quality management system (QMS) requirements
- Strategic planning for the new EU Medical Device Regulations (MDR)
- CQI/IRCA Medical Device Lead Auditor training, based on ISO 13485:2016 and MDSAP
- Medical Device Single Audit Program (MDSAP) and regulatory transitions
- EU MDR internal auditor training
- Effective CAPA and root cause investigations for medical devices
- Understanding the U.S. medical device quality system regulation
- Pharmaceutical Good Manufacturing Practice, including clinical trials
- Regulatory issues and regulatory affairs
- Pharmaceutical auditing and self-inspections (Including a CQI and IRCA certified course)
- Sterile and biotech products manufacture
- Pharmaceutical quality risk management
- Human error prevention
- Changing GMP behaviors
- Data integrity
- Process validation
- Deviation and CAPA management
- Good Distribution Practice

NSF provides comprehensive services for the health science industry in three key areas

CONTACT US

For more information visit **www.nsfhealthsciences.org** or email **healthsciences@nsf.org**.

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