Total Product Lifecycle Solutions from NSF Pharma Biotech

Experts in pharma training, consultancy, auditing and analytical testing

www.nsf.org
About Us

NSF Pharma Biotech is a major global provider of pharmaceutical education, consultancy, auditing and analytical testing. It has a strong reputation specifically for professional pharmaceutical training and has expertise in the fields of pharmaceutical quality management and regulatory compliance.

Our Expertise in Brief

> Strategic regulatory and quality systems consultancy
  – Benchmarking

> Quality Systems Remediation and Continuous Improvement
  – Consent decree, AIP, warning letter, corporate integrity
  – Technical support
  – Crisis and risk management

> Quality Leadership Education programs
  – Culture change

> Customized, in-house education programs

> Audits
  – Regulatory compliance and risks
  – FDA readiness
  – Mock FDA inspections
  – Due diligence
  – Supplier audits
  – Certification

Our People

Industry know-how (minimum 25 years in the field), senior level in multinationals, ex-regulators and policy makers.
Our Expanded Services with NSF Health Sciences

**Analytical Testing**  Verifying the safety and quality of your products

Our laboratories operate under full GLP and GMP compliance. They are FDA registered and inspected and DEA licensed to handle, store and test controlled substances (Schedule I thru V) and using the following analytical techniques NSF’s scientists and technical experts offer a full range of GMP and GLP analytical method development services. Our core competencies include:

> Method development and validation  > Stability testing
> Extractables and leachables testing  > Toxicology risk assessments
> Drug compatibility testing for successful 510(k)  > Medical device development

**Compliance & Quality Systems**  Delivering high level expertise

> GxP system-based gap analyses  > Enforcement action remediation and compliance support
> Benchmarking quality management systems assessments  – FDA-483 and warning letter responses
> Pre-approval inspection preparation (FDA/EMA)  – Injunction (consent decree)
> Corrective action development and implementation  – AIP resolution
> Corrective action development and implementation  – Corporate integrity agreement

**Regulatory Consulting**  Special knowledge, expert advice

> **Regulatory consultation:** Target product profiles, regulatory strategy, orphan drugs, unique and combination products (due diligence, regulatory pathways) and global BLA/NDA/MAA/CA strategy: response to agency questions
> **Regulatory submissions:** Orphan drug applications. Fast track designation, IND, ANDA, NDA and BLA filings as well as post-marketing submission support (PAS, CBE-30, BLA, REMS reports)
> **Meeting preparation:** Pre-IND, end-of-phase-2 (EOP2), pre-BLA, and advisory committee
> **Clinical study design and evaluation:** Patient population identification, study site evaluation, endpoint selection, statistical analysis plans, study reports and manuscripts, and publication development
> **Global regulatory filings**
Auditing  In-depth and comprehensive services

> Mock regulatory inspections: We help you prepare for a regulatory inspection by carrying out mock regulatory audits in advance of the real thing. Consultants visit your facility and carry out an inspection in the style of the relevant regulatory body (FDA, MHRA, EMEA, etc).

> Due diligence audits: We assist pharmaceutical companies, investment banks and venture capital organizations in the process of due diligence for potential acquisitions, buy-ins, joint ventures and other investment projects.

> Benchmarking audits: We assess your facilities, procedures and practices against current industry norms, based on our exposure to pharmaceutical companies, large and small, worldwide.

> Other audits: We can audit CMOs and suppliers of APIs, Excipients and OTC manufacturers.

Pharma Consulting  Providing solutions to suit your business

> Compliance consulting: An in-depth audit of your operations, or those of a third party, to assess current levels of compliance with international GxP regulations and expectations.

> Regulatory consulting: Target product profile, regulatory strategy, orphan drugs and unique and combination products (due diligence, regulatory pathways).

> QMS Consulting: Assessment of your Quality Management System against current and rapidly evolving expectations.

External Educational Training  Extending your knowledge

NSF Pharma Biotech offers an extensive range of off site professional pharmaceutical training courses. It is seen as an educational continuum for the Pharmaceutical Industry. Courses offered cover a broad range of subjects and are designed to help you:

> Prepare for the next challenge

> Improve your competitiveness

> Build your knowledge base

NSF Pharma Biotech offers the first international pharmaceutical QMS auditor/lead auditor lead course. It is independently certified by IRCA (www.irca.org) and meets the training requirements for the new IRCA Certification of Pharmaceutical Quality Management Systems Auditor/Lead Auditor (PQMS).
In-House Educational Training  Bringing expert trainers to your door

At NSF Pharma Biotech, in-house training is a premium client service offering. Customers, in some cases, have benefited from other NSF Pharma Biotech services before expanding to NSF’s extensive range of educational resources. The majority of our in-house educational training courses are specifically designed to meet your company’s precise needs and are built in modular form. Once the number of modules have been determined, they can be conducted over a 12-24 month period. In-house training courses can vary in duration from half a day up to five days. The optimum attendance is 12 to 30 delegates to enable interactive learning.

Training is most effective when it is directly relevant to the activities performed by the attendees. Courses are therefore designed with you enabling your employees to immediately relate to the topic and pose relevant questions.

Our comprehensive range of professional in-house course topics includes:

| Analysis and Testing – cGMPs and Best Practices in Pharma Labs |
| Deviation and CAPA Systems – Certification and Best Industry Practices |
| Effective Pharmaceutical Audits and Self-Inspections |
| Investigational Medicinal Products |
| Human Error Avoidance |
| Pharmaceutical GMP |
| Pharmaceutical Law and Administration |
| Pharmaceutical Quality Systems – Best Industry Practice |
| Practical Application of Quality Risk Management |
| Pharmaceutical Microbiology |
| Risk-Based Decision Making in Sterile Products Manufacture |
| Satisfying Regulatory and Quality Requirements in Key Emerging Markets |
| Supply Chain Assurance and Anti-Counterfeiting |

How it Works

| STEP 1  | Discuss the course – aims, audience, location(s) and duration |
| STEP 2  | Formal proposal submitted including draft course program/costs |
| STEP 3  | Feedback received, revisions made and final program created |
| STEP 4  | Training delivered, course materials provided and teamwork tasks distributed |
| STEP 5  | Review of course undertaken and follow-up actions noted and shared |
NSF Health Sciences Locations

NORTH AMERICA
> Ann Arbor, MI
> Bristol, CT
> Washington, DC

LATIN AMERICA
> Lima, Peru

EUROPE
> Geneva, Switzerland
> York, United Kingdom

ASIA
> Shanghai, China

For more information about NSF Pharma/Biotech services, contact pharma@nsf.org or visit www.nsf.org