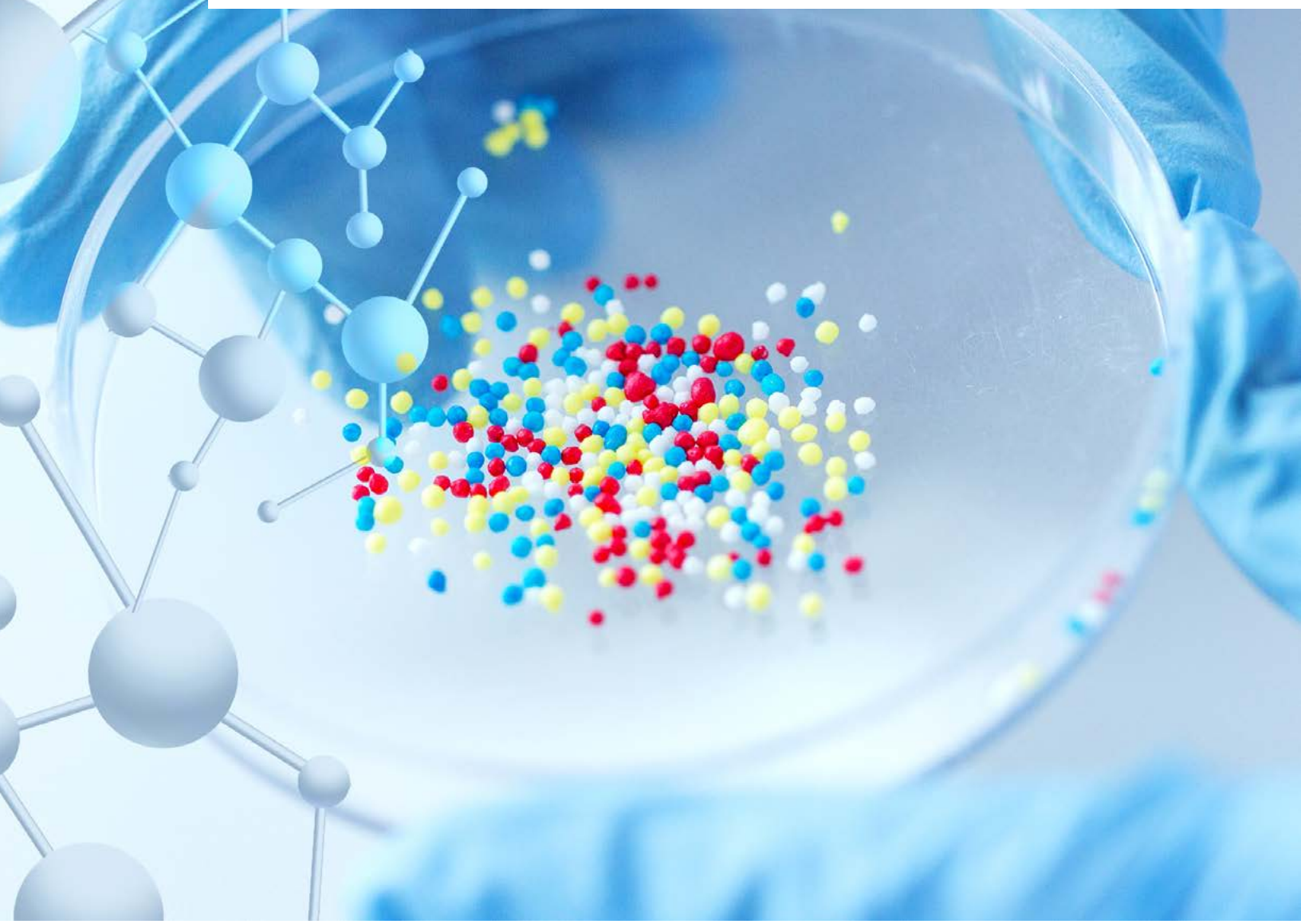
TOTAL PRODUCT LIFECYCLE SOLUTIONS

EXPERTS IN PHARMA TRAINING, CONSULTANCY, AUDITING AND ANALYTICAL TESTING



ABOUT US

NSF is a leading provider of strategic regulatory, quality systems, and compliance consulting services, as well as education and training, to pharmaceutical, biologics, and medical device life sciences companies. Our core expertise lies in the design and implementation of robust solutions to complex issues related to the development, approval, marketing, and manufacturing of FDA-regulated products throughout the total product lifecycle.

OUR PEOPLE

Our strengths lie in the company's global perspective and in the talents of its consultants specifically selected for the depth of their experience. Many have held senior management roles and can offer a hands-on perspective. The consultant team includes several ex-regulatory agency inspectors, individuals closely involved in current regulatory "hot topics" and individuals who served on industry association boards and committees. Our recent experience with human drug product manufacturing internationally, combined with our executive management's extensive experience working across geographical areas and cultures, positions us well to assist you in achieving your objectives.

OUR EXPERTISE

NSF KEY FACTORS TO SUCCESS

OUR EXPANDED SERVICES

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. Enforcement action remediation and compliance support
  - FDA-483 and warning letter responses
  - Injunction (consent decree)
  - AIP resolution
  - Corporate integrity agreement

> **Regulatory strategy:** Target product profile, regulatory strategy, orphan drugs and unique andcombination products (due diligence, regulatory pathways)

> **QMS consulting:** Assessment of your quality management system against current and rapidly evolving expectations
  - GxP system-based gap analyses
  - Benchmarking quality management systems assessments

COMPLIANCE & QUALITY SYSTEMS

Delivering high-level expertise

> GxP system-based gap analyses

> Benchmarking quality management systems assessments

> Pre-approval inspection preparation (FDA/EMA)

> Corrective action development and implementation

> Enforcement action remediation and compliance support
  - FDA 483 and warning letter responses
  - Injunction (consent decree)
  - AIP resolution
  - 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.

EXTERNAL EDUCATIONAL TRAINING

Extending your knowledge

NSF offers an extensive range of on-site and off-site professional pharmaceutical training courses that 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 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 BRIEF

- > Strategic regulatory and quality systems consulting
- > Quality systems remediation and continuous improvement
  - Consent decree, AIP, warning letter, corporate integrity
  - Technical support
  - Crisis and risk management
- > Customized, in-house education programs
- > Audits
  - Regulatory compliance and risks
  - FDA readiness
  - Mock FDA inspections
  - Due diligence
  - Supplier audits

QUALIFICATIONS

We have extensive experience working domestically and internationally, on small- and large-scale projects. In the last two years alone, we have worked on numerous international assignments including quality systems development, assessment, and remediation; cGMP gap assessments and audits; mock-FDA inspections and training; and third-party audits for clients in the U.S., Canada, China, India, Columbia, Switzerland, France, and Germany. We also developed and implemented a quality system that included extensive cGMP training, certification, and FDA preparation and readiness for the pre-approval inspection for a Chinese human drug manufacturer that resulted in the first U.S. approval for an aseptic injectable product manufactured in China. Likewise we have worked on several large-scale AIP and quality systems remediation projects in India.

IN-HOUSE EDUCATIONAL TRAINING

Bringing expert trainers to your door

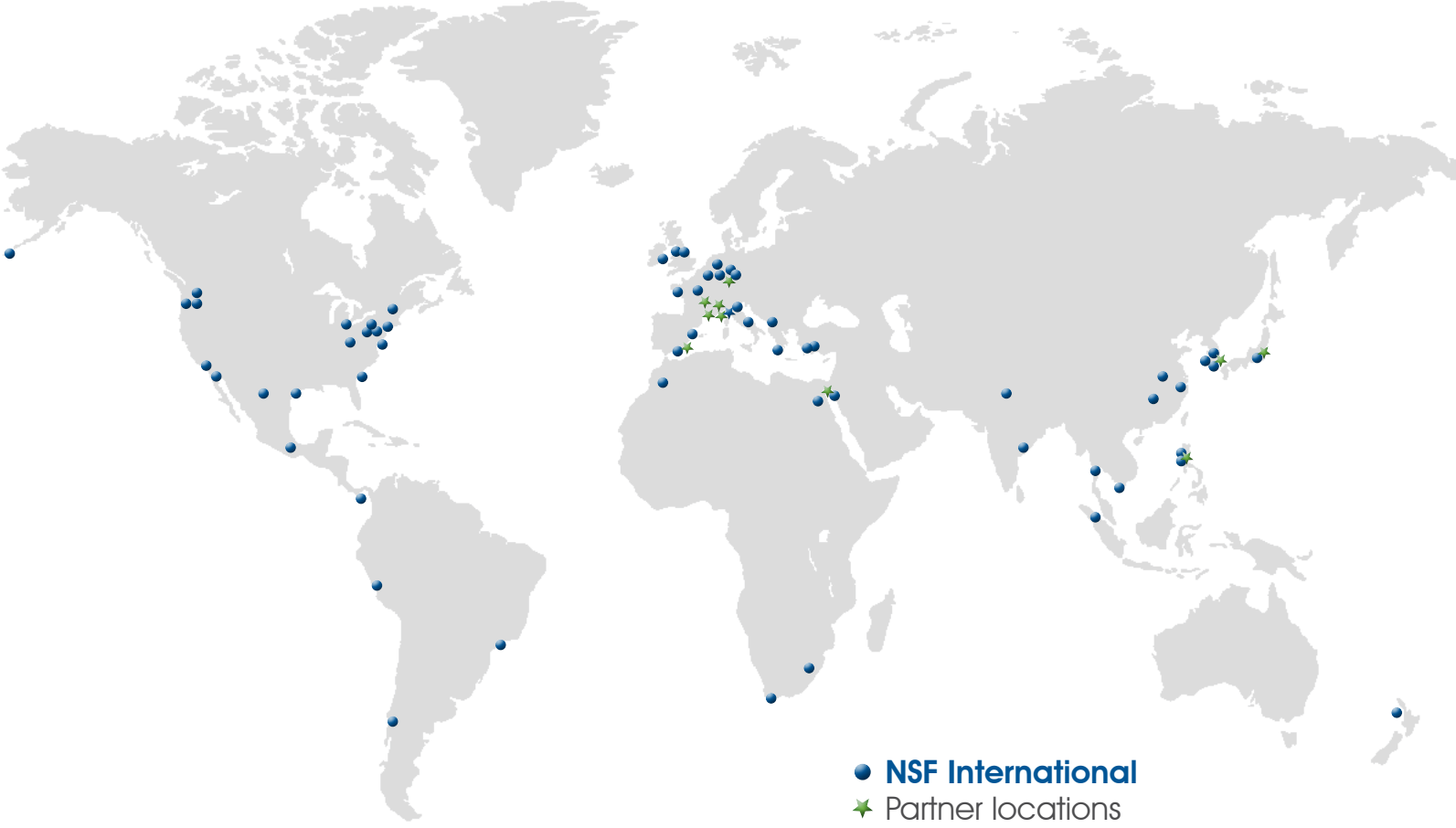
At NSF International, in-house training is a premium service offering for clients in the Pharma Biotech industry. Customers, in some cases, have benefited from other NSF services before expanding to NSF's extensive range of educational resources. The majority of our in-house educational training courses 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 participants to enable interactive learning.

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

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
Discuss the course – aims, audience, location(s) and duration	Submit formal proposal including draft course program/ costs	Receive feedback, make revisions and create final program	Deliver training, provide course materials and distribute teamwork tasks	Review course and share follow-up actions

OUR COMPREHENSIVE RANGE OF PROFESSIONAL IN-HOUSE COURSE TOPICS INCLUDES:

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



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