Global Lab Capabilities | **Pharma Biotech**

NSF Health Sciences' global network of laboratories delivers expert solutions to pharmaceutical, biotechnology and medical device companies in the areas of analytical testing, regulatory consulting, research and development, and regulatory submissions.

www.nsf.org

About NSF International

NSF International is a global independent organization that writes standards, and tests and certifies products for the food, water and consumer goods industries to minimize adverse health effects and protect the environment (nsf.org). Founded in 1944, NSF is committed to protecting human health and safety worldwide. NSF International is a Pan American Health Organization/World Health Organization Collaborating Center on Food Safety, Water Quality and Indoor Environment.

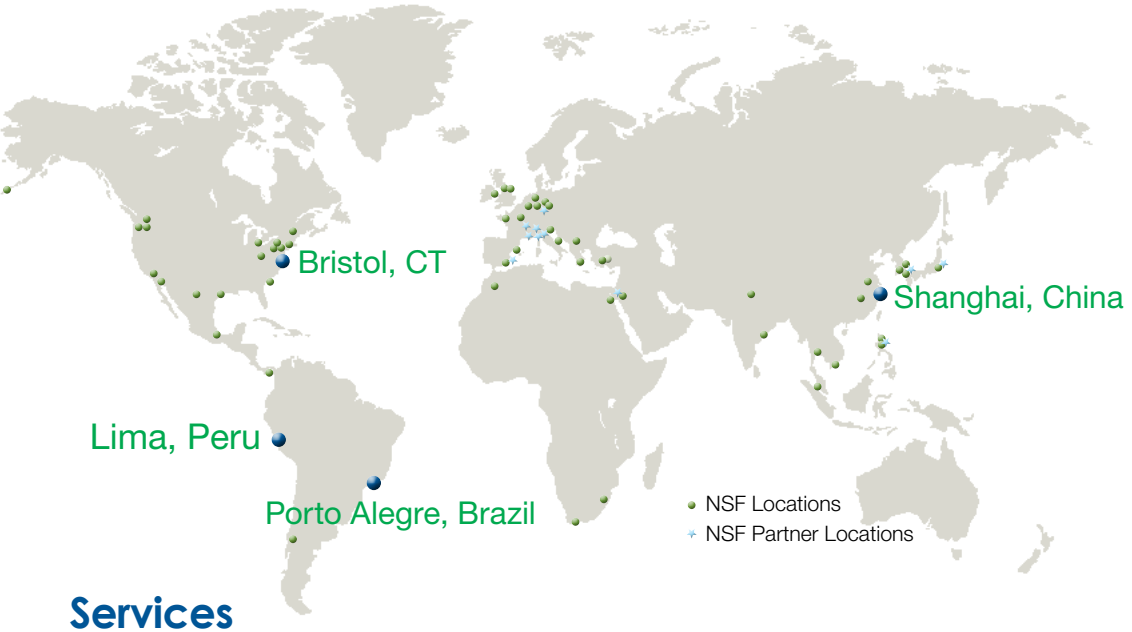
Our Services

NSF supports the global pharmaceutical marketplace, including regulators, manufacturers and consumers of pharma, biotech, medical/combination devices and single-use systems, in the development of innovative products by providing expert support services from preclinical activities to post-market changes. Our global network of accredited labs and industry experts help bring safe products to market and assure that projects are completed to your satisfaction and on time. NSF has more than 2,100 experienced professionals including microbiologists, toxicologists, chemists, engineers and experts in public health.

Our Labs

Our global network of labs utilize QA systems and maintain strategic accreditations such as ISO/IEC 17025. Our Bristol lab operates as an independent GLP and GMP contract laboratory, which is U.S. FDA registered and U.S. DEA licensed. Other lab accreditations include INMETRO/MAPA/REBLAS/ANVISA (Brazil); CMA/CMAF (China); and Authorized laboratory for Quality Control in Pharmaceutical – Members of Official Networks Laboratory by the National Institute of Health-INS (Peru). For accreditations specific to each lab, please see the lab profiles.

NSF's scientific knowledge, technical expertise, lab capabilities and customer service enable us to manage the most challenging projects and to assure that your projects are completed to your satisfaction and on time.



Services

NSF delivers expert support services from preclinical activities to phase I-IV clinical trials, pharmaceutical development, bioanalytical, protein characterization, biosafety and quality control testing of small and large molecules, raw materials, finished products, containers and utilities.

Preclinical - The preclinical tests evaluates safety parameters and effectiveness of pharmaceuticals, through toxicology studies conducted to determine the degree of toxicity and potential reversibility or irreversibility of a chemical substance, to establish the relationship between dose and adverse effects, and to provide information on target organs and target functions. This allows a meaningful assessment of the data obtained and a scientifically supported extrapolation of the effects to the human situation.

Clinical – NSF provides analysis of small molecule, protein and oligonucleotide therapeutics in plasma, serum and urine through all stages of clinical development. Our scientists routinely validate methods to FDA and other regulatory guidance. NSF is able to identify and analyze for drug metabolites.

CMC Analytical – NSF develops and validates methods for drug purity, drug content, degradation products and impurities. We routinely perform these methods, compendial methods and microbiological testing in GMP compliance. Our labs perform extractable and leachables studies to assess risk from container closure systems and process equipment.

Preclinical	Brazil	USA	Peru	China
Toxicology test design	X	X		
Toxicological testing	X			
Toxicological evaluation	X	X		
Formulation development		X		
Formulation analysis	X	X		
Bioanalytical method development and validation (animal)		X		
Plasma (animal) specimen analysis		X		
Metabolite Identification	X	X		

Clinical				
Bioanalytical method development and validation (human)		X		
Plasma (human) specimen analysis		X		
Metabolite identification		X		

CMC Analytical				
Develop and validate methods for assays and impurities/degradants	X	X		X
Analytical testing to support stability	X	X		X
Forced degradation	X	X		
Compendia testing (USP, EP, BP)	X	X	X	X
Identification analysis for active pharmaceutical ingredient	X	X	X	X
Microbiological testing	X		X	X
Extractables from container closure system		X		X
Leachables from container closure system into drug product		X		X
Drug product release testing	X	X	X	
Dissolution testing			X	
Visible and sub visible particles			X	
Sampling lots			X	
Pharmaceutical packaging compatibility				X

The right people. The right solution. The first time.™

NSF®

www.nsf.org

LPH-339-1015

Lab Profile | NSF Bioensaios

Porto Alegre, Brazil

Services:

» Physical-Chemical Testing

- Studies in compliance with GLP following ANVISA and ICH guidelines
- Method development and validation for assay, impurities and degradation products for drugs in compliance with GLP
- Compendia testing (USP, EP, BP)
- Forced degradation testing
- Investigation of impurities: Identification of unknown impurities and degradation products

» Toxicological Testing

- Testing following ANVISA, FDA, EMA, ICH and OECD guidance and in compliance with GLP
- Testing development

» Microbiological Testing

- Testing in according to USP and European pharmacopeia

Size: 12,000 square feet (1,115 square meters)

Established: 1990

Employees: 70+

Accreditations:

» GLP OECD

» ISO/IEC 17025 (CGCRE - Coordenação Geral de Acreditação do INMETRO)

» MAPA - Agriculture Ministry (Veterinary Medical)

» ANVISA/REBLAS - Health Agency

Site Manager: Ellen Martha Pritsch, Director of Business Operations

Address: Rua Palermo 257 - CEP 94480-775 - Viamão - Brazil

Phone: (55) 51 3493 6888

Email: comercial.farma@nsf.org

Lab Profile | NSF Health Sciences

Bristol, CT, USA

Services:

» Preclinical and Clinical Support Services for Pharmaceuticals

- Preclinical study design, consultation and monitoring
- Preclinical formulation development and analysis
- Bioanalytical methods development, validation and sample analysis

» GMP Analytical Testing for Pharmaceuticals and Medical Devices

- Method development and validation for assay, impurities and degradation products for drugs and combination medical devices
- Support stability studies, process development and release of finished product
- USP testing
- Identification of unknown impurities and degradation products

» Extractables and Leachables Testing for Pharmaceuticals, Medical Devices and Single-Use Manufacturing Equipment

- Material Assessment and study design
- Controlled extraction studies
- Leachables analysis for drug product container closure systems

Size: 15,000 square feet (1,400 square meters)

Established: 2000

Employees: 30

Accreditations:

» GLP and GMP contract laboratories

» U.S. FDA registered

» U.S. DEA licensed

Site Manager: Kurt Moyer, Ph.D., Director of Research

Address: 719 Middle Street, Bristol, CT USA 06010

Phone: 860.940.6550

Email: hstesting@nsf.org

Lab Profile | NSF INASSA

Lima, Peru

Services:

» Physicochemical and Microbiological Testing for Pharmaceutical Dosage Forms

- Solid, semisolid and liquid
- According to regulations: USP / BP / EP

» Physicochemical Analysis

- Organoleptic analysis
- Basic analysis (pH, volume, average weight, density)
- Quantitative analysis of active ingredients APIs by HPLC, GC, UV-VIS, IR, AAS, Potentiometry, Volumetry and Polarimetry
- Identification analysis of APIs by TLC, IR and Chemical Reactions
- Complementary analysis of dosage forms Dissolution, Disintegration, Visible strange particles, Count test of Subvisibles particles for obstruction of light and Microscopy, content of water for KF

» Microbiological Analysis

- According to regulation: USP / BP / EP: Standard plate count, test for specific microorganisms, sterility test, Microbiological assays of antibiotics, Bacterial Endotoxins test, Antimicrobial effectiveness test, growth promotion testing media
- According to AOAC, PREN 12054 and NF EN 1040: Bacterial activity in soaps, Disinfectants, Germicidal and Detergents actions and Basic Quantitative assay of bactericidal activity of chemical disinfectants and antiseptics

Size: 33,260 square feet (3,090 square meters)

Established: 1981

Employees: 220+

Accreditations:

» Authorized laboratory for Quality Control in Pharmaceutical – Members of Official Networks Laboratory in Peru by the National Institute of Health (INS).

» ISO/IEC 17025 INACAL (Instituto Nacional de Calidad)

Site Manager: Carmen Catter, General Manager

Address: Av. La Marina 3035 San Miguel – Lima

Phone: 511(6165200)

Email: inassa@nsf.org

Lab Profile | NSF Shanghai Testing Company

Shanghai, China

Services:

» Extractables and Leachables Testing for Pharmaceutical Packaging Materials and Medical Devices

- Material assessment and study design
- Controlled extraction studies
- Leachables analysis for drug product container closure systems

» Compatibility Studies Between Pharmaceutical Packaging and Pharmaceuticals

- Guidelines of Evaluating Compatibility between Pharmaceutical Packaging and Pharmaceuticals (YBB00142002)
- Guidelines of Evaluating Compatibility between Chemical Injectables and Polymer Packaging
- Guidelines of Evaluating Compatibility between Injectables and Glass Packaging

» cGMP Audit and Analytical Testing for Dietary Supplements

- cGMP audited following FDA 21 CFR 111 for dietary supplement industry
- Test method development and validation for ingredient and contaminants in dietary supplements
- CHP/USP/EP testing

Size: 13,600 square feet (1,260 square meters)

Established: 2010

Employees: 30

Accreditations:

» CNAS (ISO/IEC 17025)

» CMA (China Metrology Accreditation)

» CMAF (China Metrology Accreditation for Food)

Site Manager: Ms. Dongjing Liu, Laboratory Site Manager

Address: Unit D/F, 1 Floor, Building 10 Pujiang Intelligence Valley, 1188 Lian Hang Road Shanghai, P.R. China 201112

Phone: +86-21-2428 6300

Email: dliu@nsf.org