Nelson Labs Europe

Fact Sheet

Nelson Labs
A Sotera Health company

Corporate Profile

Based in Leuven, Belgium, Nelson Labs Europe provides premium extractables and leachables testing to the pharmaceutical, biological, and medical device industries. With a strong mission of Safeguarding Global Health™ and knowing that every test matters, we provide solutions that improve patient outcomes and minimize client risk. We know the pharmaceutical products and medical devices we test are as important as the patients they represent. It is why we set such high standards, ensure accuracy, and work with clients to help solve complex issues.

QUICK FACTS

FOUNDED
Leuven, Belgium - 1991

EMPLOYEES
120 with more than 30 PhD scientists

CAPACITY
3500 m² building of which 2100 m² is laboratory space

LOCATION
Leuven, Belgium

CAPABILITIES
Access to more than 700 analytical, chemistry and microbiological tests

COMMITTEE MEMBERSHIP
ISO

Our History

Our business began as Toxikon Europe N.V. in 1991 and became the leader in extractables and leachables testing — with a world-class compound database. Acquired by Nelson Labs in 2017 and renamed Nelson Labs Europe, we retain our expertise, exclusive database, state-of-the-art equipment, and market leadership in extractables and leachables testing. Now as part of Nelson Labs, we offer a greater range of chemistry and microbiological services through a network of global laboratories.

Delivering Value

We provide superior testing solutions and personalized service for every client and project at all stages of the product development cycle offering industry-leading expertise, quality, and results that deliver exceptional value to our clients.

To learn more, visit www.nelsonlabs.com/europe

+1 801-290-7500 | +32 16 40 04 84
www.nelsonlabs.com | sales@nelsonlabs.com
US FDA registered and third-party accredited to ISO 17025 standards

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Certifications:

Nelson Lab Europe is FDA registered and third-party accredited to ISO 17025 standards and is a GLP facility. Nelson Labs Europe received a GMP accreditation from the European Authorities.

FDA FEI Identifier- 3005742674

ISO Registrar/Certificate number B-363 (BELAC)

GLP compliance OECD Directive 2004/9/EC, T02 (Sciensano)

EU GMP- GMDP 1844 Human, Verterinary, Investigational Medicinal Products (FAHMP)

Test Services

Extractables and Leachables for Pharmaceutical Containers
Chemical Characterization for Medical Devices
Extractables and Leachables for Medical Devices
Material Characterization Screens for Raw Materials
Drug-device Interactions
Combination Products Testing
Impurities Identification in Drug Components and APIs
Stability Studies- Pharmaceutical
Method Development- Pharmaceutical
Cleaning & Disinfection Validation
Microbiological Testing
Cytotoxicity Testing
Clinical Reprocessing Validations
Microbial Enumeration for Non-Sterile Products
Mycoplasma Testing
Bacterial Endotoxin Testing
Product Sterility- Isolator
Container Closure Integrity- Bacterial Immersion
Product Bioburden Testing
VDmax and Quarterly Dose Audits

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