Nelson Labs®
A Sotera Health company

Pharmaceutical Solutions

Safeguarding Global Health®
– with every test we complete.

www.**nelsonlabs**.com

Who We Are

Nelson Labs
A Sotera Health company

Nelson Labs
A Sotera Health company

Nelson Labs is a leading global provider of laboratory testing and expert advisory services for medical device and pharmaceutical companies.

REGULATORY COMPLIANCE ASSOCIATES®
A Nelson Labs company

Regulatory Compliance Associates, a Nelson Labs company, provides worldwide services to the pharmaceutical, biologic and biotechnology, sterile compounding, medical device, and lab testing industries for resolution of compliance and regulatory challenges.

Sterigenics
A Sotera Health company

Sterigenics is a global leader in comprehensive sterilization solutions meeting industrial sterilization needs in the medical device, pharmaceutical, advanced applications, commercial, and food industries.

Reasons for Choosing Nelson Labs

- Our ***decades of experience*** in a variety of markets allows us to solve challenges that are not typically addressed in routine testing.
- To meet customer expectations for quality, we keep our ***testing to the highest standards***, utilizing the most state-of-the-art equipment and facilities.
- Our cutting-edge E&L testing utilizes the ***largest database of compounds*** commercially available.
- We have successfully supported ***over 500 submissions*** to the US FDA and European regulatory authorities.
- In conjunction with Regulatory Compliance Associates, our expert advisors provide ***support services*** for all of your testing, quality, and regulatory needs.
- In partnership with our sister company Sterigenics, we are the only ***fully integrated, global provider of lab services and sterilization solutions*** for the pharmaceutical industry.

Contact our sales team for even more reasons. **sales@nelsonlabs.com**

+1 (801) 290-7500 | www.**nelsonlabs**.com

US FDA registered and third-party accredited to ISO 17025 standards

Nelson Labs®
A Sotera Health company

Nelson Labs has a long history of performing a variety of tests for pharmaceutical and biopharmaceutical companies. We have over 700 scientists, technicians, and service specialists working in multiple labs around the world who perform the necessary tests for the critical stages of drug development and commercialization. Some of the key testing that we provide covers biocompatibility, toxicology, extractables & leachables (E&L), impurities identification, container integrity, and sterility assurance.

We are committed to our mission:
Safeguarding Global Health®
– with every test we complete.

Pharmaceutical Solutions

+1 (801) 290-7500
sales@nelsonlabs.com

www.**nelsonlabs**.com

We provide **reliable testing and sterilization solutions as well as advisory services** for the critical stages of drug development and commercialization.

Consulting for Chemistry, Manufacturing, and Controls (CMC) * Quality Assurance * Regulatory Affairs * Compliance Assurance

API Production

- Active Pharmaceutical Ingredient (API) Characterization
- Assay & Related Method Development (MD) & Method Validation (MV)
- Elemental Impurities
- Physiochemical Testing
- Reference Standard Characterization
- Residual Solvents MD & MV
- ▲ API Release
- ▲ Stability Studies
- ■ Microbial Limit

IND Enabling

- Container Closure Integrity Testing (CCIT)
- Container Closure Release
- Formulation Development Support
- Assay & Related MD & MV
- Method Feasibility & Verification for Raw Materials
- Raw Material Release
- ▲ Stability Studies
- ■ Bacterial Endotoxin Testing (BET)
- ■ Microbial ID
- ■ Sterility Testing

Clinical Development

- CCIT
- Cleaning Validation
- Elemental Impurities
- Extractables & Leachables (E&L)
- Impurities & Degradation Product Characterization
- MD & MV
- Method Feasibility & Verification
- Nitrosamine Analysis
- Physical & Chemical Testing
- Residual Solvents
- ▲ Lot-Release Testing
- ▲ Stability Studies
- ■ BET
- ■ Disinfectant Studies
- ■ Filter Validation
- ■ Microbial ID
- ■ Sterility Testing
- ■ Sterilization

Commercial

- Cleaning Validation
- Container Closure Release
- Elemental Impurities
- Impurities & Degradation Products
- Nitrosamine Analysis
- Physical & Chemical Testing
- Raw Material Testing Release
- Residual Solvents
- ▲ API Release & Stability
- ▲ Drug-Product Release & Stability
- ■ BET
- ■ Microbial ID
- ■ Sterility Testing
- ■ Sterilization

Life-Cycle Management

- GAP Analysis for Analytical Methods
- Non-Sterile Formulation Support Liquids
- Remedial Validation
- ▲ Drug Release
- ▲ Stability Studies
- ▲ Terminal & Container Sterilization
- ■ Sterilization

Nelson Labs® A Sotera Health company

Sterigenics® A Sotera Health company

● = Physiochemical Testing ▲ = Physiochemical Testing & Microbiology ■ = Microbiology

+1 (801) 290-7500 | www.**nelsonlabs**.com | sales@nelsonlabs.com

US FDA registered and third-party accredited to ISO 17025 standards