



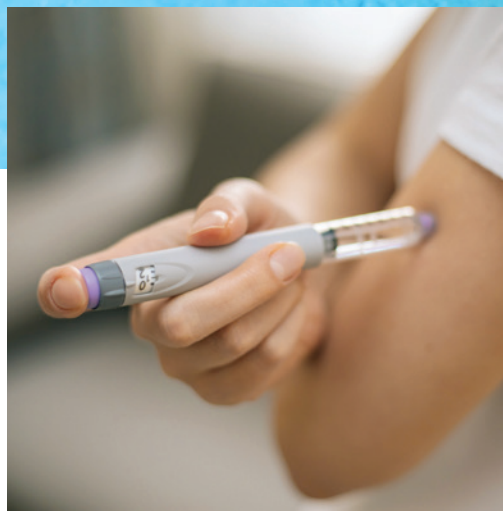
Pharmaceutical Primary Packaging Safety



sterigenics.com

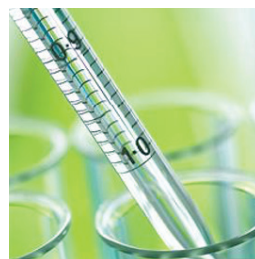
nelsonlabs.com

Primary Packaging
has a significant impact
on a drug's effectiveness
and patient safety.



The extensive expertise and industry knowledge of our **Expert Advisors** can assist you in navigating the complex regulatory landscape effectively, ensuring the achievement of your unique product goals.

Sterilization Methodologies | Biocompatibility | Extractables & Leachables | Toxicology



From product design to development, manufacturing and commercialization.

Ask about our Nelson Labs industry-leading **Proprietary Compounds Screener Database**

More than 6,000 compounds for the detection, identification, and quantification of impurities.





Impurities, such as leachables, found in pharmaceutical products due to interactions with manufacturing materials, primary packaging, and/or administration systems, have the potential to compromise their therapeutic efficacy.

Quality, Reliability and Speed to Market

Our comprehensive suite of sterilization and lab testing solutions help assure the quality and suitability of your packaging components and systems, while reducing risk and prioritizing speed to market.



Comprehensive Suite of Primary Packaging Solutions

Sterilization Services	Lab Testing	Capabilities
<ul style="list-style-type: none"> • Sterilization method development <ul style="list-style-type: none"> - Feasibility testing - Process development - Manufacturing & environmental process control - Audit and release testing • Product validations • Sterilization of primary packaging components for the point of use at the fill-finishing site • Over 1,600 engineers, scientists, safety specialists and solution providers with deep experience across Ethylene Oxide, Nitrogen Dioxide, Gamma, E-Beam, and X-Ray sterilization technologies 	<ul style="list-style-type: none"> • Package development testing • Evaluation of sterilization impact • Container closure integrity testing (CCIT) • Extractables & leachables studies • Initial qualification of the materials of construction (USP, EP, JP) • Particulate testing (visible/subvisible particles) • Elemental impurities testing (USP<233>) • Biocompatibility • Adsorption/desorption studies • Drug-device compatibility studies • Impurities identification • Environmental conditioning • Shipping & distribution testing • Microbial barrier testing • ICH stability testing • Container quality validation & release testing <ul style="list-style-type: none"> - Bioburden - Sterility - Endotoxin - Particulate matter - Toxicology 	<ul style="list-style-type: none">  Expert Advisory Services Employing Expert Advisors committed to helping you understand the regulatory landscape and deliver safe and effective products to market  Quality Systems Focusing on regulations and processes that help ensure your products are manufactured to a safe and consistent standard  Operational Expertise Leveraging digital solutions, lean principles, processes and procedures to provide transparency and speed to market  Integrated Solutions As part of Sotera Health, Sterigenics and Nelson Labs offer integrated sterilization and lab testing solutions <p>Ask about our PREMIER PARTNER PROGRAM</p> <ul style="list-style-type: none"> • Priority service • Single point of contact • Coordinated technical support • Ease of accounting/billing • And more...



As part of Sotera Health, we serve **5,000+** customers across **63** facilities in **13** countries



Sterigenics is a leading global provider of outsourced terminal sterilization services for the medical device, pharmaceutical, food safety and advanced applications markets. With our industry recognized scientific and technological expertise, we help to ensure the safety of millions of patients and healthcare practitioners around the world every year. Across our 48 global facilities that span 13 countries, we offer our customers a complete range of outsourced terminal sterilization services, primarily using the three major sterilization technologies: Gamma irradiation, Ethylene Oxide processing and Electron Beam irradiation as well as Nitrogen Dioxide sterilization and X-Ray irradiation, plus expert advisory services. We are committed to addressing the growing need for sterilization in many parts of the world and partnering with our customers to eliminate threats to human health.

Nelson Labs is a global leader in microbiological and analytical chemistry testing and advisory services for the medical device and pharmaceutical industries. We serve over 3,000 customers across 13 facilities in the United States, Mexico, Asia and Europe. With a comprehensive array of over 900 laboratory tests and the expertise of Regulatory Compliance Associates, a recognized leader in life science consulting, we support our customers from initial product development and sterilization validation, through regulatory approval and ongoing product testing for sterility, safety and quality assurance. We are regarded as a best-in-class partner with a strong track record of collaborating with customers to solve complex issues.

Safeguarding Global Health® – with every product we sterilize and every test we complete.

Contact us today to get your project started.



sterigenics.com

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*Nordion, a Sotera Health company, is a leading global provider of Cobalt-60, used in the sterilization and irradiation processes. Go to nordion.com to learn more.