Sterigenics | Nelson Labs

Prefilled Device and Injectable Product Safety & Integrity Solutions

sterigenics.com | nelsonlabs.com

Navigating the Safety & Integrity Challenges of Prefilled Devices and Injectable Products

From initial design to commercialization, each stage in the life cycle of prefilled devices and injectable products poses unique challenges.

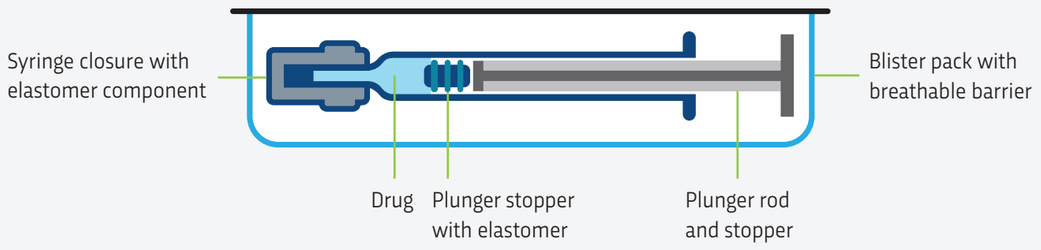
There are many considerations when ensuring sterility, maintaining product quality, and protecting patient safety are required outcomes.

Key Challenges

- Regulatory complexity
- Temperature-sensitive drug products (biologics)
- Complex formulations
- Innovative materials (plastics, coatings)
- Moveable parts (syringe plunger)
- Impurities (ingress, stability)
- Sterilization SAL ≤10^{-6}
- Sterilization validation & cycle design

Sterility issues are responsible for **37%** of FDA recalls*

Prefilled Syringe Complexities



*37% includes microbial contamination in parenteral/sterile products only. Patel, Ravi; Vhora, Aksha; Jain, Deepak; Patel, Rikin; Khunt, Dignesh; Patel, Rucha; Dyawanapelly, Sathish; Junnuthula, Vijayabhaskarreddy (2024). A retrospective regulatory analysis of FDA recalls carried out by pharmaceutical companies from 2012 to 2023. *Drug Discovery Today, 29*(6), 2-7. https://www.sciencedirect.com/science/article/pii/S1359644624001181?via%3Dihub

Quality, Reliability and Speed to Market

Our integrated pharmaceutical-grade sterilization, lab testing, and advisory solutions help assure the quality of your prefilled devices and injectable while reducing risk and prioritizing speed to market.

Pharma-Centric Integrated Service Offering

ADVISORY

Regulatory Strategy and Submission Support

Gap Analysis and **Remediation** Programs

Quality Management System

Design Requirements (user needs & engineering requirements)

Design Transfer

Product Development and Risk Management (design, use & process)

Cybersecurity considerations for connected devices

TESTING

Raw Material Testing
- Compendial testing for excipients
- Container closure
- Particulate
- Method feasibility & verification

Prefilled Device Testing
- Elemental impurities
- Extractable and leachable
- Residuals
- ID of impurities/degradation
- Container closure
- Particulate
- Deliverable volume
- Method development & validation

Microbial Testing
- Sterility assurance
- BET/bioburden
- Microbial ID

STERILIZATION SERVICES

Sterilization Method Development
- Feasibility testing
- Process development
- Materials/device compatibility

Validation
- Study protocols
- Testing & reporting
- Scale up

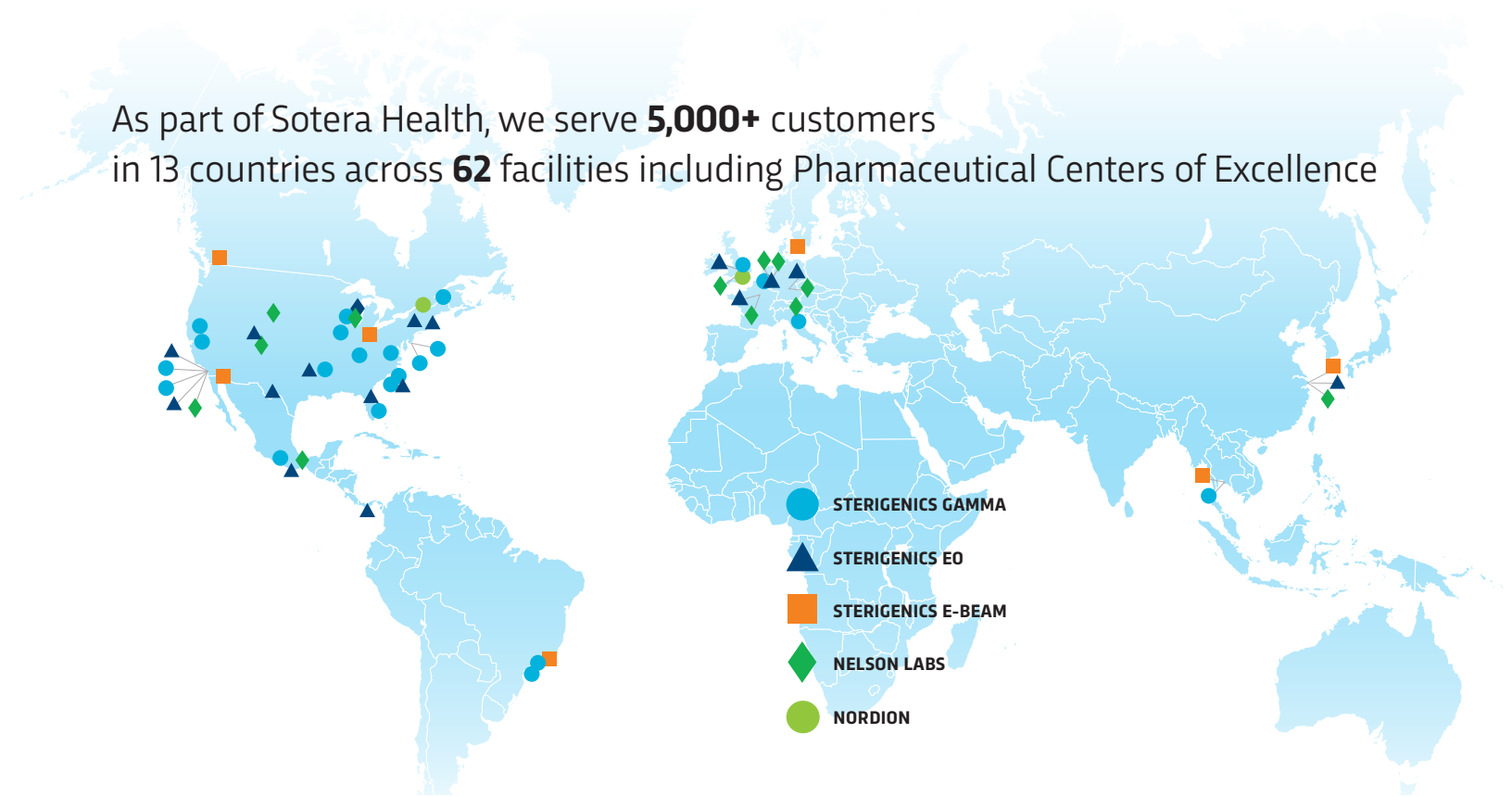
Routine Sterilization
- Gas technologies (EO, NO_2)
- Radiation (Gamma, eBeam, X-Ray)
- Fast track (STAT) processing
- Product release (e.g., safety/sterility; stability evaluation)

Global Facility Network
- Pharma Centers of Excellence
- GMP certified
- Controlled conditions
- Business continuity & security

Terminal sterilization (TS) is preferred to aseptic processing for pharmaceutical products because:
- TS provides the highest assurance of sterility and patient safety level (SAL ≤10^{-6})
- Regulatory bodies in the United States and European Union agree that TS is preferred and should be considered first to minimize the risk of contamination and its consequences.

> *"Wherever possible, a process in which the product is sterilized in its final container (terminal sterilization) is chosen."* — European Pharmacopoeia

As part of Sotera Health, we serve **5,000+** customers in 13 countries across **62** facilities including Pharmaceutical Centers of Excellence



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 expertise we help to ensure the safety of millions of patients around the world every year. Across our 48 global facilities, we offer our customers a complete range of sterilization services, primarily using the three major technologies: gamma irradiation, ethylene oxide processing and electron beam irradiation as well as X-Ray and nitrogen dioxide. We are committed to addressing the growing need for sterilization across 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. Nelson Labs serves over 3,000 customers across 12 facilities in the United States, Mexico, Asia and Europe. We have a comprehensive array of over 900 laboratory tests and the expertise of Regulatory Compliance Associates, a recognized leader in life science consulting to 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®

Contact us today to get your project started.

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