PRINCE
STERILIZATION SERVICES

Experts in Pharmaceutical Steam and Dry Heat Sterilization

Prince Sterilization Services leads in the delivery of innovative moist heat-steam and dry heat sterilization services, with special expertise in supporting aseptic manufacturing.

FDA Registered – ISO 13485 Certified – cGMP Compliant

- Air-Over-Pressure Sterilization for liquids in filled vessels
- Water for Injection [WFI] compliant towards EN285
- Development, Validation, and Commercial Support
- Parenteral Product Sterilization
- Sterilization of Reusable and Single use Manufacturing Equipment
- Practices performed in accordance with ISO 17665, dry heat, among others.
- Terminal Sterilization of Final Products/Packaging
- Cleaning/Reprocessing of Aseptic Manufacturing Equipment
- Depyrogenation/Sterilization of Vials, Seals and Stoppers
- Dry Heat Sterilization
- All Sterilization is Performed in ISO Classified Rooms
- Lean Manufacturing and 5S Visual Management Expertise

Our company specializes in the sterilization or autoclaving of heat-labile products by leveraging a bioburden-based sterilization approach.

We also sterilize manufacturing equipment used in aseptic manufacturing, along with:

❖Glassware ❖Stainless Steel Equipment ❖Medical Devices ❖Cell Culture Processing Equipment and Packaging ❖Syringes ❖Contact Lenses

Our Methods for Sterilization Include:

❖Moist Heat Steam Sterilization **❖Dry Heat Sterilization** **❖Depyrogenation**

SteriKits®, clean room ready to use kits containing vials, stoppers, and seals are available for purchase on our website. These kits are manufactured in ISO clean rooms using GMP equipment and are prepared to satisfy the strictest of pharmaceutical requirements. The vials and stoppers are certified as sterile, pyrogen free, and particulate free and the seals are certified as sterile. The kits are available as “Certified Compliant” or “Terminally Sterilized”. Both options satisfy the applicable USP <71>, <85> and <788> standards. We develop and validate our sterilization services on a case-by-case basis, usually achieving a probability of a non-sterile unit (PNSU) and a sterility assurance level (SAL) of 10^{-6} or less. Development and validation services are available as per cGMP on a custom basis.

Your protocols, your specification:

By terminally sterilizing aseptically produced products packaged in sealed containers, Prince Sterilization Services can increase sterility assurance from 10^{-3} to 10^{-6} or less. Your instruments, surgical tools, and medical devices can be validated to a SAL of 10^{-6}. Clients especially value Prince Sterilization Services’ program of cleaning, rinsing, and custom packing of devices prior to sterilization, along with their subsequent packaging in non-permeable clean room pouches under ISO class 5 conditions. Our steam sterilizer, glassware, stopper, and seal washer are each equipped with WFI that satisfies the strictest of specifications. For facilities that sterilize in-house, Prince Sterilization Services has a program to become part of your business continuity program.

Close working relationships:

We will perform your protocols in our facility, working with you to document that all sterilizers and processes are validated to your specification. In that way, should an unexpected emergency arise, we can still meet your needs by minimizing any production delays.

Locations:

57 Route 46 East
Pine Brook, NJ 07058

16 Montesano Rd
Fairfield, NJ 07004

1-888-PRINCE0

WWW.PRINCESTERILIZATION.COM