

# BLUE LINE

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## EO STERILIZATION SERVICES

### EO Validation Plan/The Basics

Blue Line Sterilization Services believes that our clients should get the fastest, most cost-effective EO sterilization service available anywhere. Therefore, we have created an efficient, economical approach to cycle validation and sampling. Note that sample quantities can vary, and often be reduced, depending on the device and the testing approaches selected.

#### **Preliminary testing**

- Bioburden – 5 product units, non-sterile

#### **Fractional/Sub-lethal Cycle (1 or 2)**

Description: Short duration cycle to show relative sterilization of the native bioburden, IP, and EPCDs.

#### Tests:

- Product Sterility – 6 product units
- IP Sterility – 5 IP units
- EPCD Sterility – 5 EPCDs

#### **Half Cycles (4)**

Description: Cycles with EO dwell periods half or less than half of the full cycle to show the ability of the full cycle to achieve an SAL of  $10^{-6}$ . (3 maximum load, 1 minimum load)

#### Tests:

- IP Sterility – 5 IP units

#### **Full Cycle (1 or 2)**

Description: Full load cycle(s) with an EO dwell the same as future routine sterilization cycles.

#### Tests:

- EO/ECH Residuals – 9 -12 product units
- EPCD sterility – 3 EPCDs
- Bacteriostasis/Fungistasis – 6 product units
- Bioburden validation – 3 product units
- LAL (if needed) – 3 product units

**BI** = Biological Indicator containing  $10^6$  or more spores

**IP** = Inoculated Product, the test device with  $10^6$  spores added

**EPCD** = External process challenge device, a device with a specified resistance to EO sterilization

**SAL** = Sterility assurance level, the probability of one non-sterile unit after being seeded with  $10^6$  difficult to sterilize spores