



**Environmental Tectonics Corp. (ETC)**-----**Sterilizer**  
**Division**

## **Sterilization Cycle Development Services**



Welcome to ETC Process Engineering Services Division. Providing our clients with cost effective process solutions in sterilization cycle development remains the primary focus within the process engineering services group.

Whether your product requires cycle definition utilizing conventional sterilization means or the latest technology in equipment and process control for effective process development, ETC technology, equipment and laboratory expertise fills the need.

### **Steam Sterilization Cycle Development**

Virtually any product such as utensils, hard goods in thermo-set or thermo-plastic materials, apparel, filled or unfilled syringes, ampoules, bottles and bags, elastomer components or any combination employing the following cycle types.

- Gravity Displacement: where conventional sterilization using simple air purge technology.
- High Vacuum: where pre-evacuation of air prior to sterilization is necessary to achieve adequate penetration in dense or porous loads.
- Air Overpressure: where adequate pressure balance over the saturation pressure is required to assure hydrostatic pressure offset protecting the product container and content.
- Superheated water sterilization and rapid cooling using recirculated water for heat sensitive products or where accelerated cycles are required.
- Purge type cycles where a multiplicity of alternating evacuation and backfill for accelerated cycles and deep penetration efficacy.

### **Pilot Production**

When small or large volumes of product must be sterilized for stability testing of sterility analysis, ETC can provide a cost effective solution utilizing the developed cycle for stability batch or sterilization efficacy testing production.

### **Adjunct Services**

When your cycle development requires support documentation for regulatory filings of various nature.

- Installation, Operation Qualification IQ/OQ documentation with full calibration report support documentation can be provided where needed to fully qualify the machine hardware, software, cycle type employed and calibration requirements for stability testing support in clinical studies and NDA filings.
- Process Development Specifications (PDS) can be provided to fully document the strategy and protocol for cycle development.
- Process Qualification report documentation is also offered to fully document the qualified product sterilization process.

### **Rates**

Consult the ETC sterilizer sales group for current lab development rates