GPS CAPABILITIES PROFILE

sterilization

Steam Autoclave Validation

Process Planning, Standard Load Design, SOP, IQ, OQ, PQ

Q. What is process planning?
A. The beginning of success.
Process planning is the systematic analysis of the steam sterilization process. The results form the basis for the autoclave specification, the development of process detail, and the validation program. Issues considered include the types of items to be sterilized, pre-sterilization and post sterilization handling, preparation, type of materials, critical design aspects of sterilized items, and many other details. This step is often neglected, despite the long standing insistence of FDA on its importance.

Design Review
We provide engineering review of the sterilizer design, especially piping and controls. We provide expert review of the sterilization process flow, including the critical post sterilization steps. Most of the serious problems in sterilization could be prevented at this stage. Improper design is not validatable!

At a Glance
Service: *Steam Autoclave Validation*
Compliance: *21CFR Part 211 (GMP)*
Capability: *Full Capability*
Best at: *High Confidence Sterility*
Project Scope: *Full or Partial*
Contact: *Blair Conley*
Sales: **1-800-700-5147**

Standard Load Design
Consistent, high confidence sterility processing requires consistent, documented loading patterns. Extra care during this critical step can save thousands of dollars in routine sterilization. We work with you to plan loads, develop load pattern diagrams, and plan sterilization cycles.

Standard Operating Procedures
Once standard loads are established, written standard operating procedures to control the process must be prepared. These documents will be used during the validation process. We are experts in writing SOP documents for compliance with cGMP.

Installation Qualification (IQ)
Excellent IQ requires expert knowledge of steam autoclaves. We verify chamber installation, piping, instruments, control panel wiring, slope, drain, controller, doors, bioshields, and much more.

Operational Qualification (OQ)
OQ tests the functional operation of every part of the autoclave. Critical attention is given to temperature controls and monitoring system, computer controls, recorders, batch documentation. Empty chamber profiles of heat distribution are normally included.

Performance Qualification (PQ)
This phase typically includes cycle development, an intensive procedure to establish the right parameters for each standard load. Time and temperature studies include high quality thermocouple calibration, which we provide. Biological challenge studies are the final critical link to proving the lethality of the sterilization cycle. We can work with your microbiology laboratory to establish the necessary control procedures and documentation, or outsource the laboratory support.

Act Today
Call today to discuss your project!
1-800-700-5147