Sterilization: 5 Must Know Facts For Re-using A Medical Device

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1. What is Sterilization
Sterilization refers to any process that effectively kills or eliminates transmissible agents (such as fungi, bacteria, spore forms, viruses etc.) from equipment, surface, article of food or medication, or biological culture medium. In aseptic processing, components and containers are individually sterilized, and then assembled to provide a sterile process and product in the end.

2. Sterilization regulatory requirements
Common sterilization methods and practices can be found in numerous industry guidance documents that are not legally binding but are often used as guidelines when audited by regulatory authorities. Some of these include ISO Standards, PDA Technical Monograph #1, FDA Guidance documents, etc. Regulatory standards such as the CFR, USP, Orange Book of the MHRA and other foreign regulations will generally only define the “end point” of what industry must achieve and prove to claim sterilization. Methods are left up to the companies to decide and defend when challenged by auditors. In the “Industry Guidance for Sterile Drug Products Produced by Aseptic Processing (2004) states that “a sterility assurance level” (SAL) of 10 or better should be demonstrated for a sterilization process.

3. Sterilization process audit
The point of focus during a sterilization process audit must be operating parameters for variables such as time, temperature, pressure and vacuum levels, gas concentrations, belt speeds, etc. Production limits as defined in SOPs must be supported by validation data. Cycles that run outside of the limits set are often the basis for rejection of the run. Use of actual production containers, equipment components, wrapping methods, etc. If not used, rationale must be provided in the validation summary.

4. Common sterilization techniques
Dry heat, EtO sterilization, of steam sterilization process, gamma radiation, X-ray radiation and many more

5. What impacts a Sterilization process
Any sterilization process is impacted by operator actions, cleanliness of items to be sterilized (bio-burden levels), properly validated and operating equipment, maintenance of a clean environment, lack of control of any one of these items can adversely impact the sterility assurance levels claimed.

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