Change Control: ongoing process control

After completion of sterilization cycle development and performance qualification, monitoring of the sterilization process is conducted in order to assure state of control, important elements of the ongoing sterilization program include: review of critical and key operating parameters during routine sterilization cycles, confirmation of sterilizer suitability, deployment of an effective change control program, as well as calibration, maintenance, and requalification of the process.

In order to maintain the state of control of a sterilization system, a change control program should be in place. This program should document sterilization system or product changes and include documentation of any testing required to ensure the qualified state of control.

Changes involving modifications of the sterilizer chamber, product carrier / tray design, load arrangement, sterilization medium supply / distribution systems, or the sterilizer operation / control mode may necessitate temperature distribution, heat penetration, and / or microbiological challenge studies. Replacement of 'like for like' sterilization equipment parts is generally not considered a major change, provided that it is demonstrated that sterilizer performance is not affected.

Changes to product, including design, materials of construction, item or product tolerances, mass, venting, formulation or packaging, may require temperature distribution, heat penetration and / or microbiological requalification.

Requalification of the sterilization process should be performed whenever there is major medication of the sterilization system (including prior-to-sterilizer decommissioning) or product that has the potential to affect process efficacy.

A change control package should identify qualification documents that are affected by the change and should include:

- A description of the proposed change
- A documented reason /rationale for the proposed change
- A description of the tests needed to qualify the sterilization process after the change is made, or a technical rationale supporting that the change has no impact on the sterilization process efficacy
- Supporting documentation for tests performed, interpretation of results and conclusions
- Confirmation that documents affected have been updated
- Approval of the change control package by the quality unit and other management representatives

Ref: PDA journal of Pharmaceutical Science and Technology