Parametric Release in Central Sterile Supply Department
Background

To ensure sterile products after sterilization processes, each process run has to be monitored. Traditionally, for medicines parameters like purity, identity and amount, are tested, before given the load free. For medical instruments, used during surgery this method is not possible. Because, once a device is tested, it is no longer sterile, and cannot be used for its purpose in sterile environment. The answer to ensure sterilization for the medical devices is to monitor every sterilization process with indicators. Biological and chemical indicators are available for this purpose. The results of the indicators have to show that a load is sterile after a process and that it can be given free and used safely. If an indicator gives a fail after the process, the load should not be used and must be reprocessed.

The development of machinery and of measurement equipment has made it possible to monitor the physical parameters of processes, e.g., surface steam sterilization. With specific conditions and requirements it is possible to give loads free on predetermined physical parameter. This is called parametric release. In order to make use of parametric release requirements, conditions and protocols have to be fulfilled.

Key Learnings

- Conditions and requirements for parametric release

To be able to apply parametric release in a responsible and safe way the following conditions, requirements and protocols must be fulfilled:

- Production according to GMP (Good Manufacturing Process) or cGMP (Current Good Manufacturing Process).
- Process must be validated
- Process parameters must be registered
- The process parameters must be judged with a set of predetermined criteria.

Production according to GMP

Safety for Medical Devices (MDs) is of utmost importance for the patient, staff and environment and should be guaranteed. The essential claim made for Sterile Medical Devices is that the devices are Sterile. According to the Medical Device Directive (93/42/EEC) an essential claim must be proven and documented. The essential claim made by a Central Sterile Supply Departments (CSSD) is that they produce sterile Medical Devices. In order to fulfil their claim they have to prove and document the claim. To design and document adequate production methods and procedures to come to sterile products with safe and good manufacturing processes, GMP and CEN directives, guidelines and norms can be of assistance.

In Pharmaceutical industries quality systems are often, if not always, implemented. If a CSSD is using parametric release for sterilization a quality system has to be in place incorporating:

- All handlings performed in written protocols and procedures
- The structure of the department and the responsibilities in the department have to be identified and documented
- The work flow of the department must be identified and documented
- Procedures for operating the sterilizer must be documented
- Loads to be sterilized have to be identified and described (including loading pattern and wrapping systems)
- Machinery has to be identified, maintained and validated. The use of the machineries has to documented, maintenance and validation protocols must be available and results must be documented and available
- Staff must be educated in the work they have to perform and the systems. They have to be authorized for the protocols, procedures and machinery they are using

The topics will be addressed here below. For more information on the different aspects references are given.
Validated processes

In order to make use of parametric release, the essential machinery in the department, e.g. washer/disinfectors and sterilizers, have to be maintained and validated. A maintenance plan and validation plan must be available and documented. The validation has to prove that the machines are working effectively and reproducible. Meaning that every time the machine is used the results are the same and sterile.

For example, in case of a steam sterilizer, the combinations of the sterilizer, its process, the load, loading pattern and wrapping have to be standardized to come to the same results. The load, the loading pattern and wrapping material and method must be documented in protocols. Different combinations of machine, process, load, loading pattern and wrapping have to be documented and validated. In case of a large steam sterilizer the validation can be performed according to the EN 285 and the ISO 17665. That validation is necessary if parametric release is applied is proven in literature.

In validation not only the combination of the machine, process, load, loading pattern, and wrapping (if applicable) is inspected, but also the routine test (e.g., penetration test and air leakage test) and the technical lay out are checked. Independent registration, important for parametric release should be inspected during a validation, as well.

Registration of process parameters

To be able to use parametric release, an independent monitoring and registration of the essential parameters must be in place. E.g., the process parameters for steam sterilization are the temperature and the pressure throughout the whole process. For these (at least) the essential parameters, registration equipment must be mounted on the sterilizer. The equipment must be independent from the control system of the machine, e.g. the steam sterilizer process controller (EN 285). The independently acquired data must be judges after a process run to predetermined criteria.

Judgement of process parameter

After a process the independent registration, which is often a graph and a set of numerical values, is inspected. The values of the essential parameters are judged against a set of predetermined values, e.g., a graph and a set of numerical values that is acquired during a validation. The person giving free the load must be sufficiently educated and trained to the procedures.

If a quality system according to the GMP and CEN and/or ISO norms is implemented and parametric release is used, it is still necessary to use penetration tests and exposure indictors in steam sterilization.
More information can be found in:

- B6110 Parametric release van gesteriliseerde producten,
- Bundel ‘Steriliseren en Steriliteit’ of the Dutch norm committee, NEN, Delft.
- Best practice equipment control
- Best practice exposure control
- Best practice load control
- Best practice pack control
- Medical Device Directive 93/42/EEC
- cGMP (http://www.fda.gov/cdrh/comp/gmp.html)
- A validation survey of 197 hospital steam sterilizers in The Netherlands in 2001 and 2002,
- EN 285
- EN 13060
- ISO 17665