1. How do we validate a sterilization process and which standards have to be used?

Autoclaves can never be never validated as such but only the combination of:

1. an autoclave installation including the steam generator
2. the selected process
3. the load which has to be specified by the type of material (solid, porous or hollow, like tubes, endoscopic and arthroscopic instrumentation) and packaging

which is in combination a sterilization process.

Only the selected process in combination with the load defines a process which can be validated. The machine alone having several processes which are used for different products may provide satisfying results in one case. When changing the load depending on its complexity the result may be in-acceptable.

1. The user (hospital) has to decide which sterility assurance level (SAL) they need (normally SAL=10^{-6} CFU/ part).

2. How clean are the products after they have been sterilized?
   (Determination of the Bioburden)

Depending on both factors the kill kinetics of the sterilization process has to be selected. Depending on the complexity of the load itself (solid, porous and/ or hollow) the air removal and therefore steam penetration into the inner surfaces have to be controlled with the selected sterilization process to make sure that not only outside surfaces but all inside surfaces are sterilized as well. The corresponding standards are:

EN 556	to define sterility and
EN ISO 17665	to describe the validation of a steam sterilization process how the validation has to be carried out.

This is a complex procedure containing:

1. Physical methods, like temperature-pressure-time-diagrams where the thermo-couples are placed inside of the sterilizer and inside of the package. (Normally 10 – 15 pieces)

2. Biological indicators are used which are placed at the worst-case penetration places.

3. Chemical indicator systems are used which are made of a process challenge device (PCD) where a chemical indicator is located inside to test worst case penetration conditions. The stability of the process is checked to be highly reproducible in terms of all process conditions especially the non-condensable gases in steam and air removal cycles.

We provide a training course of 2 weeks to give to present to train all the details.

2. How can the GKE Helix-PCD be used for this validation?

The GKE batch control consists of a 1,5 m long dead-ended Teflon tube of 2 mm inner diameter with a chamber at the end to host a biological or chemical indicator checking the right process conditions. This batch control system is used during the validation process to check the penetration condition of tubes. It must be harder to penetrate inside of this PCD in comparison to the worst case situation in the load, which normally is the case, depending on the goods being sterilized.

After the validation it must always make sure that the selected process conditions remain stable over the period of time. Therefore the major parameters have to be checked at each cycle. Details on routine sterilization control may also be discussed in detail in a seminar. The traditional test with biological indicators and/ or chemical indicators strips is not anymore adequate due to the fact that they usually are not placed at the worst penetration place and therefore should not exclusively be used in sterilization processes. Indicators placed between packs or on top of packs are in general absolutely useless. Costs for these indicators can be avoided.

3. How often a sterilization process has to be validated?

As already described above, not autoclaves but sterilization processes are validated, usually only once, to make sure that the right process for the right load is selected. The moment the load itself, a process parameter or major parts of the sterilizer or of supply sources are changed a re-validation is absolutely necessary to ensure again that the new process is adequate to the load (re-validation). Usually after each year the check-up of the mayor parameters is done (not a full validation), guarantee that the process conditions selected still remain stable (only PQ). The biggest problem we usually see in hospitals is, that the steam supply is not constant and contains non-condensable gases like air and CO_2 which are able to totally ruin the process. Also the efficiency of the air removal process prior to sterilization is of extreme importance. Otherwise air remains in the chamber and in packages and partially the sterilization process is carried out with air instead with steam requiring much higher temperatures and longer times in comparison to a steam sterilization process. Therefore in those areas where air is present no sterilization takes place.

Unfortunately during the process steam and air is very often separated in packages, tubes, and porous loads, which are by far the most critical products being sterilized. Also advanced packaging techniques can hinder the air to be removed out of the packages and the steam to penetrate into the package. Very often gravity displacement cycles are used with advanced packaging materials and the modern packaging materials are going to ruin the success of the process if gravity displacement cycles are used.