Validation – do I have to do that?

What are the benefits of validation?
By measuring temperature distribution and heat penetration, **proof of process safety** can be achieved as well as a process optimization with **improved product quality** and **shorter process times**.

- **Proof of process safety:**
- The validation of sterilization processes proves that the validated processes produce safe products. The proof is provided by the validation certificate issued by the manufacturer / service provider. Each certificate refers to an individual autoclave and to the individually tested process (defined product, defined packaging, defined packing scheme, defined sterilization program).
- **Product quality:** By determining “cold spot” and “hot spot”, the sterilization process can be designed in such a way, that even at the “cold spot” an adequate F-value and thus a safe product id achieved. At the same time, any potential product damage due to overcooking at the “hot spot” can be minimized. Simultaneous use of deflection measurement modules can eliminate container deformation.
- **Process time:** From the determination of “cold spot” / “hot spot” and the delta-t between both, measures can be derived that reduce process times, increase productivity and minimize resource consumption (steam, water, compressed air, electricity, etc.).

Fig. 1: Accessories for optimizing the temperature distribution are e.g. whaffled spacer mats (left) or special trays for product placement (right).

Basically, all measures aimed at improvement of temperature distribution in the respective process offer possibilities for **process optimization.** It is about a uniform, good flooding of the containers. Suitable measures include:

dft technology GmbH

Postfach 2611
24516 Neumünster

Rendsburger Str. 93
24537 Neumünster

Tel. +49 (0)4321 188 – 0
Fax +49 (0)4321 188 205

mail@dft-technology.de
www.dft-technology.de

Geschäftsführer:
Michael Timm,
Tim-Christian Schnack

Kiel HRB 1789 NM

- the autoclave itself (e.g. improvement of the circulation capacity),
- the autoclave accessories (e.g. special trays or spacer mats with improved water flow)
- the product (e.g. reduction of packing density to avoid the building of blocks, introduction of line and layer offset into the packing scheme to reduce shadowing)

When is validation required?
An up-to-date validation report with certificate offers legal security in front of customers and audit authorities. Therefore, when commissioning a new autoclave, it is recommended that the autoclave be validated, ideally for all products sterilized in it. If further products are added at a later date or if the packaging or the packing scheme changes, a validation of these new processes is urgently recommended.

Once validated, always validated?
Even if nothing changes in the manufactured products, their packaging and their packing scheme, a regular revalidation is important, because different influencing factors can change the process characteristics of the autoclave. This can e.g. be caused by calcification of the water heater, wear of the circulation pump and valves, drift of the control sensors, changes in the media supply (steam, cooling water), changes in the cooking program, etc.

An annual revalidation at least by way of example for 1-2 products, is recommended accordingly as well as a regular own control between validations. The latter should be carried out with 2-3 loggers at the “cold spot”.

In the context of certifications (e.g. IFS) regular validations or revalidations and controls are indispensable as the sterilization process is definitely a CCP.

dft technology GmbH

Postfach 2611
24516 Neumünster

Rendsburger Str. 93
24537 Neumünster

Tel. +49 (0)4321 188 – 0
Fax +49 (0)4321 188 205

mail@dft-technology.de
www.dft-technology.de

Geschäftsführer:
Michael Timm,
Tim-Christian Schnack

Kiel HRB 1789 NM