

First course

**“Validation
in the practice of
sterile supply“**

**EFHSS / DSc Congress 2005
London**

Legislators require:

medical devices are processed according to validated methods in public health institutions
quality management systems have to implemented and developed further

§ 4 Maintenance

(1) The operator may only entrust maintenance, inspection, repair and processing of medical devices to people, companies or institutions with the professional know-how, qualifications and requisite means to properly conduct this task

Medical devices

have to be processed in accordance with the manufacturer's instructions and appropriate validated methods in such a way

.....

The same applies to medical devices which are disinfected or sterilised prior to their first use

The requirements according to clause 1 are met if the people instructed with maintenance are provided with

- 3. the required professional know-how by virtue of their training and practical experience when maintaining medical devices and*
- 5. the locations required thereto including their properties, sizes, equipment and facilities as well as the required devices and other working appliances*

(4) After the maintenance or repair of medical devices, the constructive and functional characteristics which are essential to safety and functional performance must be tested in that they can be affected by maintenance interventions

(5) The persons, companies or institutions instructed by the operator to carry out the tests as per paragraph 4 must meet with the requirements in line with paragraph 3 and must be independent in their professional judgement when carrying out and evaluating the tests.

This means that validations :

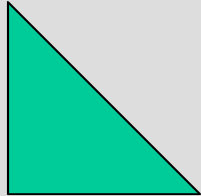
carried out by persons in possession of the required professional know-how by virtue of their professional training and experience gained through practical activities in parametric and microbiological tests

be particularly knowledgeable of the relevant provisions and standards

able to carry out validations in a proper and comprehensive manner

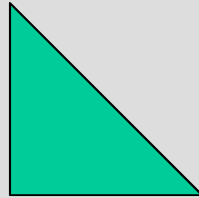
must be provided with adequate metrological facilities and contacts with microbiological testing laboratories

But what happend in the past 10 years?



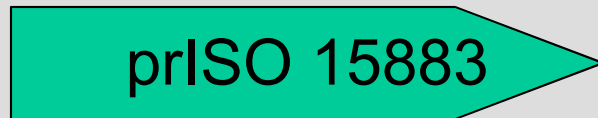
Germany about 2500 Hospitals

= 20 %



Switzerland about 250 Hospitals

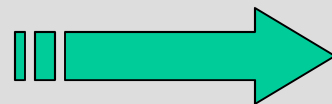
EN 554
EN 285



= 10 years , 20 %

Why aren't the processes validated?

- economic
- many managers in central sterile supply feel unable to deal with excessive demand of technical issues
- the various advantages have not yet been considered by hospitals
- lack the necessary rationale



Training

Training course on the

“validation in the practice of sterile supply”

University Hospital Tübingen, February 2005

- Recommended prerequisite for attending
- Certificate of the professional course level II or similar knowledge

The framework plan for the course “validation in the practice of sterile supply” was set up in co-operation with experts from industry, science and practice. The course comprised one week (45 hours).

Member of the Working Group:

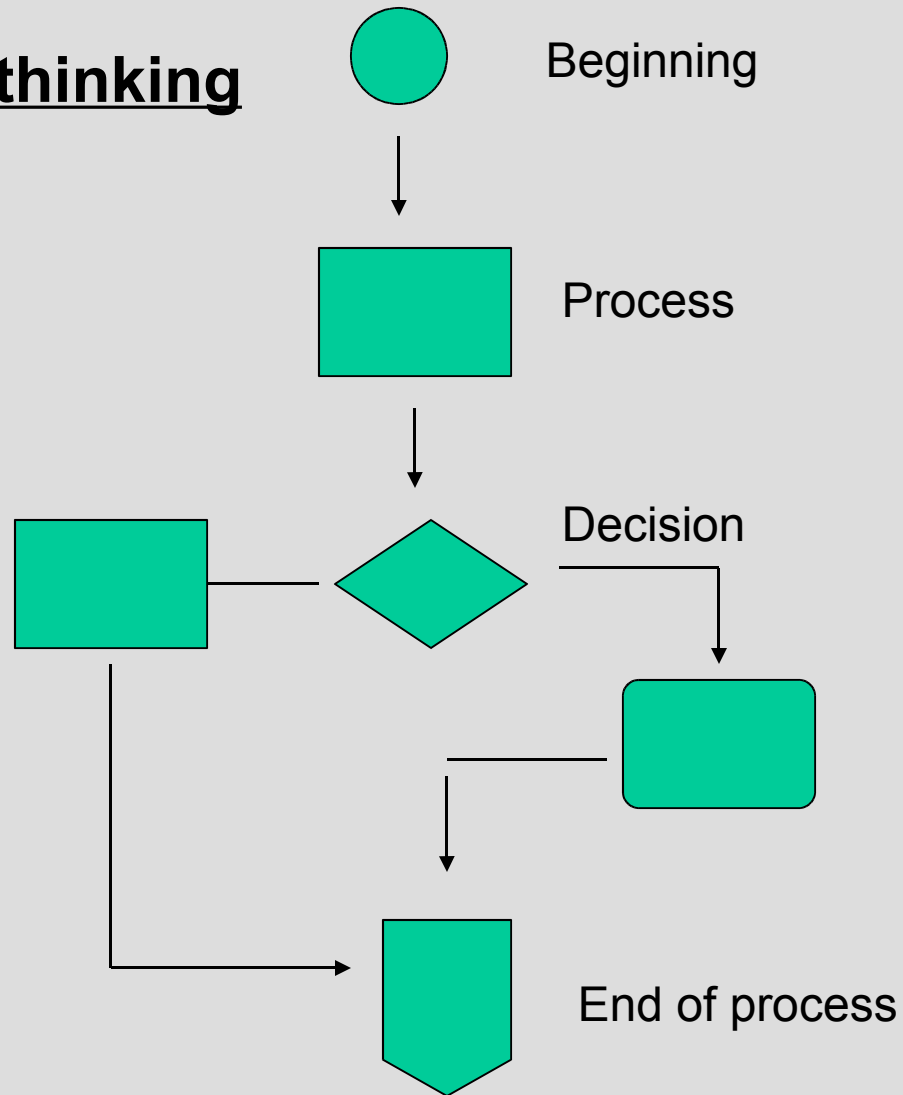
Mr. Brose Herbert, Bellimed, Switzerland
Mr. Frank Rainer, Frank GmbH, Germany
Mrs. Krüger Sigrid, Hygiene Consulting, Germany
Mr. Kruse Iven, Ebro Electronic, Germany
Mr. Pfenninger Moritz, Gehring AG, Switzerland
Mr. Rosenberg Urs, Borer Chemie, Switzerland
Mr. Zanette Toni, Manager CSSD, Germany
Mrs. Hugo Cornelia, QM, Germany / Switzerland

Training target

- teach general basic knowledge on process analysis
- to capacitate them to assist and co-operate in process validations
- enable them to check and approve validation reports

By looking on the circle of the Medical Devices

Process thinking



Normative term definitions

- type tests
 - operation qualification
 - installation qualification
 - performance qualification
- etc.

Organisational prerequisites

- Quality assurance
- configurations and packing lists
- instructions and information provided by the manufacturers of apparatuses and medical devices

Constructional and spatial preconditions

- segregation between clean and unclean areas



- the professional competencies of the responsible members in the CSSD

Resources and media

- quality of feed water
- differences between demineralised and fully desalted water
- fields of application
- Interactions between used water subject to temperature, time
- possible discolorations on the instruments
- influence on alkalinity
- Fundamental terms of conductivity measurements
- dispersion of chemicals

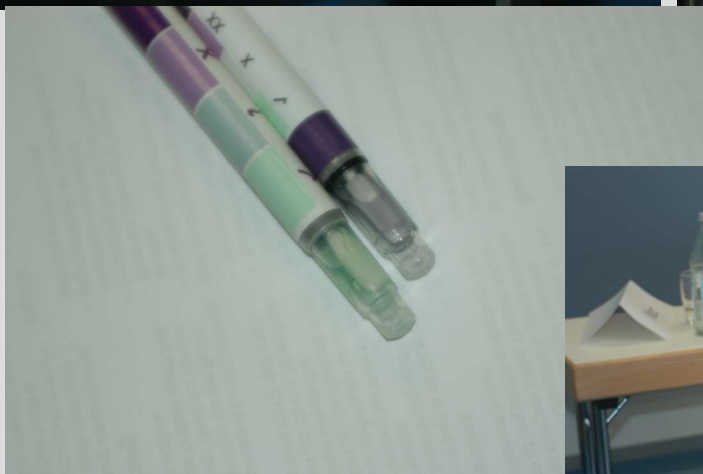
Chemistry

- effectiveness of a variety of cleaners
- Interactions at various temperatures
- contraindications and sensible combinations
- removal of prion proteins and protein fixing
- disinfection possibilities thermally and chemothermally
- Foam formation and prevention possibilities
- ingredients, additives and their effectiveness

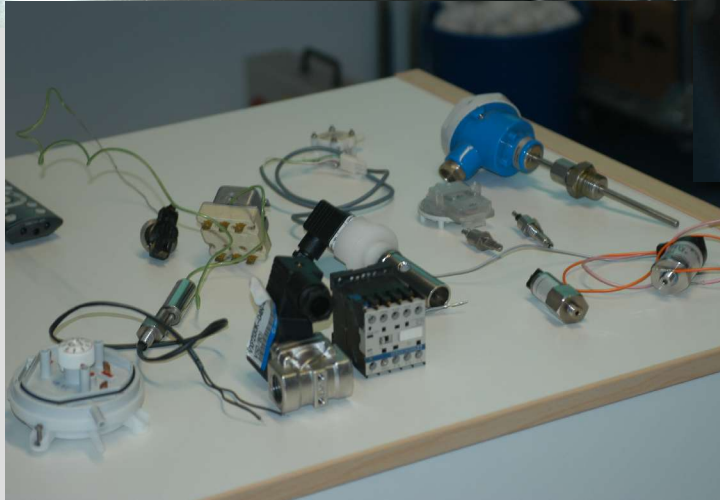
Principles of mechanics, process, equipment, tools

- physical fundamentals for cleaning
- water quantity, water pressure
- fundamentals of hydraulics and hydromechanics
- mechanical and technical control possibilities
- influence of the circulation systems to the WD's rotary arms
- dosing technique and its monitoring
- security concepts, process monitoring
- crisis management

Workshop 1



Workshop 2



Curing, maintaining, sorting and packaging

All remaining aforementioned tasks are carried out manually and cannot be validated.

High reproducibility, however, can be achieved in these manual activities through detailed operating instructions and the processing instructions of the manufacturers of medical devices.

Sealing of soft packaging

sealing seam and the seal's strength

tear strength of the seal

the required traction forces for opening the packaging
("peelability")

sealing temperature and contact pressure

Steam sterilisation

instrument design

the interaction between control and process engineering

chamber assembly

Doors

Piping

valve technology and control technology

Media supply

steam generation

Vacuum technology

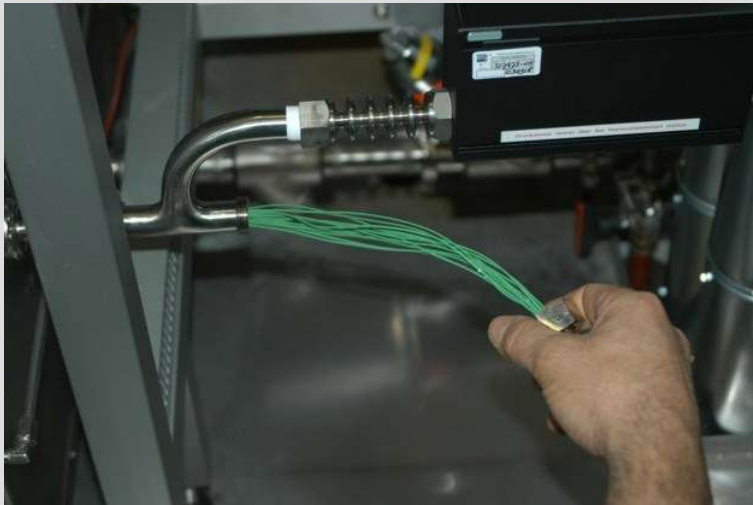
physics



Workshop 3

partial demonstration validation of a steam sterilizer
load configuration

Thermologgers and a measuring unit comprising 16
thermo-elements were used as measuring technique.



Calibration of the measuring equipment inserting of the thermo-elements and the pressure transducer



Feedback from the participants and speakers

- in-depth training in the field of process analysis is necessary
- professional courses are not yet sufficient to relate the interaction between the various factors of influence
- direct co-operation between those involved in practical applications and the industry can lead to the best possible results

Reached objective

The objective of the course, namely to sensitise participants regarding the problems of process analysis and validation and arouse their interest in the matter was therefore reached.

The qualification to actively co-operate with the production industry and suppliers of validation services was definitely obtained.

How we going on ?

- consider the length and organisation of the courses
- The highly complex contents and time-consuming workshops actually make it necessary to extend the provided period of 45 hours

By viewing that

- many hospitals actually find it difficult to release managers from work for one week of training

What do we have to do ?

It is also up to us working in the practical field to change this situation,
to communicate the advantages of the training and

to address hospitals and possibly health authorities with concrete demands.

What do the health authorities have to do ?

- created the prerequisites and resources for to translate into action !!

Thank you very much