

Validation of sterilisation methods in practice

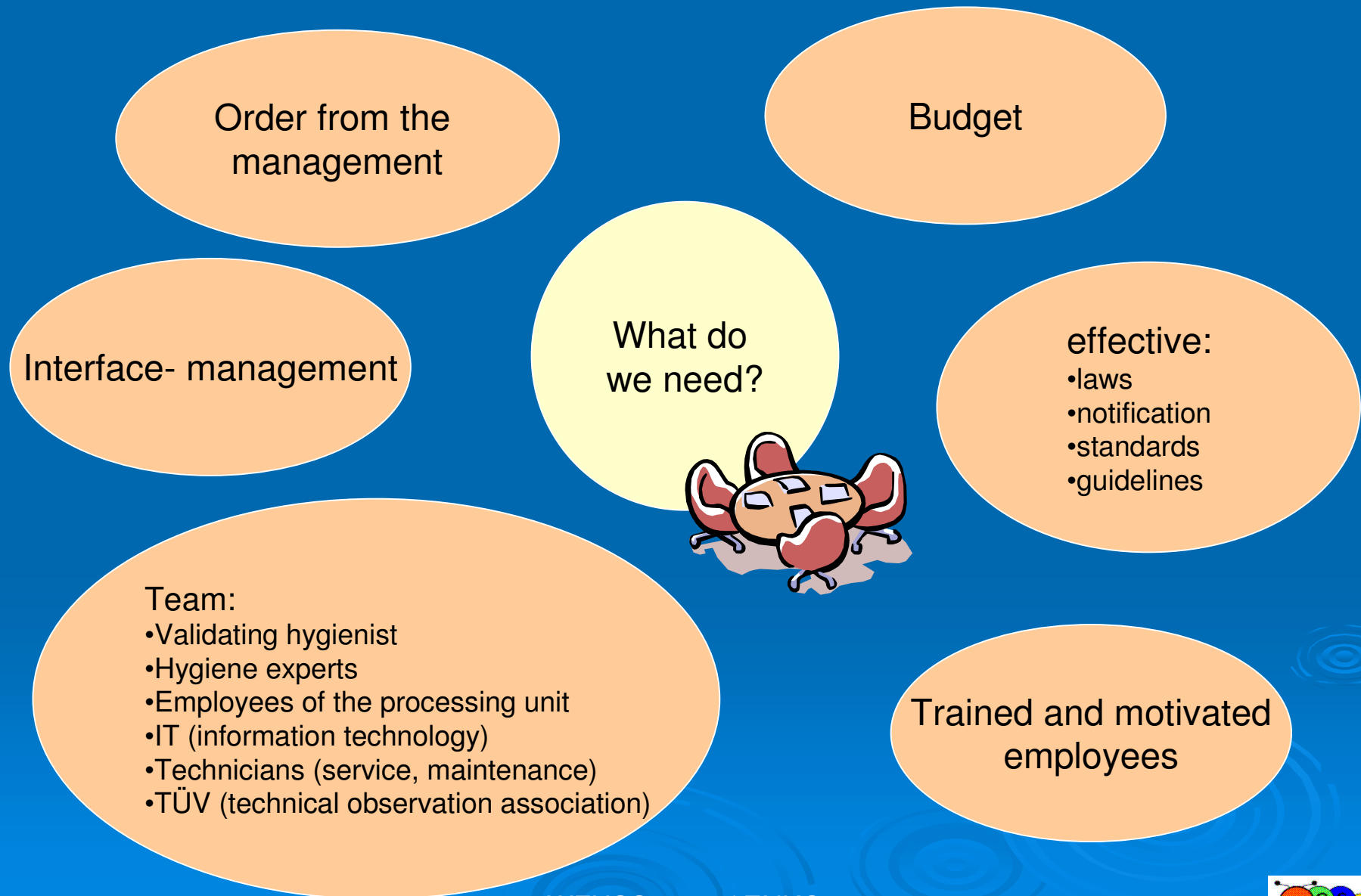
ÖGSV-WFHSS Congress
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The bottom right corner of the slide features several faint, concentric circles in a lighter shade of blue, resembling ripples on water.

- The term „practice“ comes from the Greek language and means
- „Performance“
- „Act“ and
- Characterises the actual performance of an act
- In contrary to theory

Sterilisation process / Validation in practice



Sterilisation process / Validation in practice

Process description
„target status“

„Analysis
of the current status“

Define procedure and
goal of the project

Follow the effective laws,
notifications, standards
and guidelines

Tasks of the
team



Inspection and evaluation
of the premises

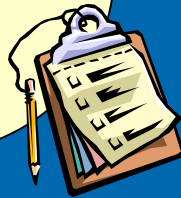
Clarification of the technical
presettings

Education evaluation and
creation of education plans

Plans for
Maintenance, Routine control
(for all technical equipment used
in the process)

Sterilisation process / Validation in practice

Tasks of the
team



Instruction of the employees with regard to
the employee protective act

Demand manufacturers' instructions

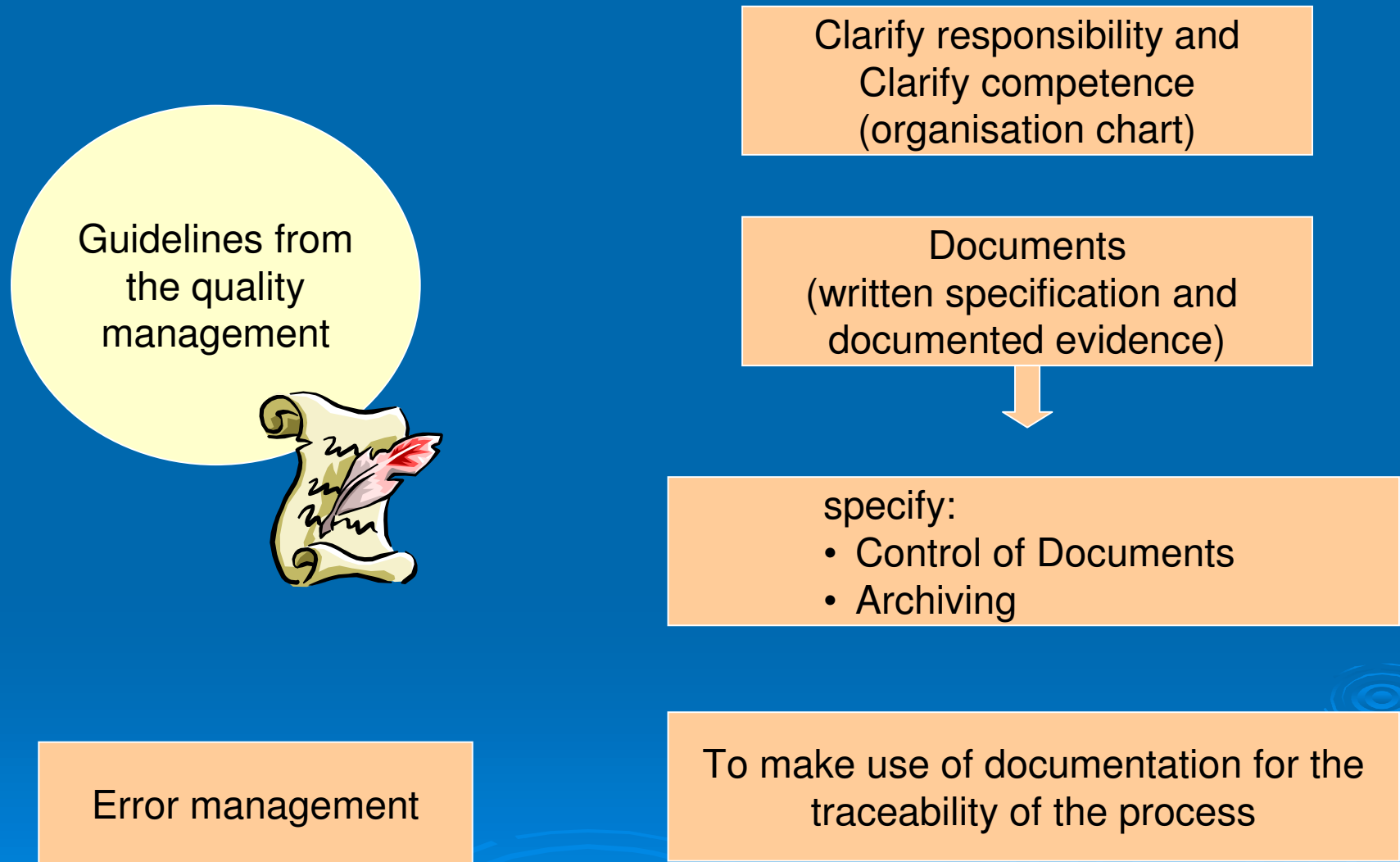
Creation of instructions in
collaboration with the
quality manager

Creation of a packing list

Division of the medical
devices in groups of
higher and lower risk
(guideline Robert Koch institute)

Steriliser load
(definition of the worst case load)

Sterilisation process / Validation in practice



Sterilisation process / Validation in practice

Examples for problems, which occur while preparing the validation



Water analysis does not fulfill claimed values

Manufacturers' instructions for the processing are missing or deficient

Problematic medical devices
(long tubes with large diameter)
(medical devices with excess length)

Amount of medical devices insufficient

Premises don't meet the requirements

Interface
Reprocessing unit / User
Reprocessing unit / Procurement

Steriliser is too old
(doesn't meet the requirements of the standard)

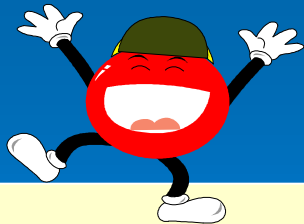
Sterilisation process / Validation in practice

The day of
validation

Prepare enough MDs
for process qualification

Prepare the worst case configuration

Arrange technician :
Technical problems during
testing
can be solved on site



After successful completion of the validation
CELEBRATE!

Sterilisation process / Validation in practice

- The patient can't decide whether the medical device, he/she is going to be treated with is prepared well
- The operator and the employees who take part in the processing process have to make this decision
- Every employee, every operator and every director of a health care facility should be aware of this fact!

Thank you for your attention!

