CIP VALIDATION

Achieving your food safety, food quality, productivity & sustainability goals

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Agenda

Purpose

- Setting up valid cleaning concepts
- Meet your food safety & quality, sustainability and productivity goals

Process

1. Requirements for successful cleaning
2. Contents of the EHEDG Guideline 45
3. Summary

Pay-off

- Identify relevant *hygienic design* influences
- Implement the right measures if required to ensure food safety & quality, sustainability and productivity

Prerequisite cleaning validation

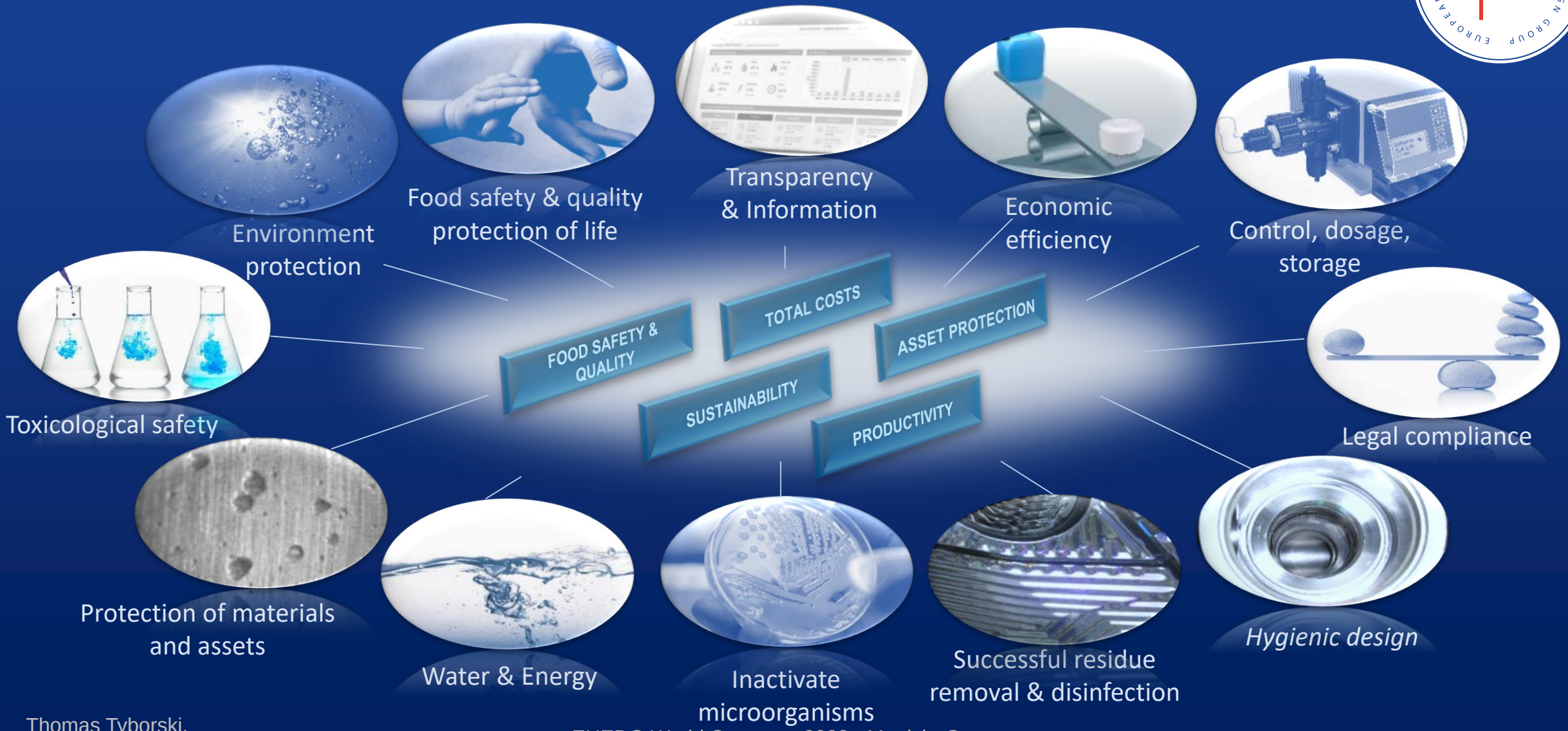
No "silo thinking”
"I do not paint and remove branches".

Think first! Never rely on someone else to solve the problem!

- ✓ Act!
- ✓ Be proactive!
- ✓ Communicate!

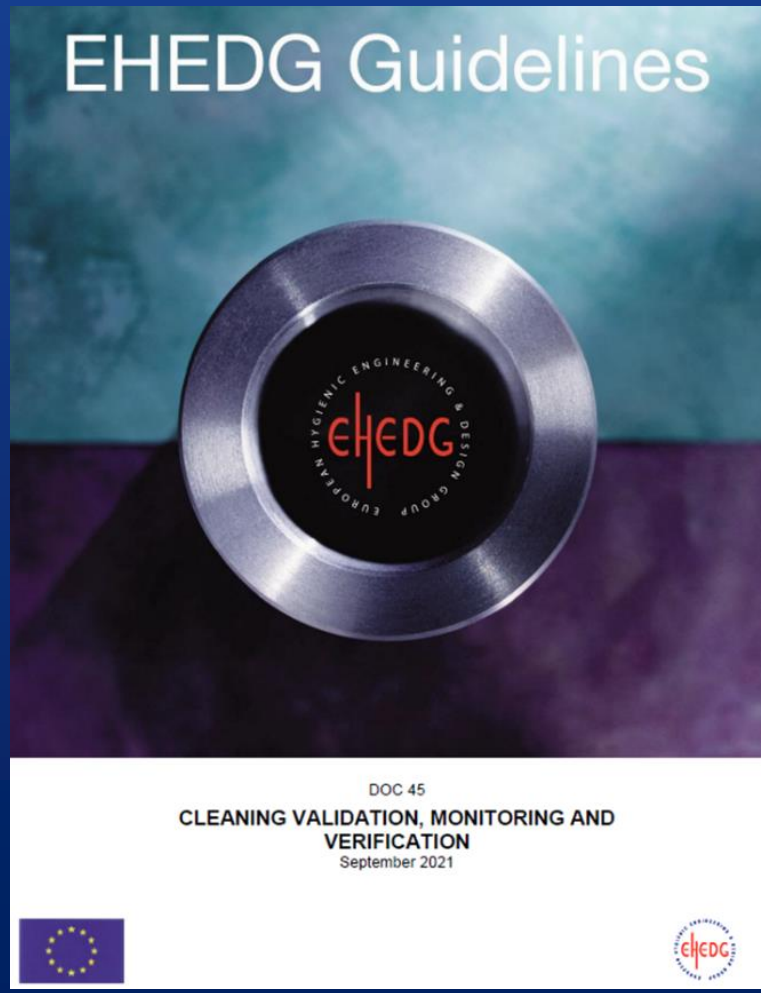
*Focus on Product for Prevention; Maggie Duke Nestec S.A.; Nestlé Vevey

Requirements for cleaning processes



Increasing relevance of cleaning validation

- HACCP requirements such as cleaning can be as important to food safety management as food processing CCPs.
- Physical, chemical and microbiological cleanliness is therefore a prerequisite for:
  - compliance with quality standards
  - food safety and brand protection
  - costs and to achieve sustainability goals.



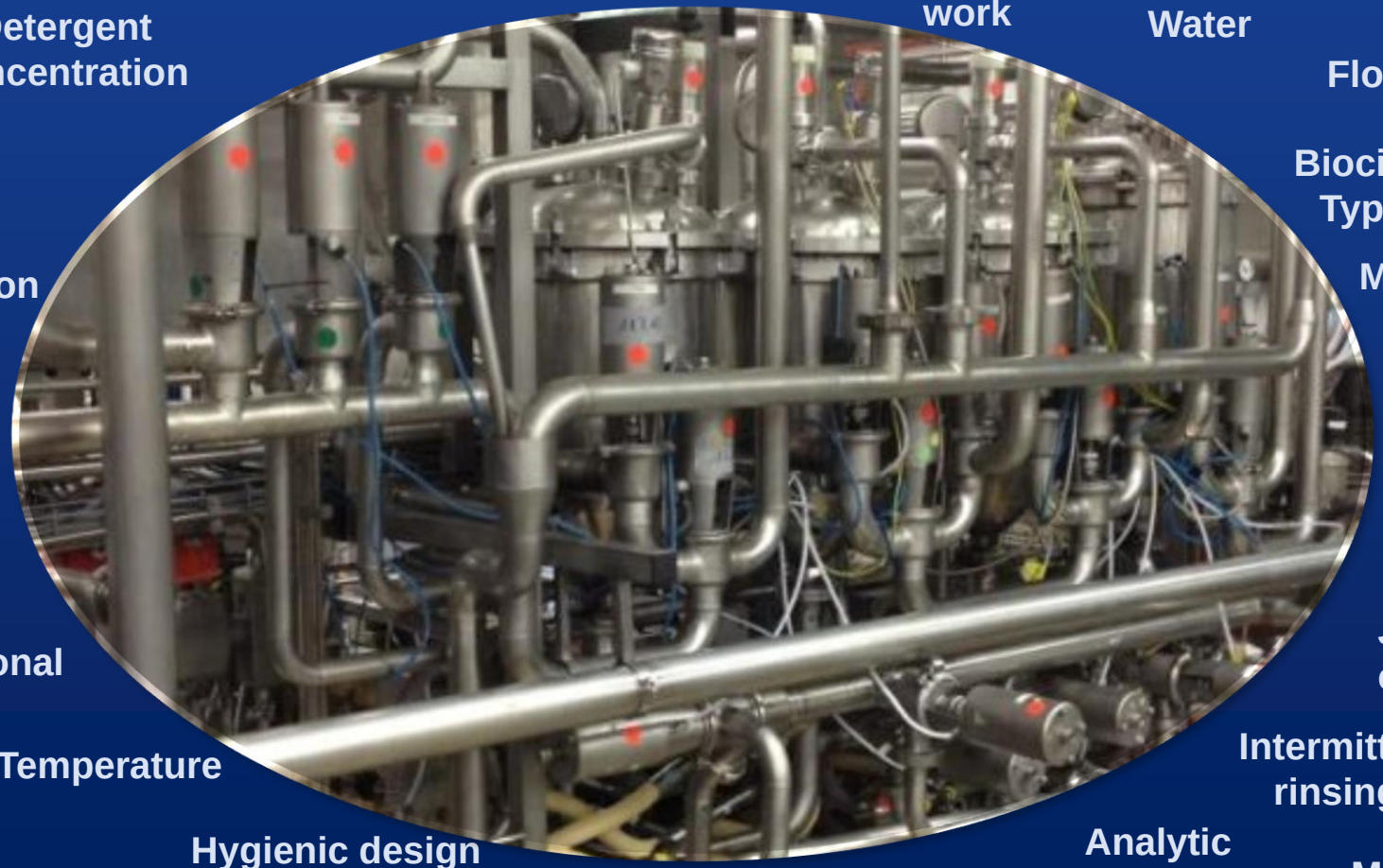
Cleaning validation

lat. *validus*: strong, *effective, healthy*

Validation is the proof of the reproducibility of a result from a described, approved procedure

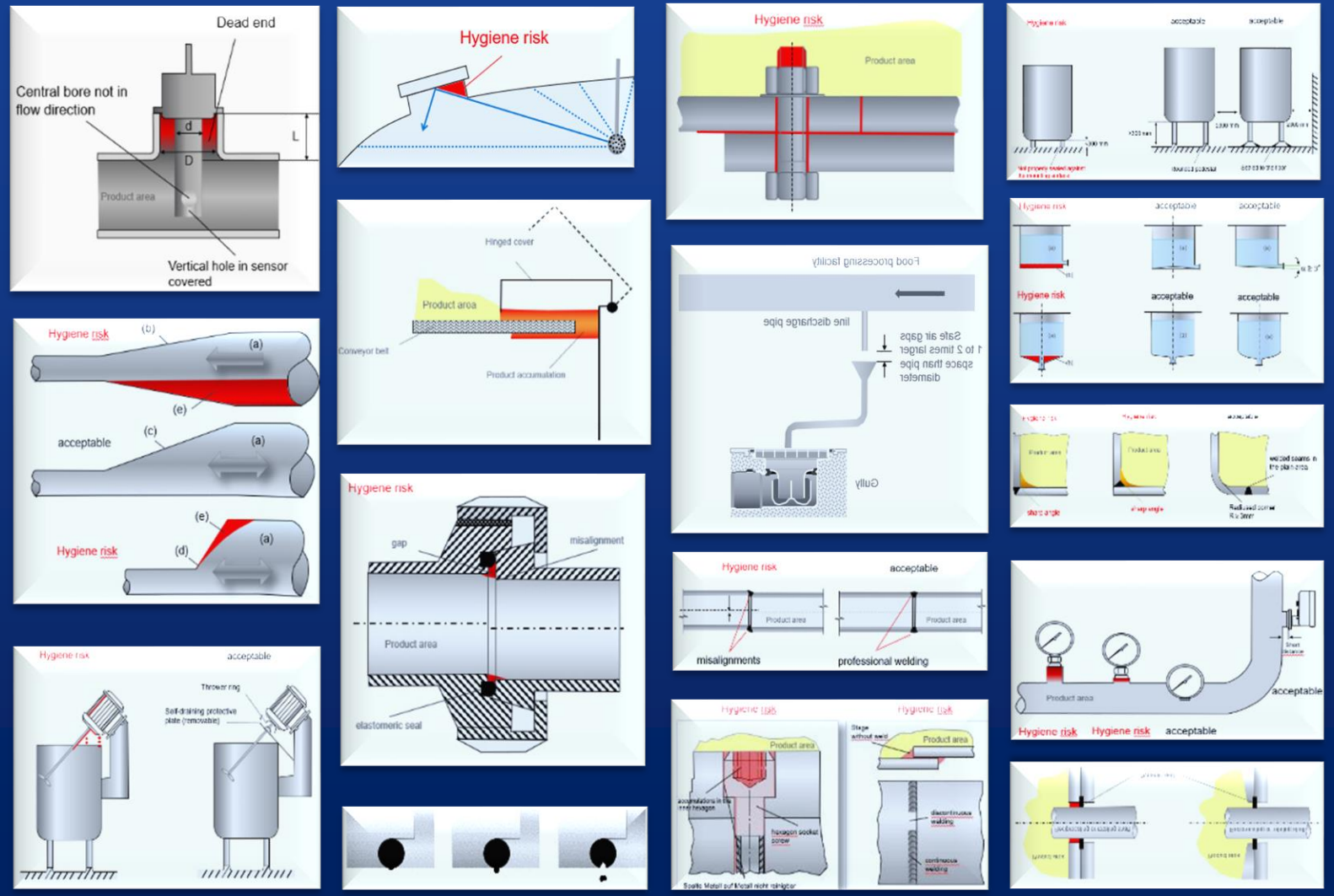
…proof of the reproducibility…	: = ☑→ ☑→ ☑→ ☑→ ☑→ ☑→ ☑→ ☑→…
… of a result …	: = based on defined *acceptance crit*eria under *worst-case* considerations
…described…	: = objective, documented, consistent
…approved procedure…	: = interdisciplinary; understandable for everyone, approved

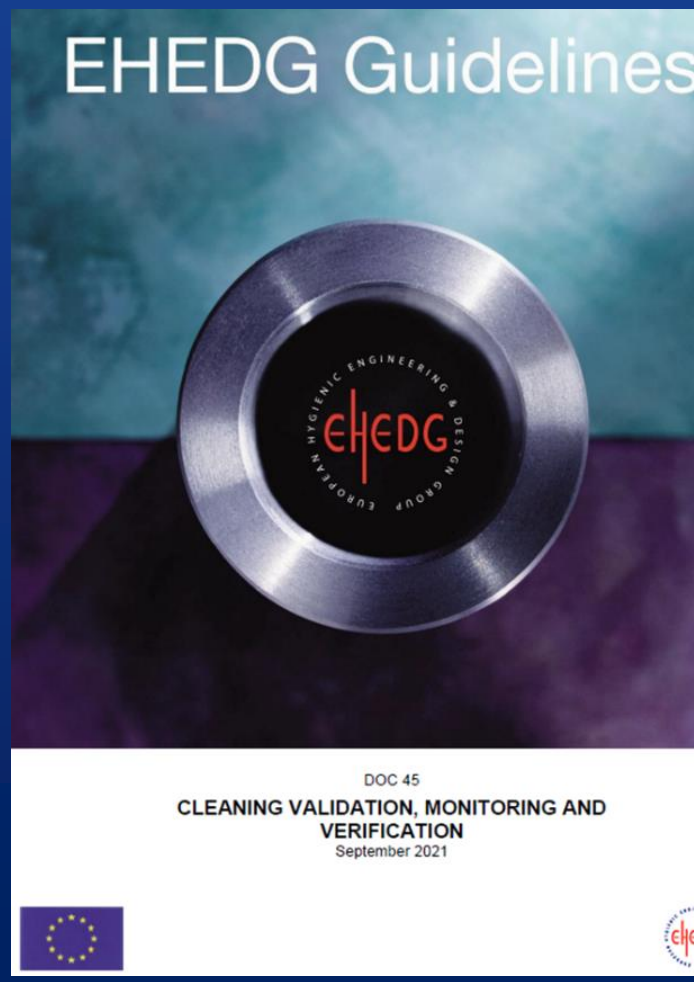
Everything under control?



Time
Aerosols
Dust
Cleaning utensils
Acceptance criteria
Fouling
Microbiology & biofilms
Disinfectant concentration
Assembly work
Material specifications
Building
Detergent concentration
Water
Flow paths
Sampling
Dilution of residual rinsing water
Biocide Type
Confirmation correct cleaning
Fittings
Verification
Material damage
Dead ends
Hoses
Leakages
Intermitted cleaning
Air
Wet area
Blockages
Condense water
Foam
Alarm information
Parallel cleaning routes
Joints & system connections
Personal
Steering & Metering
Temperature
Intermitted rinsing
Influence of modifications, conversion measures
Hygienic design
Analytic
Type and amount of residues
Process management
Detergent type
Material topography
Hydrodynamic Influences
Material roughness
manual intervention during cleaning

EHEDG Guidelines



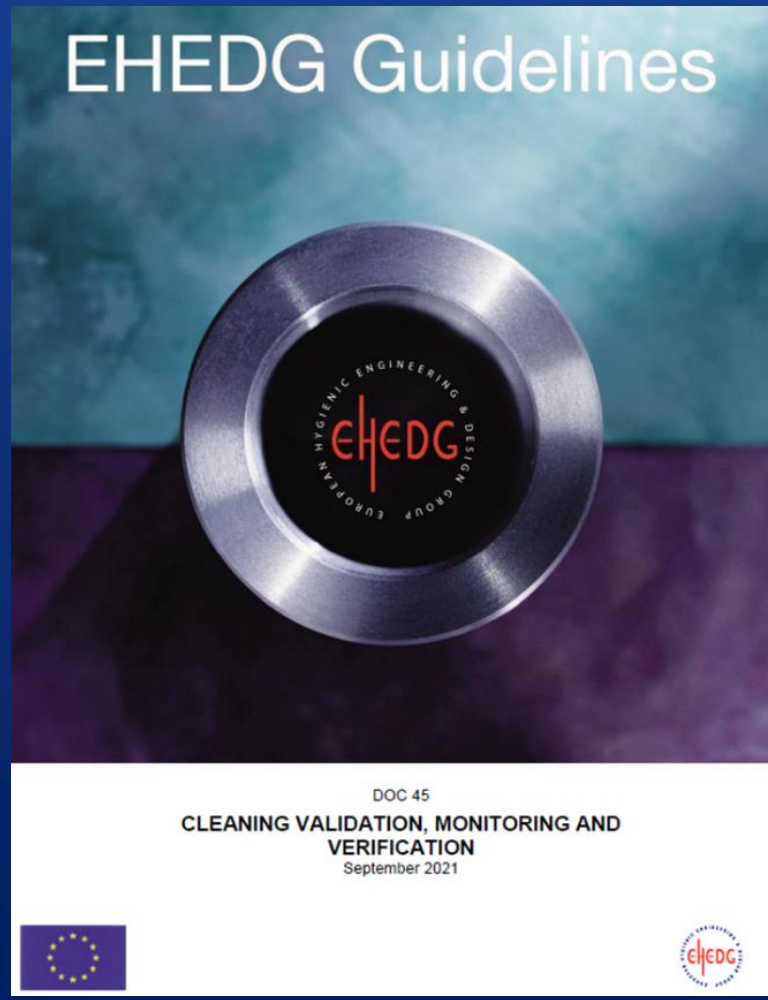


EHEDG Guideline 45

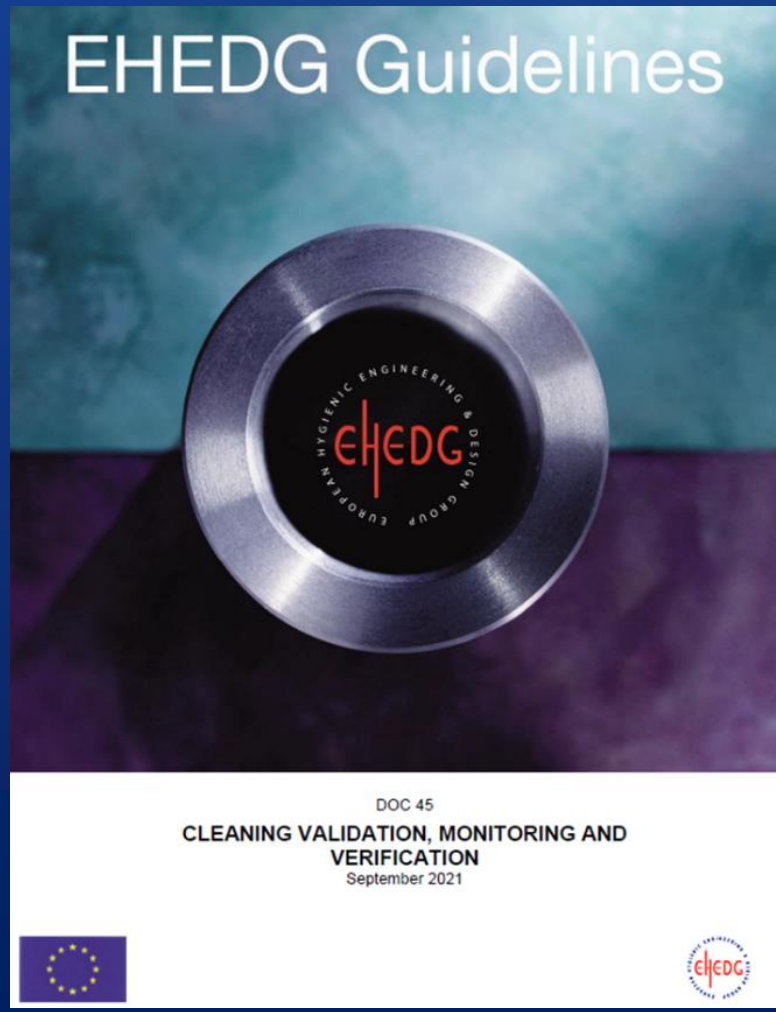
CLEANING VALIDATION, MONITORING AND VERIFICATION

- **provides recommendations** for food manufacturing environments.
- **explains the overall concept**
- **provides templates and practical examples**

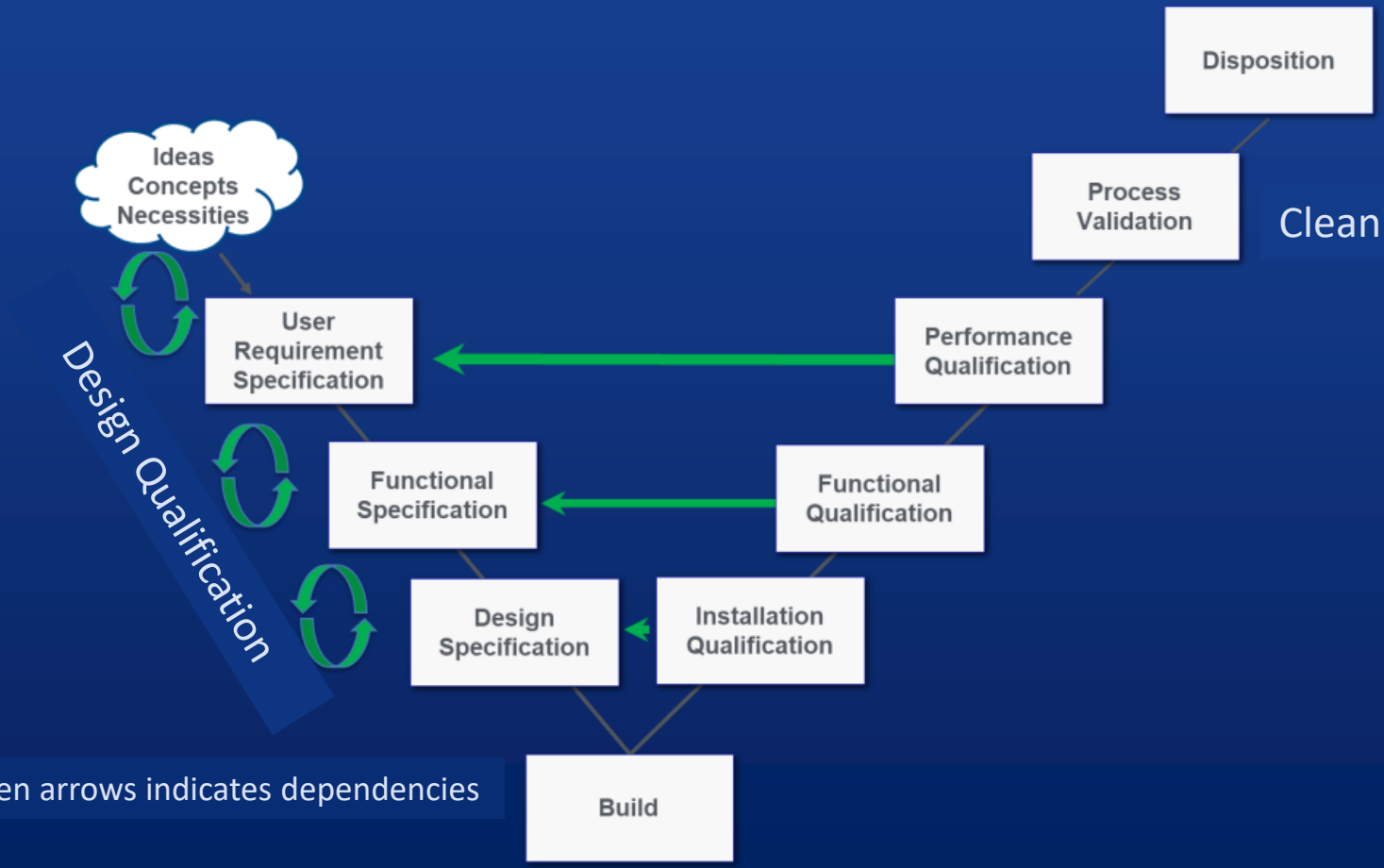
EHEDG guideline 45 provides **general advice** and does **not cover specific** validation, monitoring and verification programs



EHEDG Guideline 45 - Table of Contents

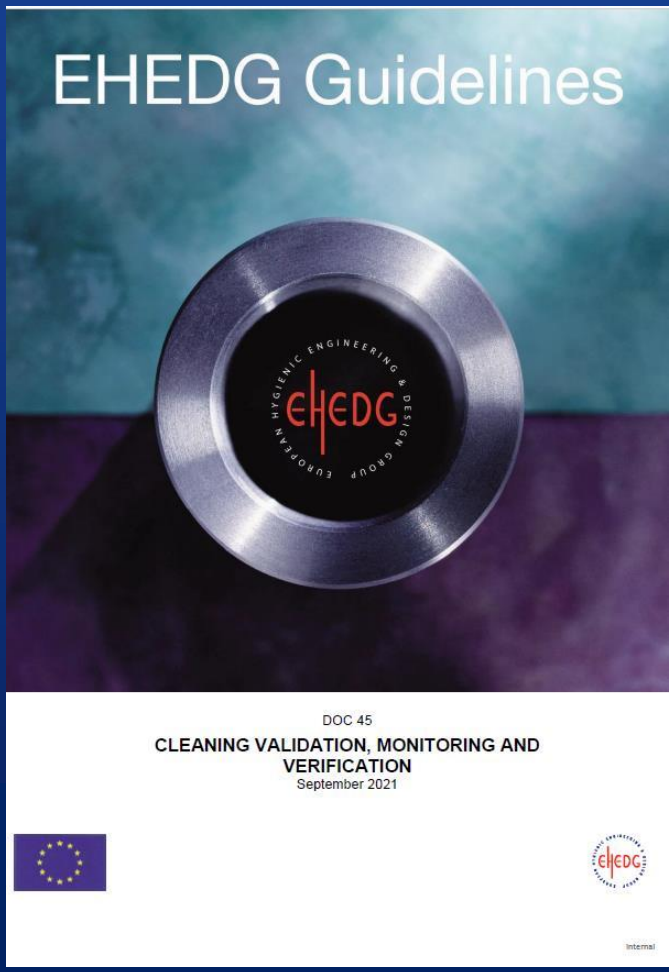


The V-Model

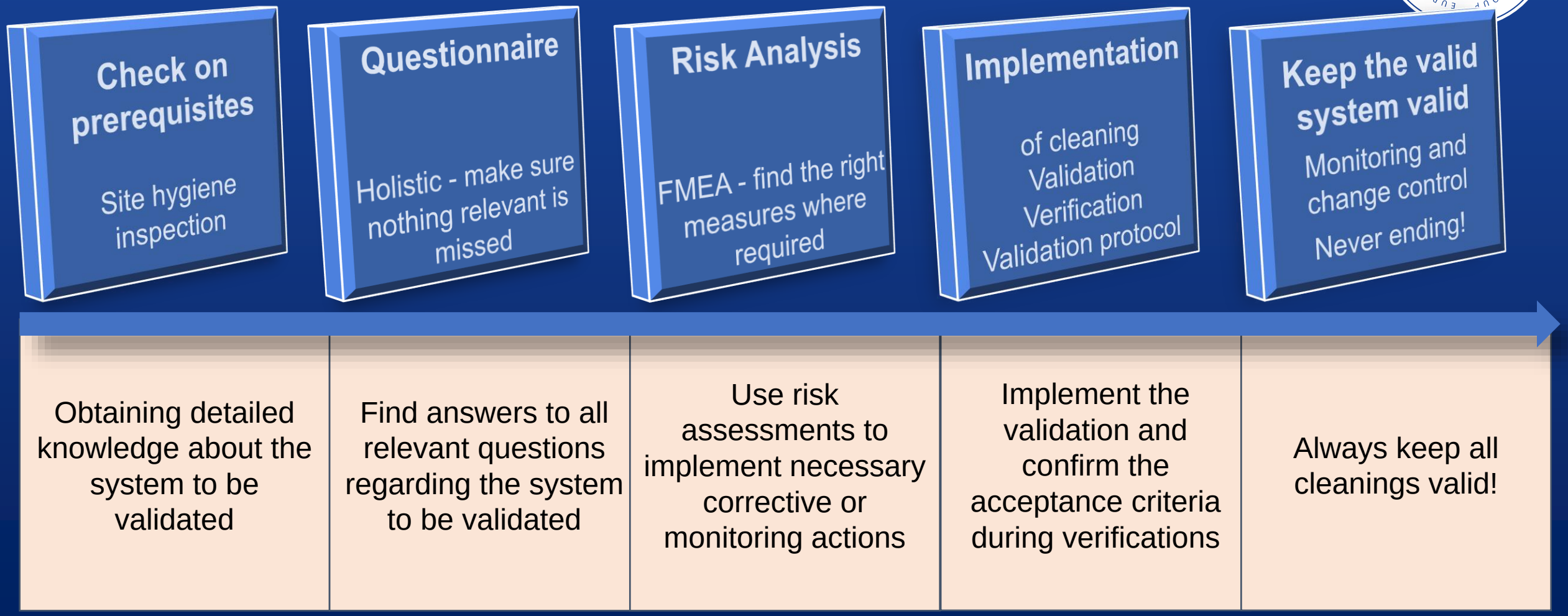


Cleaning validation

Green arrows indicates dependencies



Steps to set up a valid cleaning



Obtaining detailed knowledge about the system to be validated	Find answers to all relevant questions regarding the system to be validated	Use risk assessments to implement necessary corrective or monitoring actions	Implement the validation and confirm the acceptance criteria during verifications	Always keep all cleanings valid!

Risk analysis

Possibility / frequency - detection - meaning / impact

ECOLAB | FMEA (Failure Mode and Effects Analysis) | Ecolab Allee 1, 40789 Monheim am Rhein, Germany

$$. December 2020

Hazard analysis / risk assessment food safety for the preparation of the Cleaning Validation

Background:

The following risk analysis explores potential hazards associated with ($$$ e.g. CIP) cleaning at the $$$ location:

- Reference objects from the CIP circuits $$$ to $$$
- Tank groups with the reference tanks: $$$
- Pipings/lines $$$
- Heater $$$
- Filler $$$
- Evaporator $$$

Risk assessment and risk reduction:

1. determination of the boundaries of the system
2. determination of the hazards and the associated hazardous situations that may arise from the system
3. determination of the types of errors, causes of errors and consequences of errors
4. estimation of risks, taking into account the severity of possible hazards to health and the probability of their occurrence
5. evaluation of the risks to determine whether risk reduction is required
6. eliminating the hazards or reducing the risks associated with these hazards

Risk assessment is an iterative process, the repetition of which may be required to sufficiently reduce risks.

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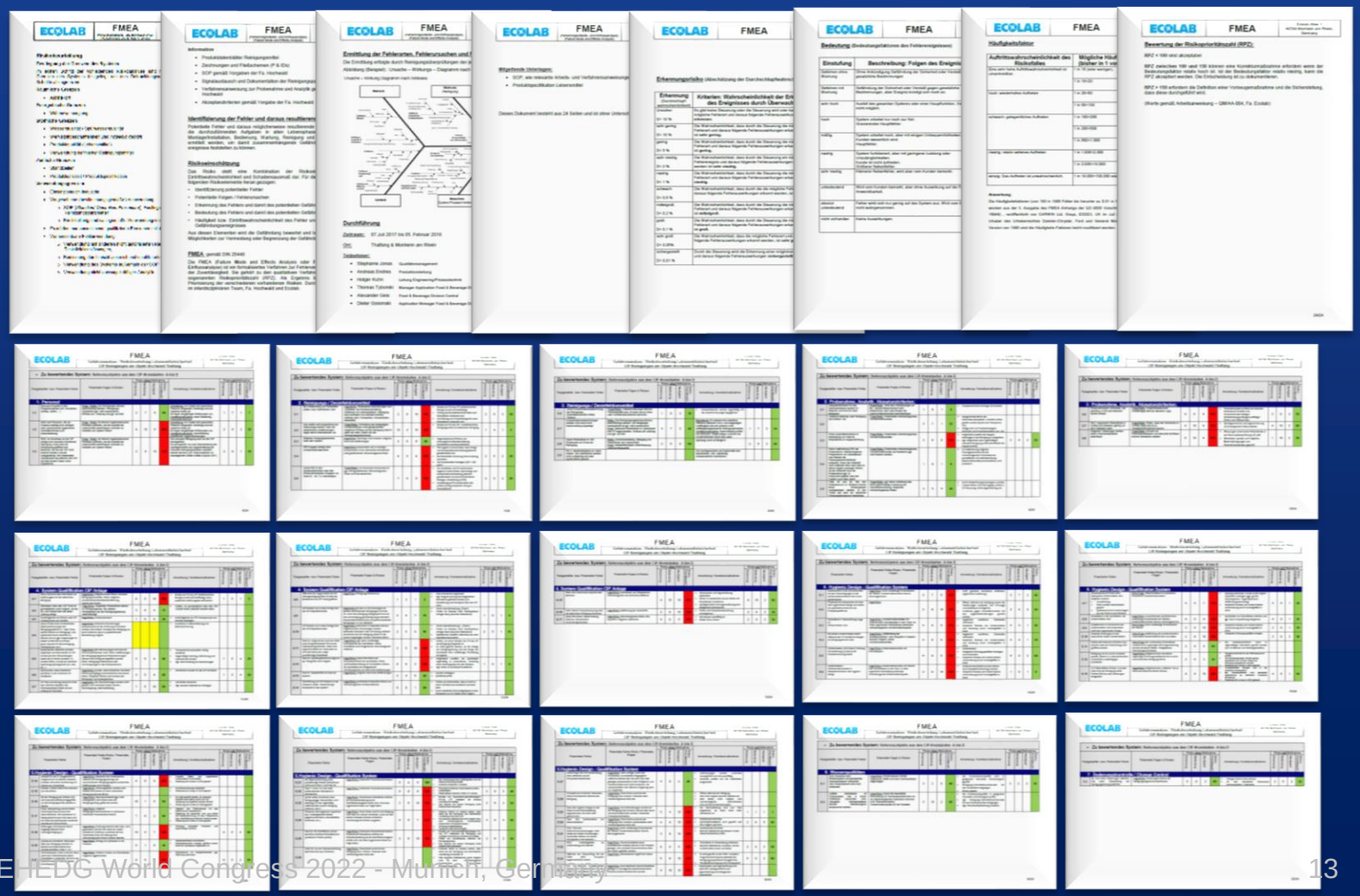
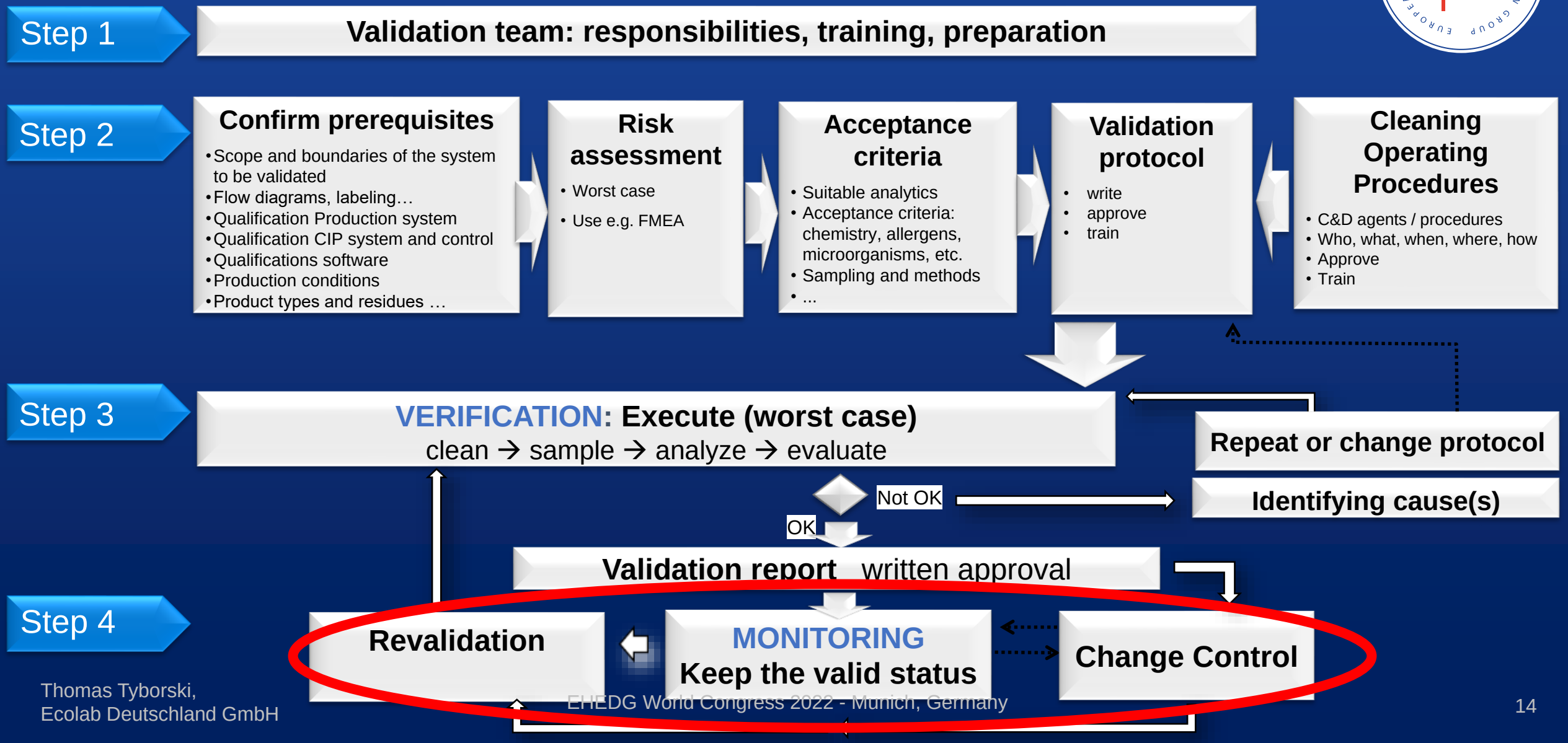


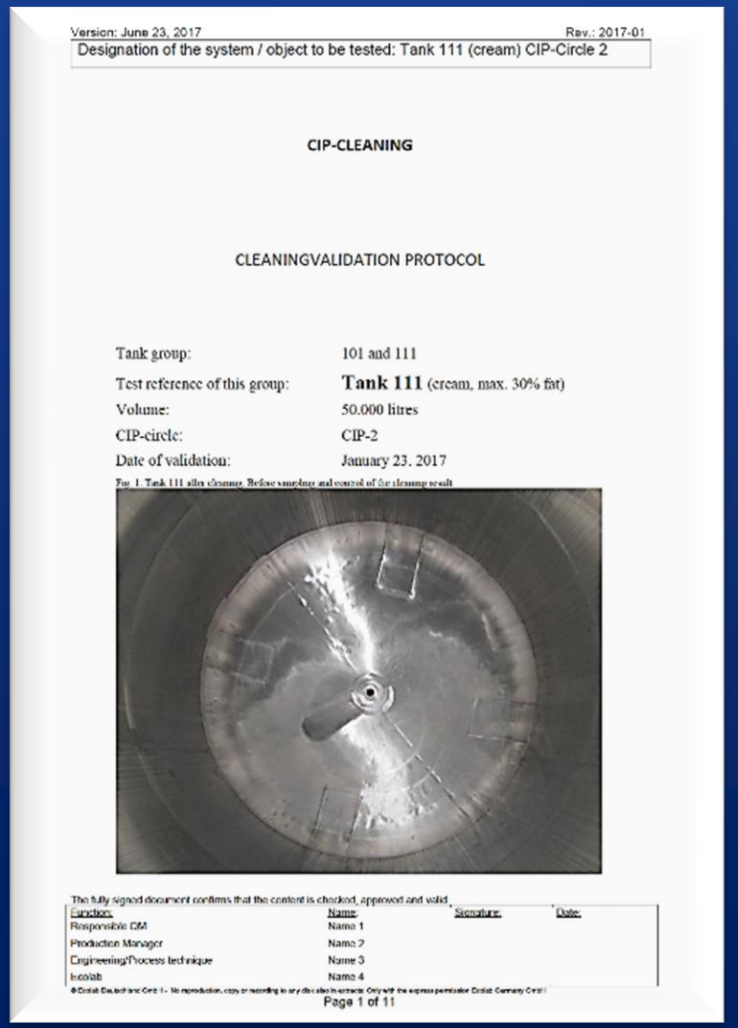
Steps of the Cleaning Validation



Verification complete Cleaning Validation

Use validation protocol (central document) - Describes, confirms & documents

1. Requirements (target & scope)
2. Type of review
3. Type of cleaning
4. Dangers and risks
5. Aim of review & general information
6. Description of measuring equipment and procedure in the event of deviations
7. Qualifications / current status
8. Components of the cleaning cycle
9. Limit control, alarm messages
10. Flow paths and valve positions / circuits
11. Checkpoints after cleaning / assessment of compliance with acceptance criteria
12. Measurement methods / devices
13. Detergent & cleaning process
14. Alarms
15. Checking results after cleaning check - residue analysis
16. Microbiological review
17. Summary evaluations of the results
18. Reference to the applicable documents
19. Change control
20. Confirmation of verification success / approval


Version: June 23, 2017 Rev.: 2017-01

Designation of the system / object to be tested: Tank 111 (cream) CIP-Circle 2

CIP-CLEANING

CLEANINGVALIDATION PROTOCOL

Tank group:	101 and 111
Test reference of this group:	**Tank 111** (cream, max. 30% fat)
Volume:	50.000 litres
CIP-circle:	CIP-2
Date of validation:	January 23. 2017

For 1. Tank 111 after cleaning. Before sanitizer and control of the cleaning result

The fully signed document confirms that the content is checked, approved and valid.

Function	Name	Signature	Date
Responsible QM	Name 1		
Production Manager	Name 2		
Engineering/Process technique	Name 3		
Ecolab	Name 4		

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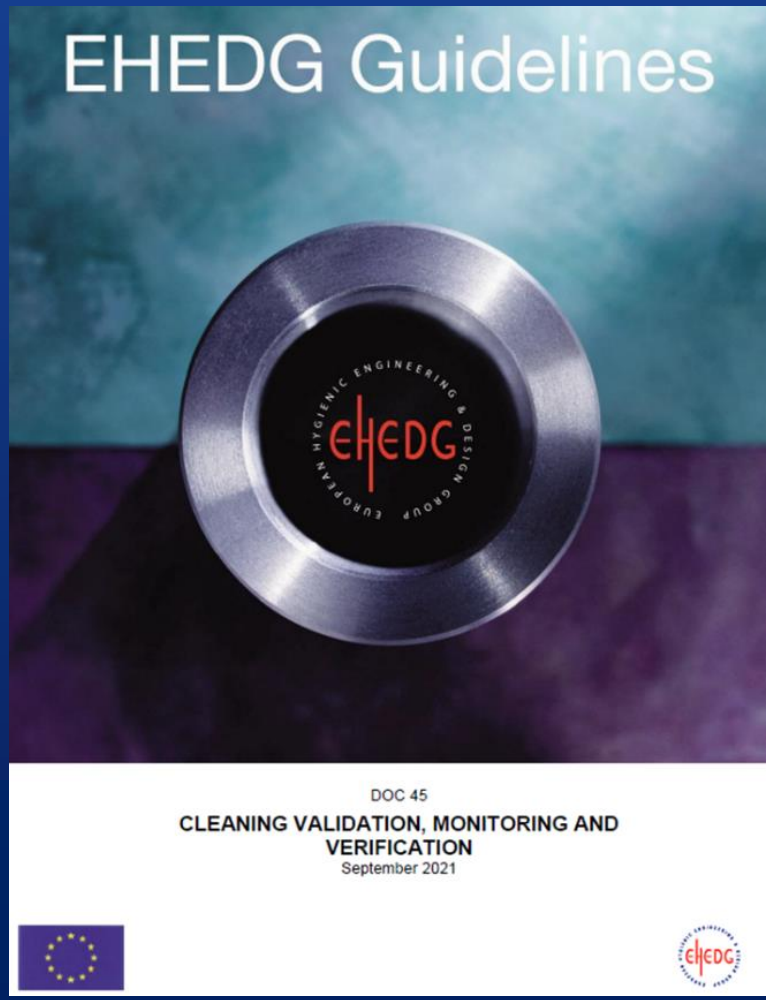
3D TRASAR CIP - keep the valid status

Installation	Standardization	Optimization	Ongoing Service
	Wash correctly	Wash optimally	Maintain consistency
	• Identify % wash compliance • Reach 90%+ consistently • Decrease risk of inconsistent product	• Capture savings from optimization • Drive toward 100%	• Keep you at 90%+ • Tracking keeps Ecolab accountable • Spread best practices across network

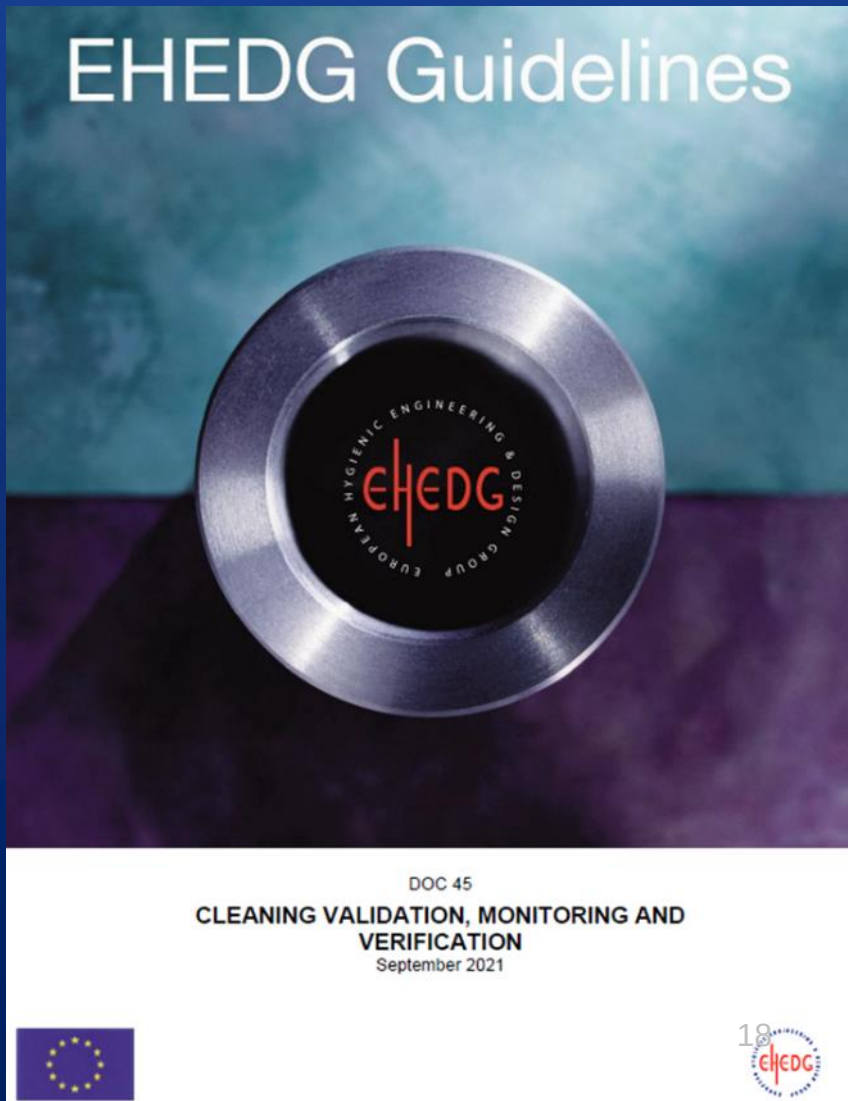
Cleaning validation - Key Learning Points

- Cleaning is a pre-requisite for food safety & quality
- Regulatory agencies, the Global Food Safety Initiative (GFSI), etc. require validation of cleaning in food manufacturing
  - ***Does it work?*** Demonstrates that a cleaning procedure is effective
  - ***Is it working?*** Monitoring effectiveness is performed during each cleaning
  - ***Has it worked?*** Verification - control parameters have been implemented
- Three different ways: **prospective, concurrent and retrospective**



Cleaning validation - Key Learning Points

- Validation Master Plan is recommended, …**Validation Protocol**, … Execution … **Validation Report**, …**Revalidation**
- … sufficient **qualified personnel**
- physical walk through of the process (visual inspection), … documentation review, observations during cleaning, and a … sampling and testing.
- outcome of the cleaning validation: Cleaning Validation Report
- For any deviation corrective and preventive actions should be defined.
- **Revalidations**
- **Changes Control**



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Summary

Holistic cleaning validation as a basic requirement

- Well trained and motivated staff for all cleaning work
- Ensure / confirm cleanability - hygienic design
- Use of suitable cleaning agents suitable cleaning systems
- Know, recognize and avoid errors
- Use remote technologies such as ***3DTrasar for CIP*** to monitor your valid cleaning systems

Execution of cleaning validation and keeping of the valid status is only possible by the food factory **but** it makes sense to involve external expert bodies / expertise

THANK YOU!