

Bio-Decontamination of 900 m² pharma production using one fully automated decontamination system

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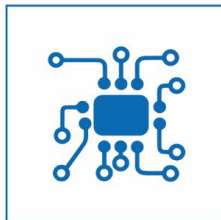
ORTNER - a System Supplier for Cleanroom Systems and Technologies

Focus on research and development and manufacturing of innovative systems and decontamination technologies for clean and safe production processes.

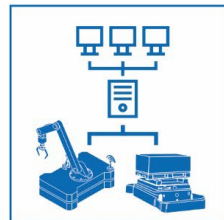
- Founded **1985**
- Family-owned company
- **Headquarter:** Villach (Carinthia/Austria)
- **Branches:**
 - Germany, Denmark, Switzerland
 - Austria (manufacturing site)
- Employees: **170** and growing



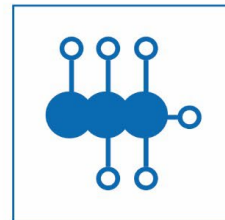
Hardware



Software



Industry 4.0



Process engineering



Validation



Service/maintenance

IDT Biologika - Advancing Biologics. Protecting Life.



Worldwide

Services for the global biopharmaceutical industry and governments



€ 275 m

turnover in 2021



Over € 550 m

invested since 1993, including € 350 m since 2011



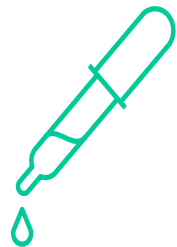
1,600

employees in 2021

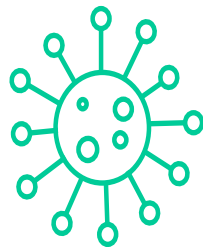
Owner

Klocke Holding GmbH (Carsten Klocke, Stefan Klocke)

IDT Biologika is a **full service provider**. We cover the **entire value chain** from contract development through clinical phases I to III to commercial production of vaccines, gene and immune therapeutics, including quality control, packaging and storage.



Process Development



Drug Substance Manufacturing



Fill & Finish



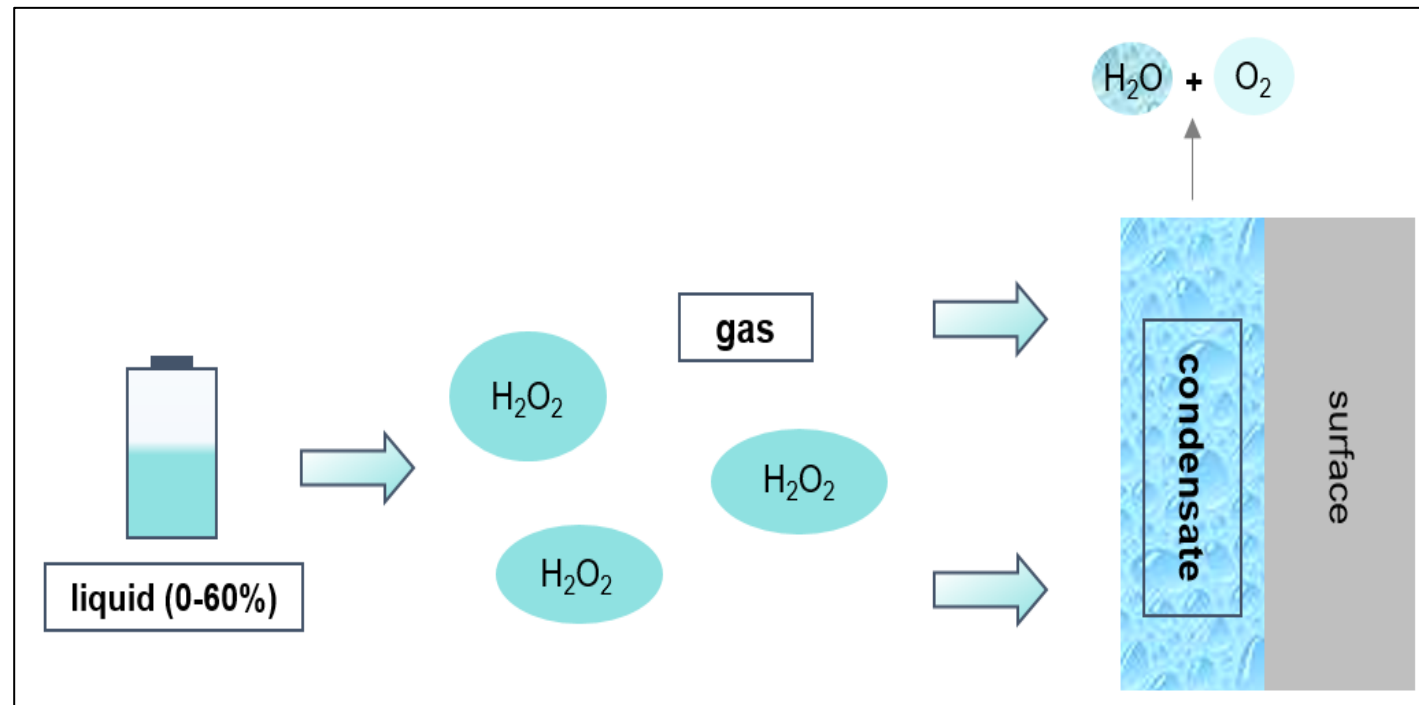
Secondary Packaging and Storage



Quality Control

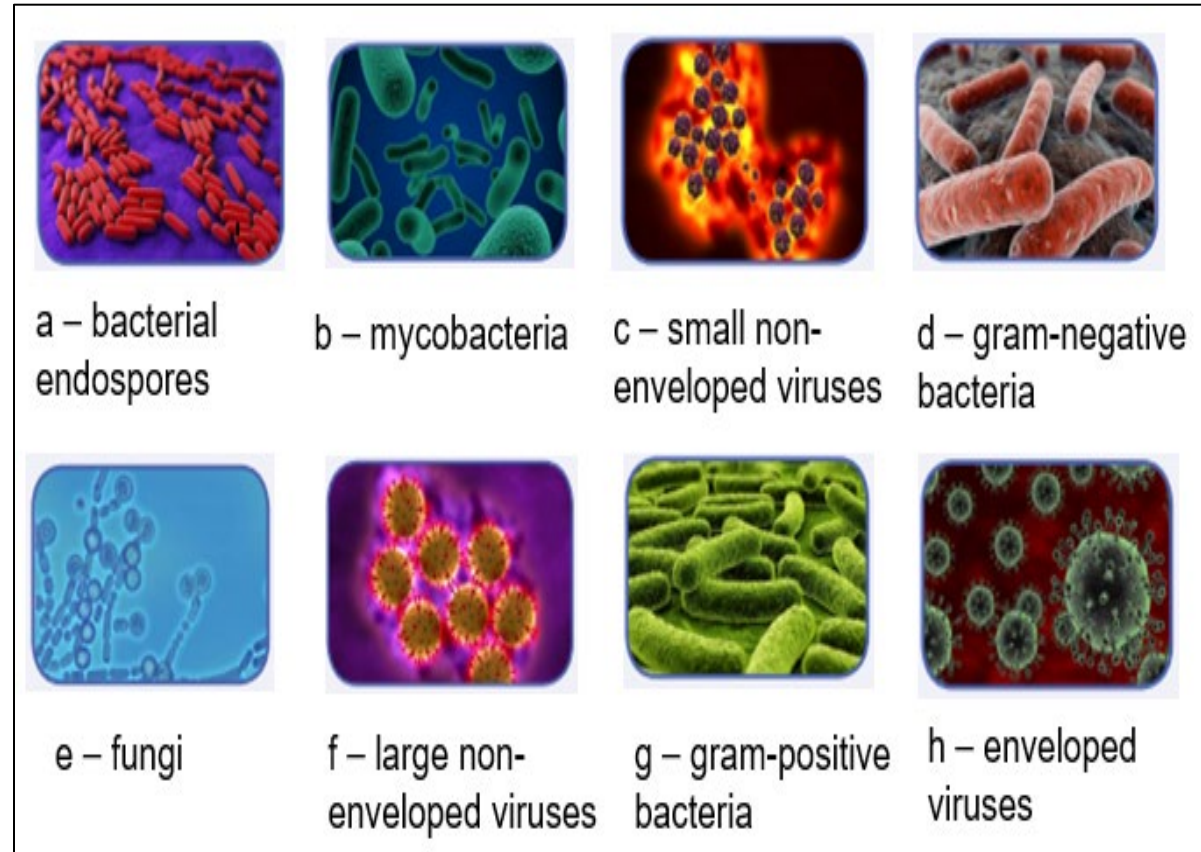
Hydrogen Peroxide (H_2O_2) Decontamination

- H_2O_2 as efficient decontaminant in aseptic production of parenterals
 - + efficient inactivation of bacterial spores and viruses
 - + decomposition into harmless by-products
 - + high material compatibility
- multiparameter problem
- possibility of long aeration phase



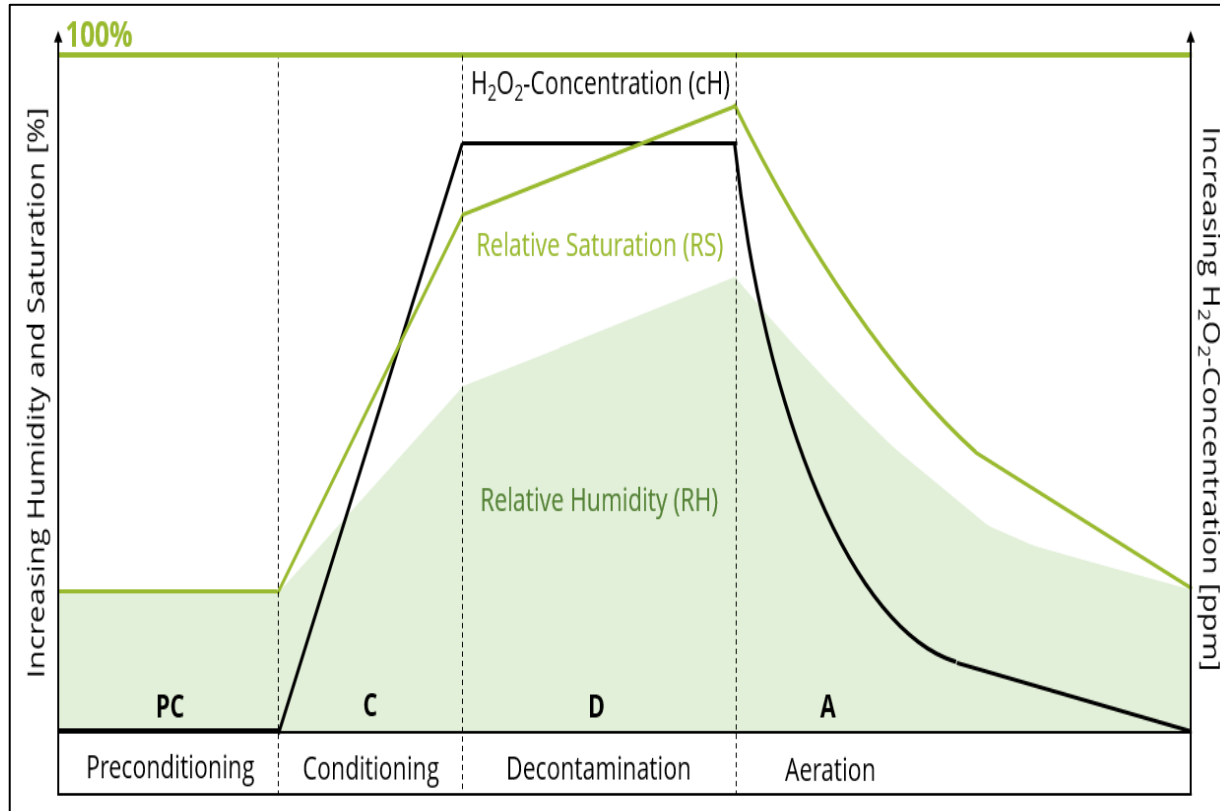
Hydrogen Peroxide (H₂O₂) Decontamination

- H₂O₂ is effective against numerous microorganisms
- several studies suggest the difference of contaminants by regardless of their resistance to chemical and physical treatments
- bacterial spores and small non-enveloped viruses are the most resistant microorganisms, according to E. H. SPAULDING

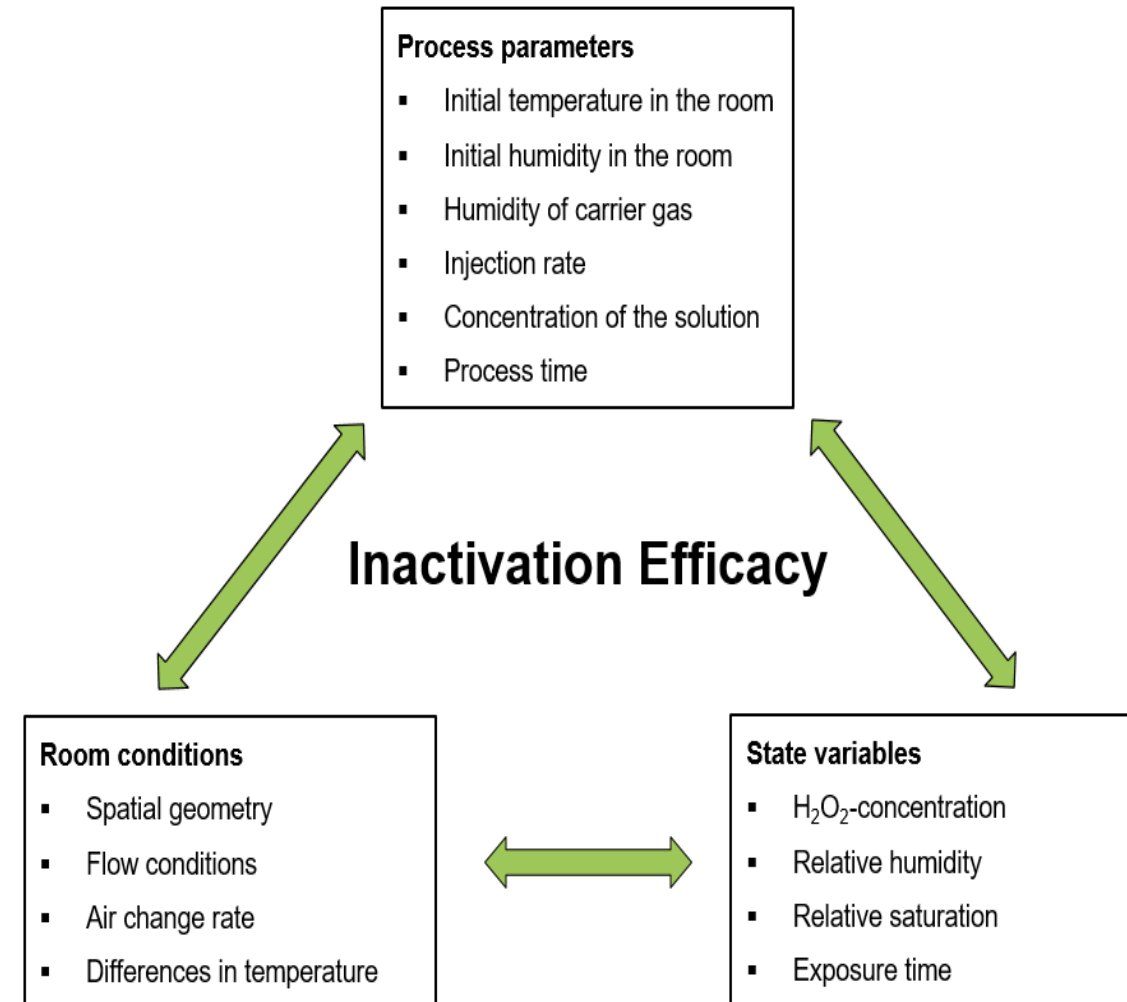


Classification after E.H. SPAULDING. Adapted after Bioquell UK Ltd., „Hydrogen Peroxide Vapor biological efficacy -MICROBIOLOGY SHEET“. 2017.

Key Parameters of H₂O₂ – Decontamination



- room-specific definition of key process parameters necessary
- monitoring and measurement of state variables in the room



ISU (Interactive Superinduce Unit) Mobile

The ISU, one of the most modern and advanced H_2O_2 generation facilities, interacts – through various channels – with different infrastructure systems, plants or devices.

Gas flow can be generated either “intensively highly concentrated” or “gliding continuously” (= superinduction effect).

- Powerful preheating function
- Variable air flow up to 350 m³/h
- Powerful built-in catalyzer
- External nozzle control
- Shorter decontamination cycles
- Intuitive user interface (red/green/blue)
- Uncomplicated maintenance



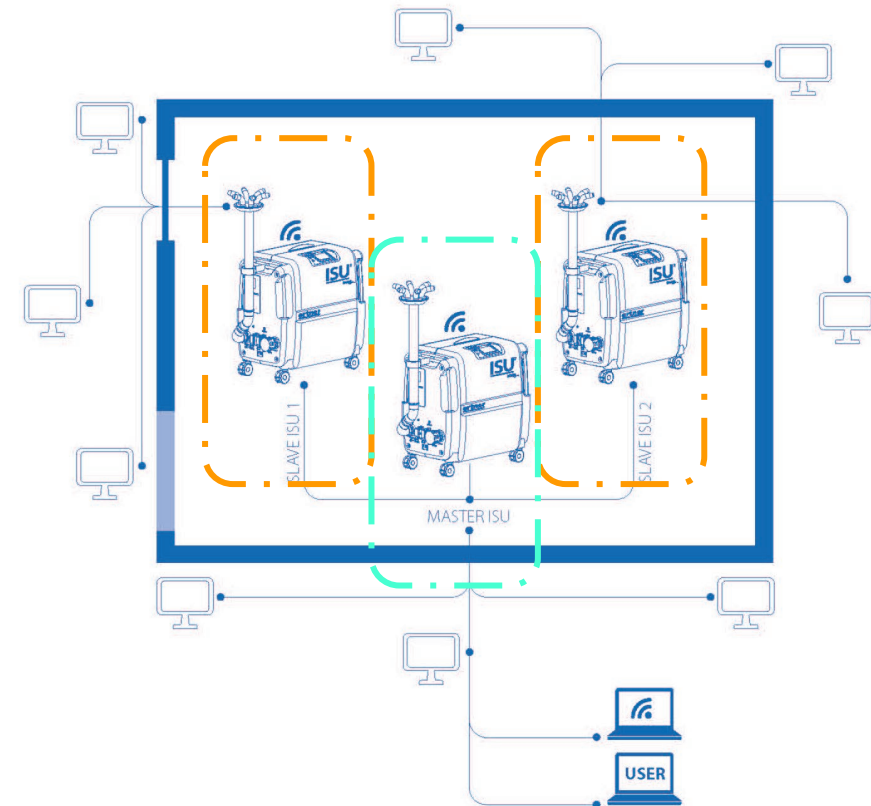
Interconnection: Master - Slave

Network connected is a operating mode where several generators are connected and controlled via one generator.

One generator takes on the function as the “**Master**” and controls all the other generators acting as “**Slaves**”.

Advantages:

- **Time savings** – several generators can be controlled by one generator
- **Simple operation** – the Master generator can be remotely controlled via a tablet or via the network of the company
- **Flexibility** – each of the generators in the network can be configured as a Master or a Slave
- **Increased safety** – Up to 3 LC sensors per generator can immediately make an alarm of unwanted vapour leakage



ISU Stationary

A large system for complex and high-performance decontamination processes.



- The system is monitored and controlled by a superordinate process control system
- Decontamination is performed fully automatically and is logged by the system
- The size of the system allows enormous volumes of space to be decontaminated

Special features:

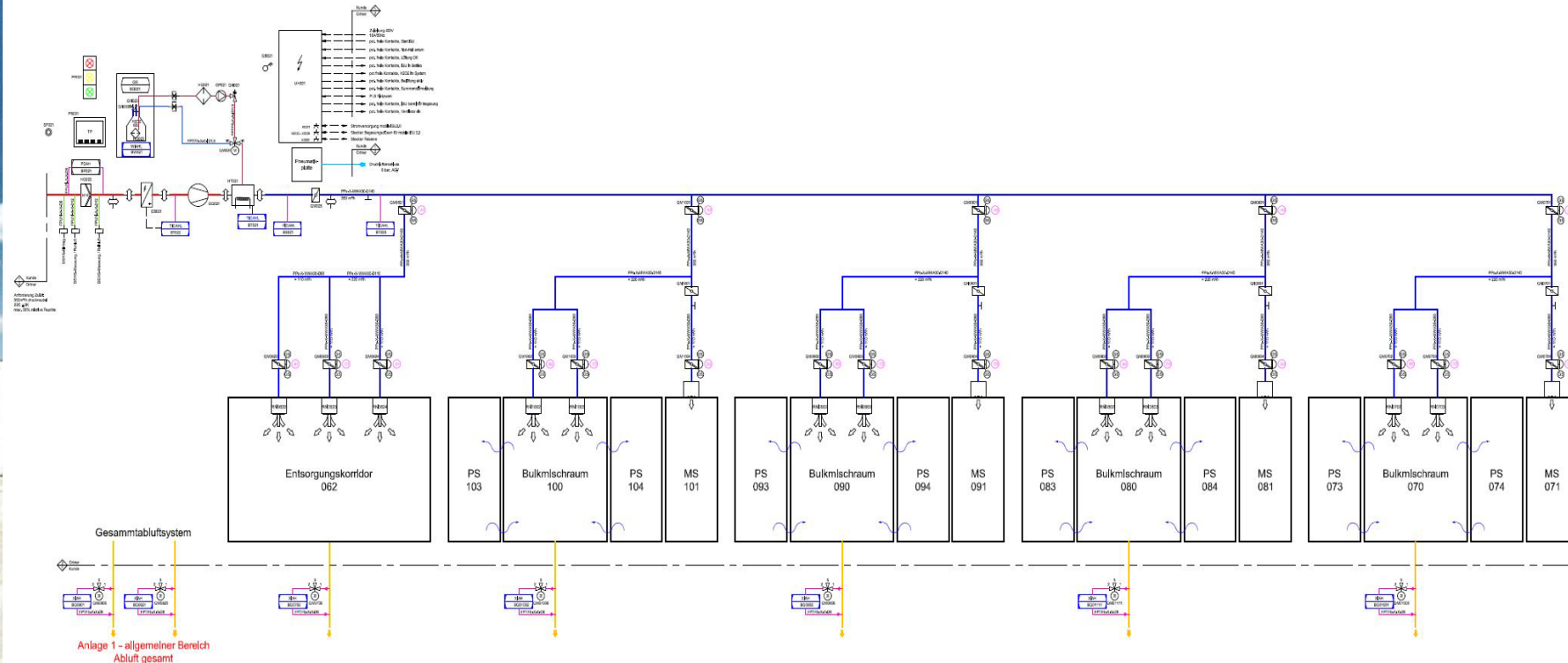
- Room volume: > 800 m³
- H₂O₂ reservoir: 65 L
- Vaporizer: up to 40g H₂O₂ /min



Case Example: Automated Central H₂O₂ Room Fumigation



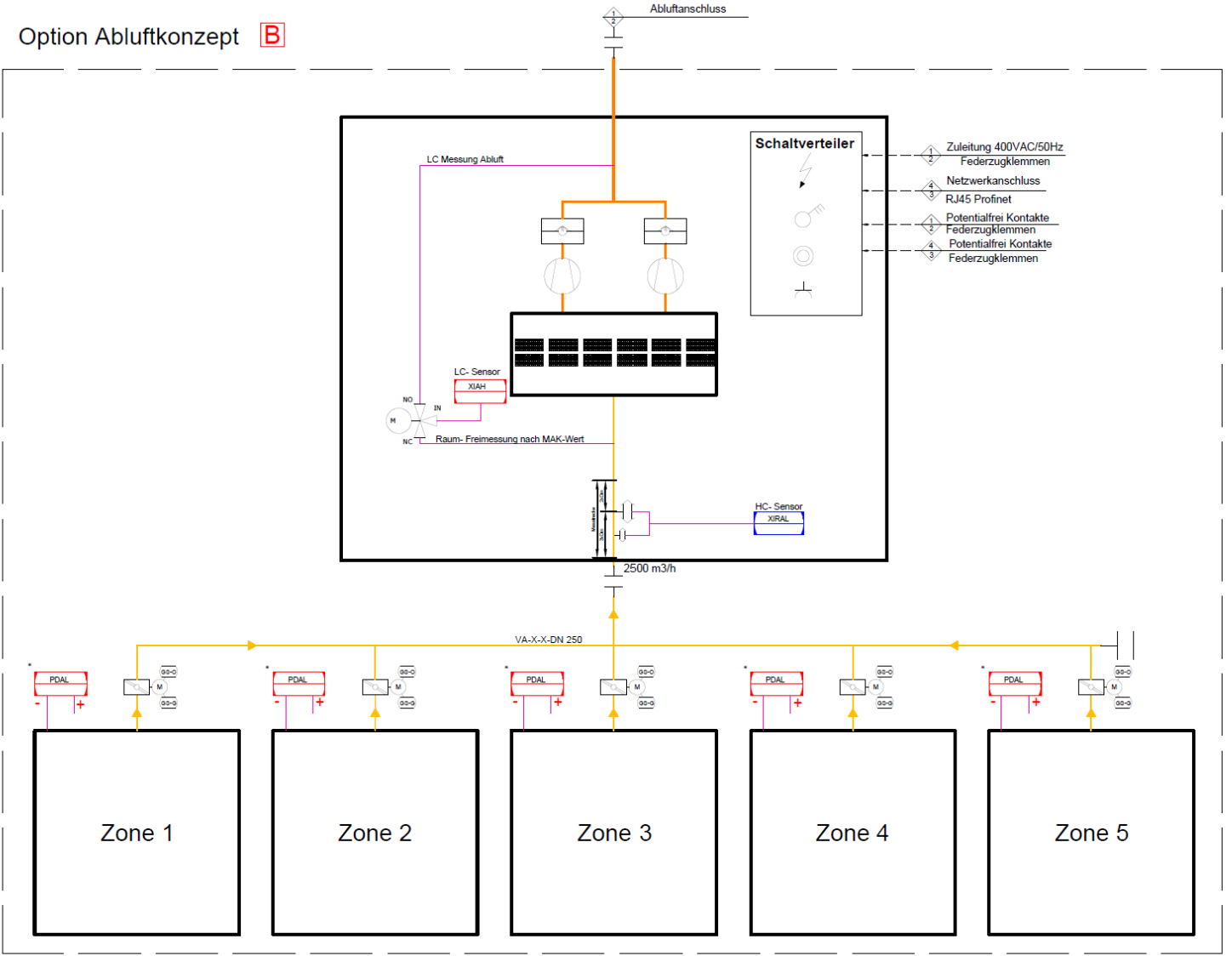
A new modern pharmaceutical production plant was built with the requirement of using modern automation and process technologies.



Case Example: Automated Central H₂O₂ Room Fumigation

A new modern pharmaceutical production plant was built with the **requirement of using modern automation and process technologies.**

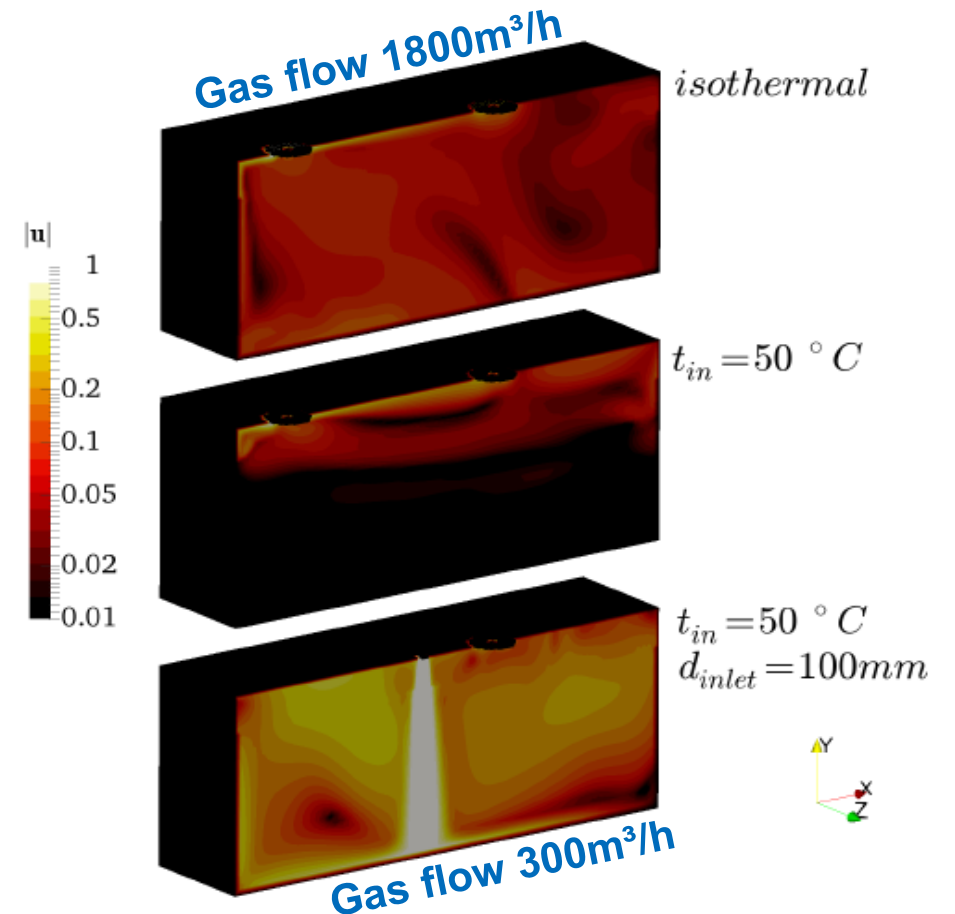
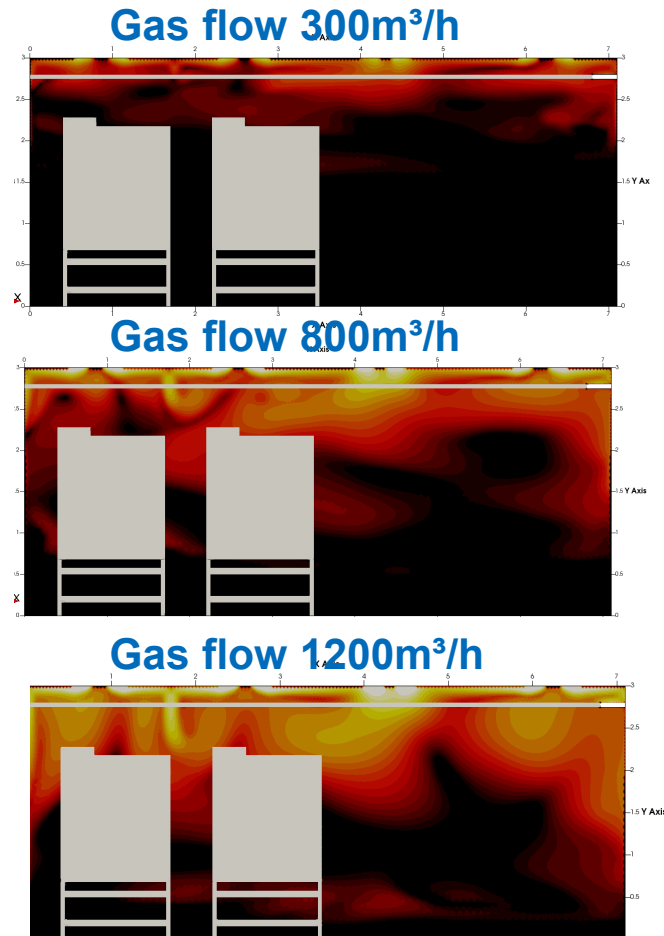
This also includes the **central exhaust air flow** and the **targeted H₂O₂ degradation via suitable catalysts.**



H₂O₂ Decontamination – Simulation of a Gas Distribution

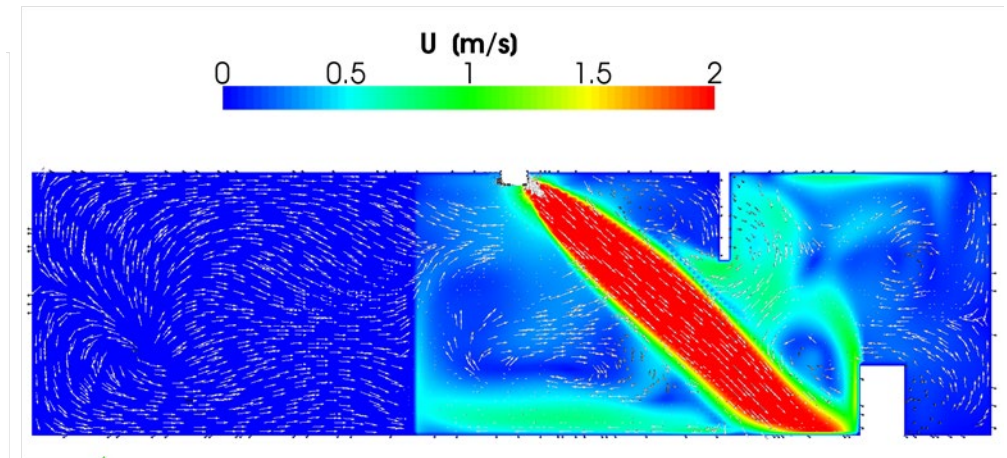
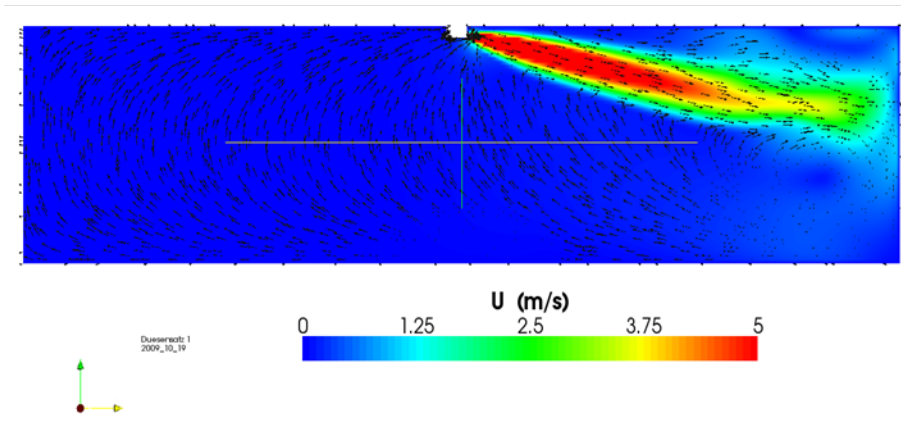
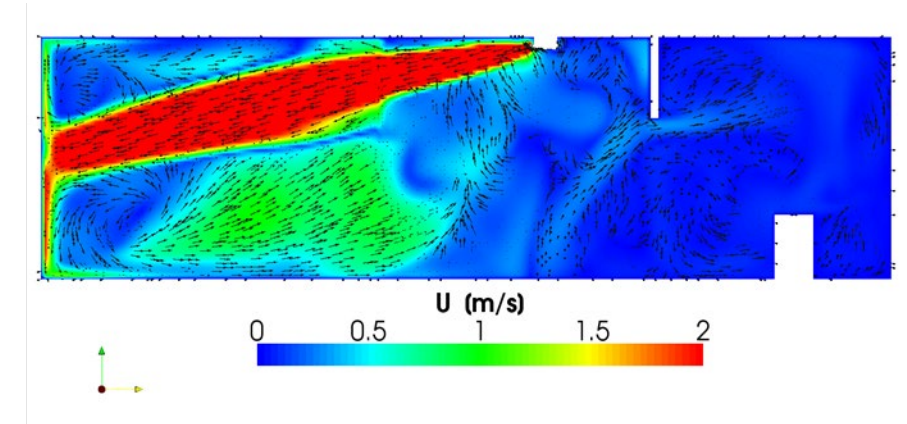
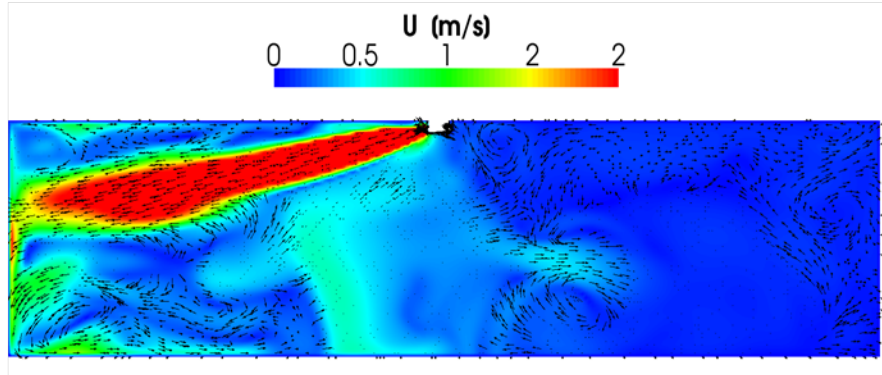
Simulation of a fumigation state with different gas flow quantities via the ventilation system (design 1800 m³/h) with swirl outlets. The result shows that effective fumigation does not work, or does not work optimally, even with higher gas flow quantities.

Simulation comparison of a fumigation state – upper representation fumigation isothermal via the ventilation system with swirl outlets – lower image with simple gas injection (300 m³/h gas flow) via a pipe piece. The concentration distribution is almost optimal.



H₂O₂ Decontamination – Simulation of a Gas Distribution

Gas injection via dynamic jet nozzles



H₂O₂ Decontamination – Simulation of a Gas Distribution



Nozzle STAR

Due to the finely tuned form of the nozzle, the gas stream is optimally introduced into the room. The evenly arranged nozzle outlets guarantee a very good formation of the free jet, which ensures an adequate flow speed and consequently a blending is ensured, even on walls and in the corners of rooms.

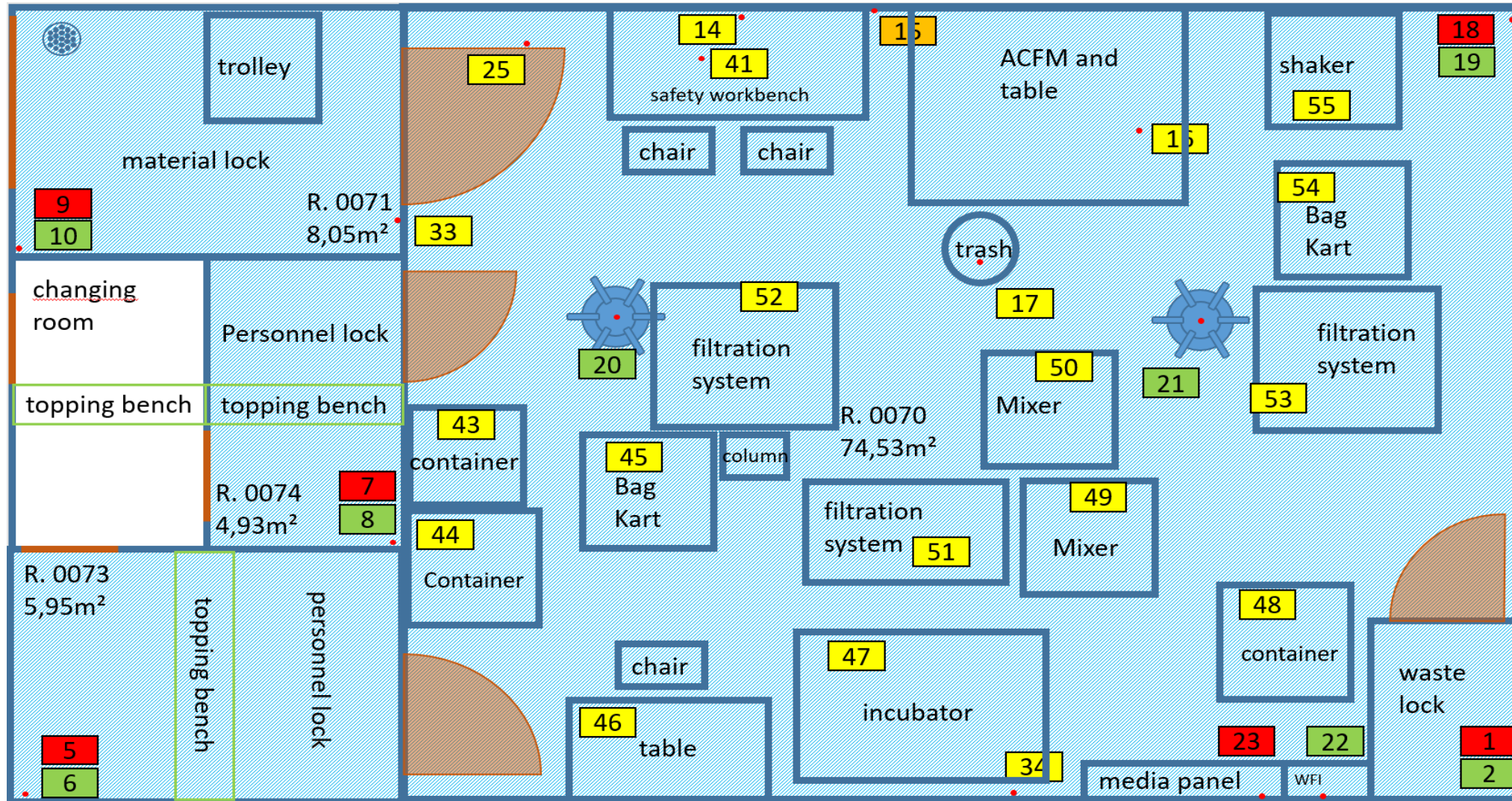
FEATURES:

- Even distribution of the gas concentration in the entire room including niches
- Fast achievement of an even concentration in the room
- The nozzle can be integrated planar into all common ceiling grids
- The gas supply nozzle has a positive influence on the free-purge
- Process and desorption performance
- Controllable nozzle elements allow the gas flow to be introduced



Case Example: Central H₂O₂ Room Fumigation

Automated H₂O₂ decontamination from the technical center

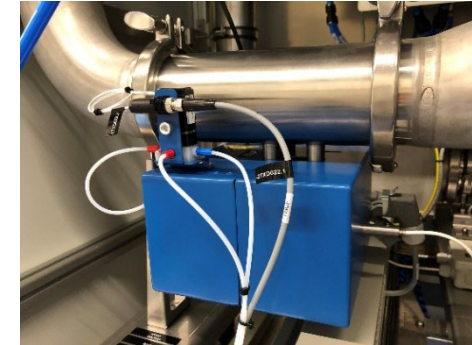


Case Example: Central H₂O₂ Room Fumigation

High-performance generator system in technical centre



H₂O₂ evaporator module with evaporator capacity up to 40g/min



Case Example: Central H₂O₂ Room Fumigation

Infrastructure installation H₂O₂ gassing

The nozzle systems provide uniform distribution of gas concentration in rooms or niches.

This is the best way to realize the penetration depth, room air rollers and niche cover and to avoid condensation with great certainty.



460 linear meter trace heating



Case Example: Central H₂O₂ Room Fumigation

Process assurance through automation

To monitor the H₂O₂ decontamination process, parameters are monitored, or resp. checked by sensor technology.

Flow Sensor:

To monitor the air volume flow, a flow sensor is installed in the supply air pipe.

Temperature sensor preheater:

A temperature sensor is installed in the heating register to control and monitor the air preheating.

Scale ISU:

The H₂O₂ container with the liquid H₂O₂ is placed on a scale. The scale is used to control the consumed H₂O₂ per cycle run.

Door contact sensor H₂O₂ reservoir:

The weight of the H₂O₂ container is permanently monitored during a decontamination process.

In order to ensure that the container is not touched during the process, the door contact sensor monitors the sliding door to the H₂O₂ container.

Temperature sensor evaporator unit ISU:

The liquid H₂O₂ is evaporated in the evaporator and the achieved evaporator temperature is recorded via a temperature sensor in the evaporator.

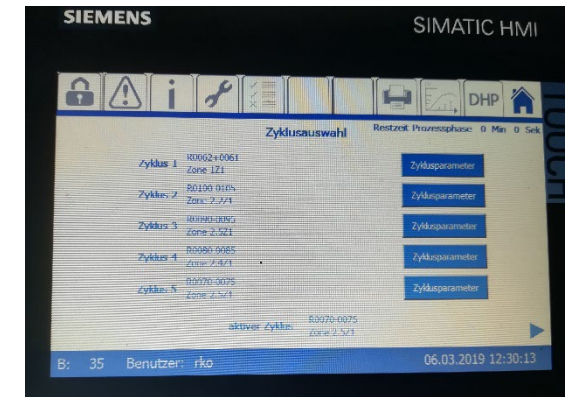
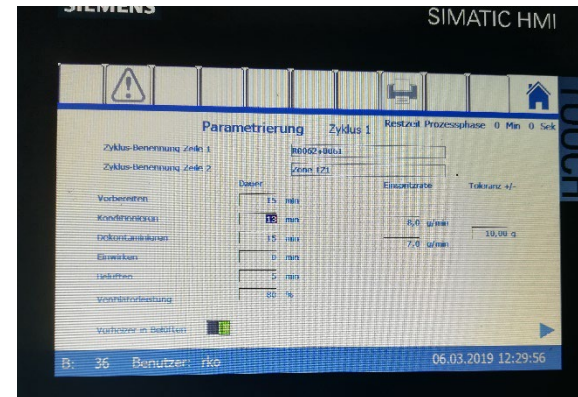
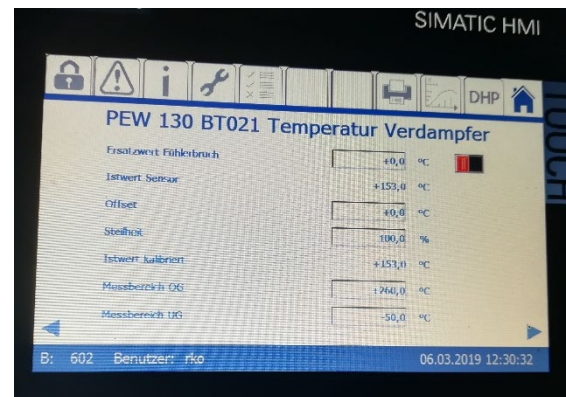
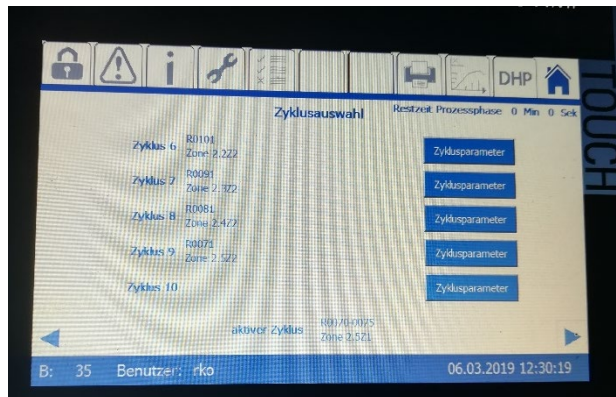
Temperature sensor pipe trace heating:

For monitoring and controlling the temperature of the pipe trace heating system.

Case Example: Central H₂O₂ Room Fumigation

Process assurance through automation

Zone 1Z1 R0062	Normalbetrieb	Vorbereitungsbetrieb	Begasungsbetrieb	Türfreigabe	Trocknungsbetrieb	🔍
Zone 2Z1 R0100-R0105	Normalbetrieb	Vorbereitungsbetrieb	Begasungsbetrieb	Türfreigabe	Trocknungsbetrieb	🔍
Zone 2Z2 R0101	Normalbetrieb	Vorbereitungsbetrieb	Begasungsbetrieb	Türfreigabe	Trocknungsbetrieb	🔍
Zone 3Z1 R0090-R0095	Normalbetrieb	Vorbereitungsbetrieb	Begasungsbetrieb	Türfreigabe	Trocknungsbetrieb	🔍
Zone 3Z2 R0091	Normalbetrieb	Vorbereitungsbetrieb	Begasungsbetrieb	Türfreigabe	Trocknungsbetrieb	🔍



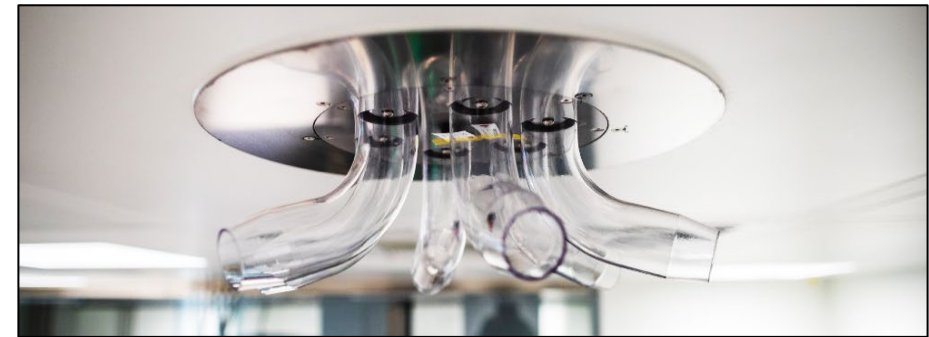
Implementation of H₂O₂ – Decontamination in IDT Biologika



- Drug Substance Manufacturing Facility 205 → clean room area of 900 m²
 - multipurpose manufacturing facility Containment Concept
 - 5 process rooms and dirty corridor with three-chamber lock - separate entrance and exit to the process room
 - controlled independent supply and exhaust air for the entire cleanroom area via H14 HEPA filter
 - Containment and product protection through suitable pressure cascades
 - necessity of disinfection and decontamination of the clean rooms for maintaining GMP- compliant production conditions

Implementation of H₂O₂ – Decontamination in IDT Biologika

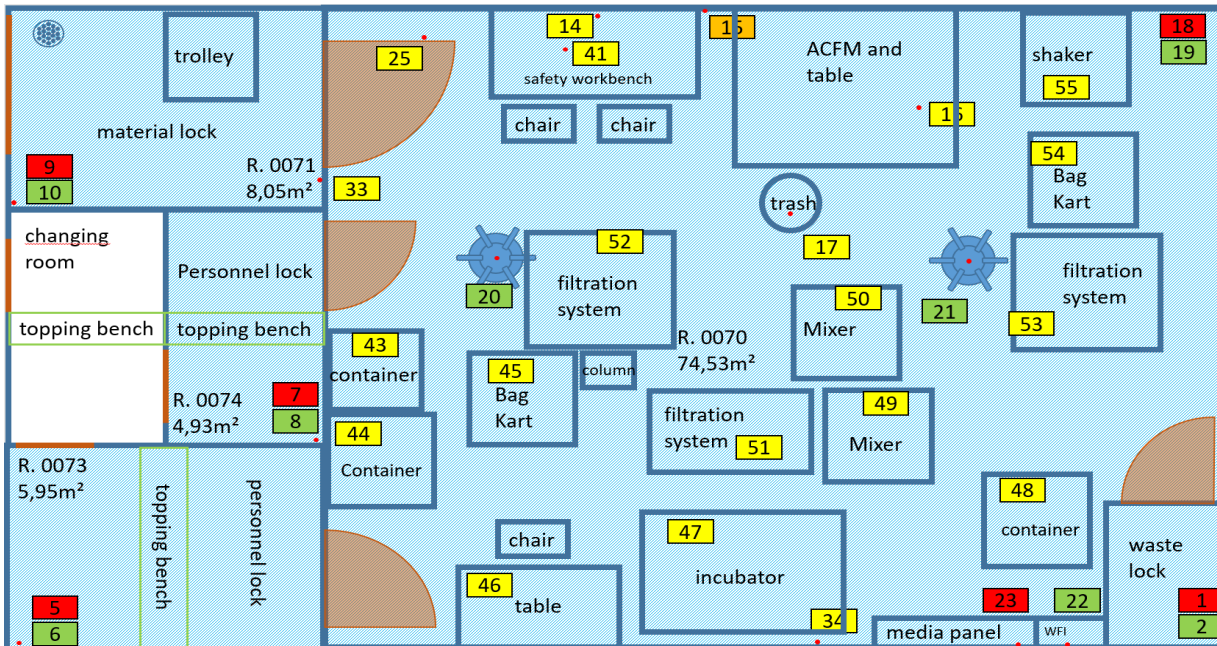
- Quality-relevant process parameters, such as the air exchange rate, relative humidity and temperature, are recorded continuously by the building control and management system



- user-friendly fully automated decontamination system by Ortnier Reinraumtechnik
- usage of sensors for measurement of relative humidity and saturation, H₂O₂ – concentration and temperature within the process rooms → highly effective & safe fumigation processes

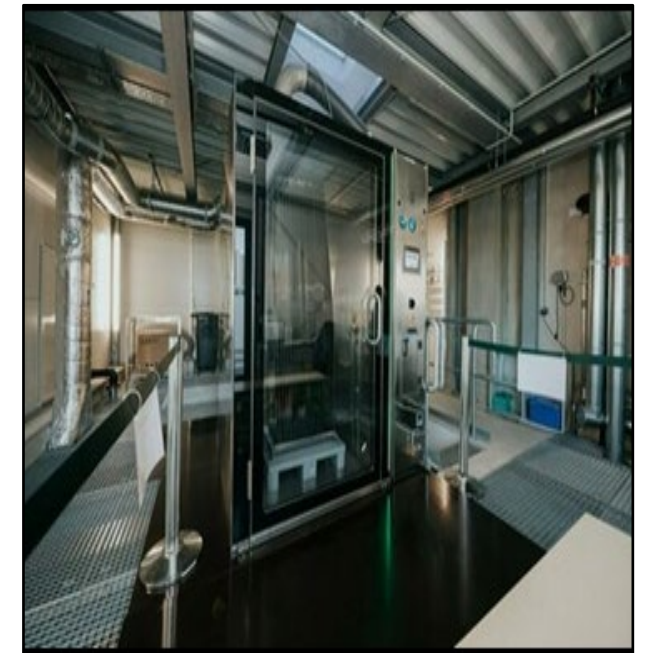
Cycle Development & Cycle Validation

- the effectiveness of our fumigation processes against various contaminants is regularly checked within the scope of revalidations
- usage of bioindicators with
 - spores of *Geobacillus stearothermophilus*
 - virus (MVA & MVM)
- demonstrably inactivation of the initial population by at least 4 log, we enable complete decontamination of the room according to the expected bioburden



Steady optimisation of the fumigation system

- fumigation system independent of room loading
 - control and regulation of the key process parameters via H_2O_2 – sensor
- degassing via catalyst system for reduction of the aeration phase in building 203
- usage of an experimental airlock of Ortner Reinraumtechnik as a test system, to guarantee our customers perfectly decontaminated production units for aseptic production of biologicals



Thanks to our highly motivated teams and our partners !
Thank you for your attention.

QUESTIONS ?

More informations in our White Paper



ortner
cleanrooms unlimited

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