Impact of hygienic design on cleaning and sterilization processes

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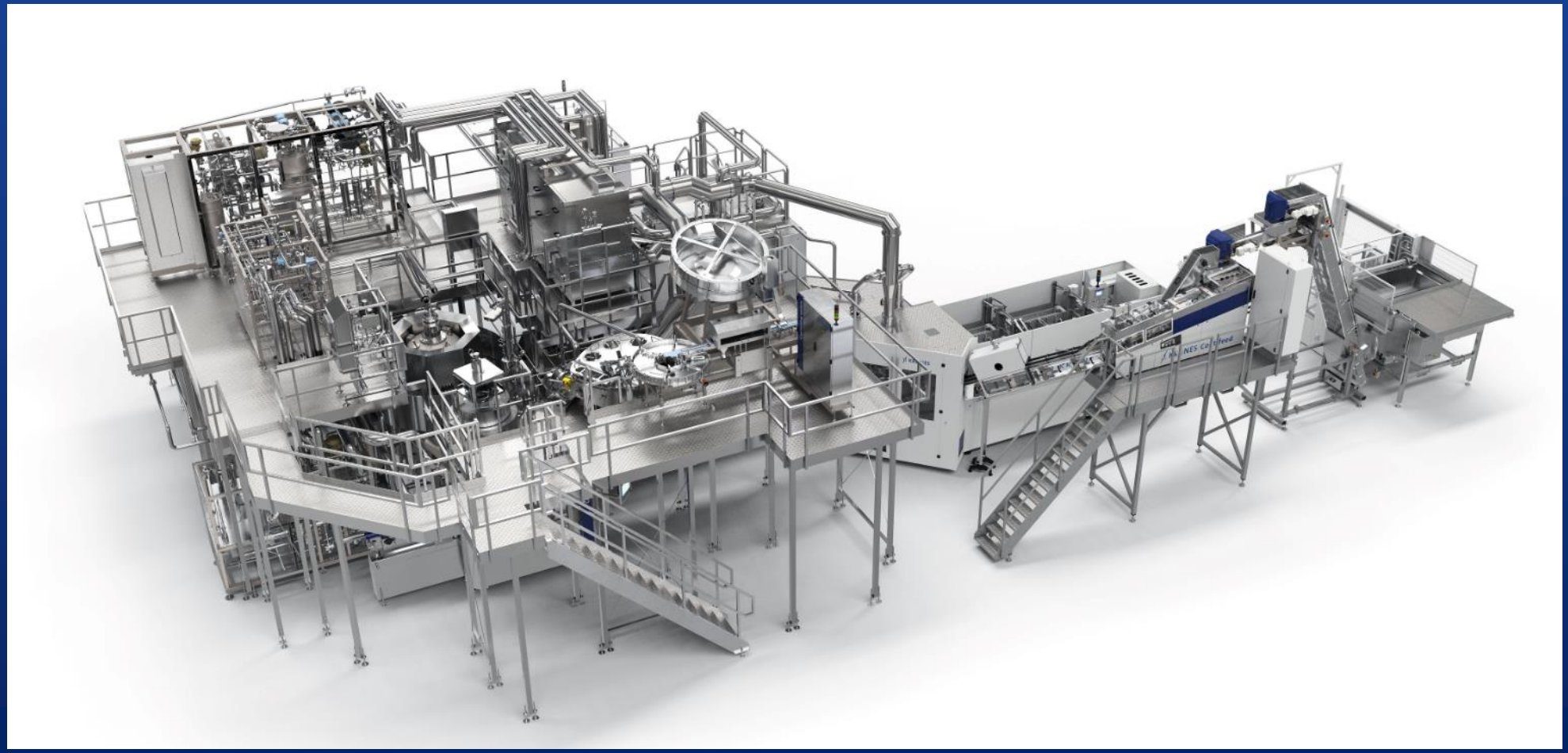
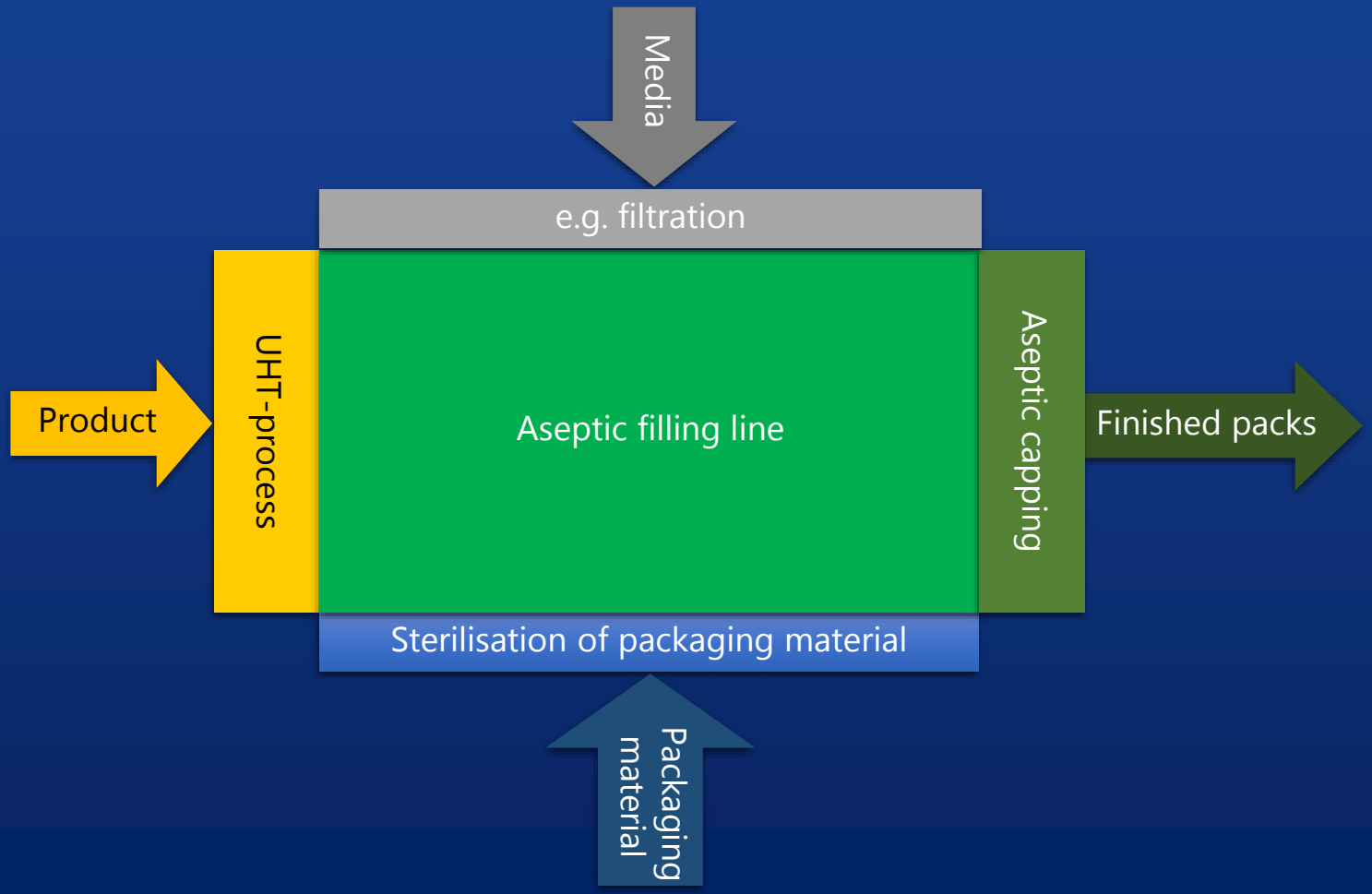
Overview over the technical system



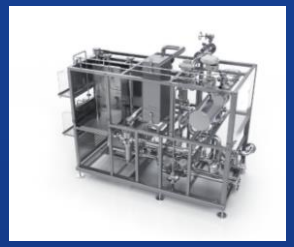
- Aseptic blow moulder filler capper bloc for PET bottles

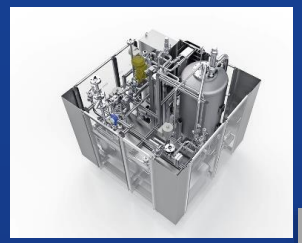
Aseptic process



- Everything entering the sterile zone needs to be treated

Components





Media

e.g. filtration

Product

UHT-process

Aseptic filling line

Aseptic capping

Finished packs

Sterilisation of packaging material

Packaging material

- Every component has to be validated to show the boundary

Achievements through hygienic design

Cleaning and sterilisation time: 4.5 h → 2.5 h (1.5 h)

Continuous production time: 24 h → 168 h

Intermittent disinfection time: 32 h/w → 0 h/w

- Hygienic design allows to drastically reduce planned downtimes

Cost evaluation

Assumptions:

- Three-shift operation 6000h/a
- 50w/a
- The line performance is the restriction for sales
- Speed: 600bpm
- Profit per bottle: 0.03 €
- Low acid product
- Changeovers und unplanned downtimes neglected
- Energy and media costs neglected

- Profit per hour: 1,080 €
- 120 h/w*1,080 €/h = 129.600 €/w

Losses through cleaning and sterilisation downtime with 4.5 h/d
+ 8*0.5 h/d intermittent disinfection

= 9,180 €/d

= 55,080 €/w

Losses through cleaning and sterilisation downtime with 2.5 h/w (actual)

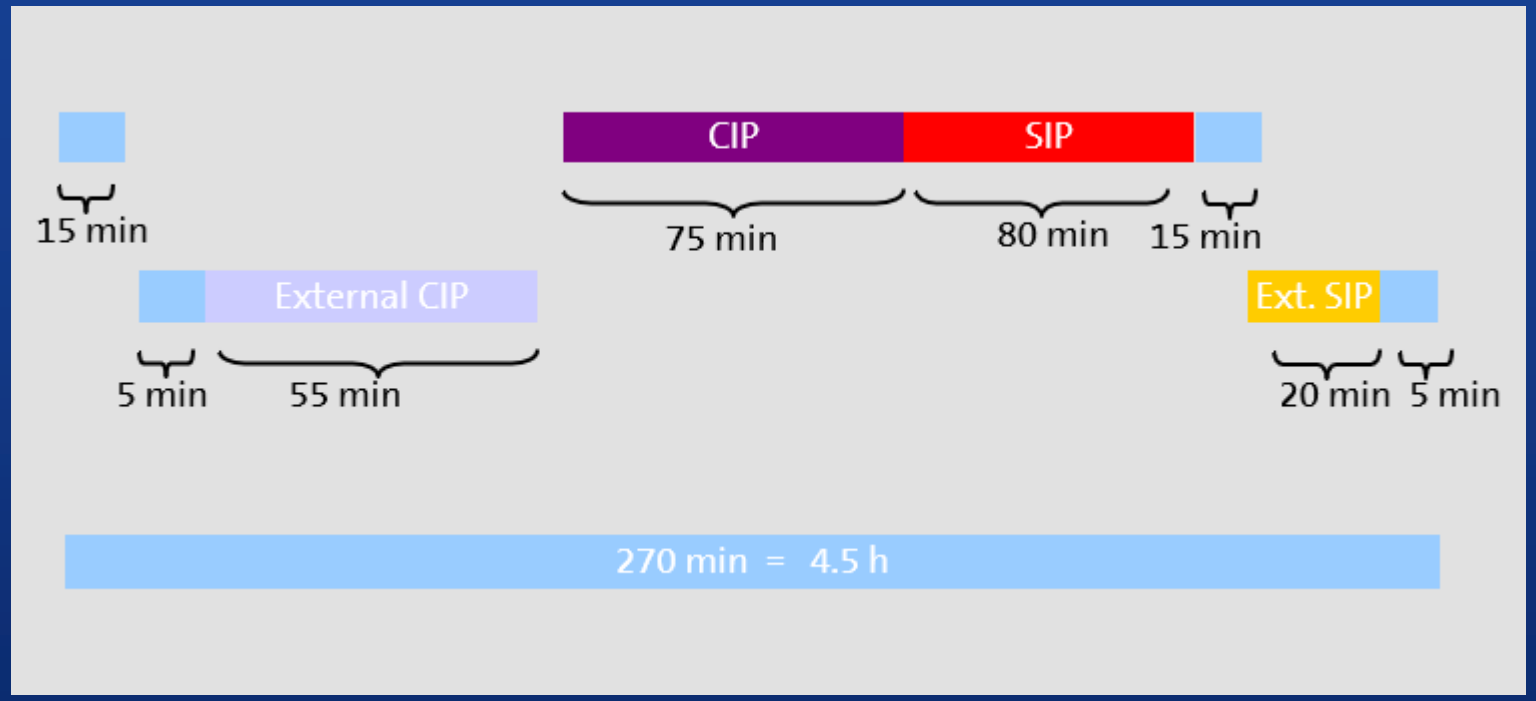
= 2,700 €/w

Cost for poor hygienic design:

= 55,080 €/w - 2,700 €/w = 52,380 €/w

- Poor hygienic design easily accounts for > 50,000 € per week

Standard procedure using foam cleaning



First step: external CIP

residence time of foam

no hot surfaces allowed because of foam

Second step: CIP with caustic
SIP with hot water

External SIP with peracetic acid
sterile water flush

- Using foam cleaning means a sequential procedure is necessary

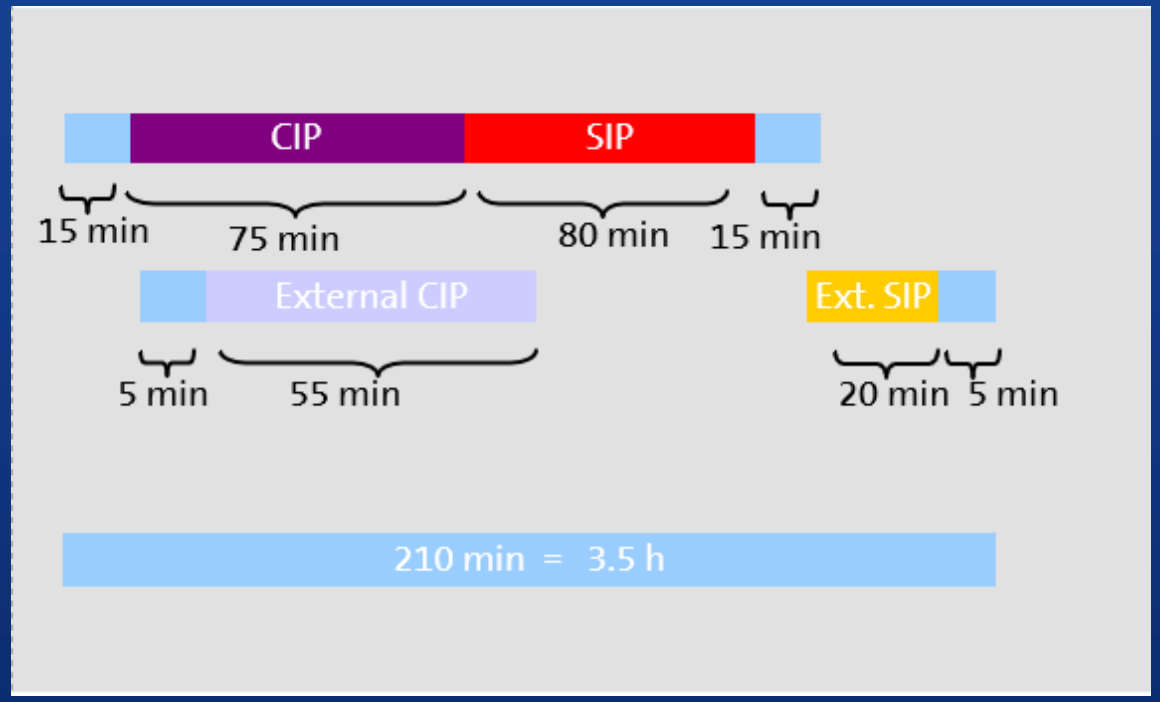
From large cleanroom to isolator technology

- Isolater technology is one enabler for external caustic cleaning

From manual to automatic CIP-cup insertion

- Automatic CIP-cups insertion saves downtime

Standard procedure using caustic cleaning



Parallel treatment of CIP/SIP and external

caustic cleaning of isolator surfaces

no residence time for caustic

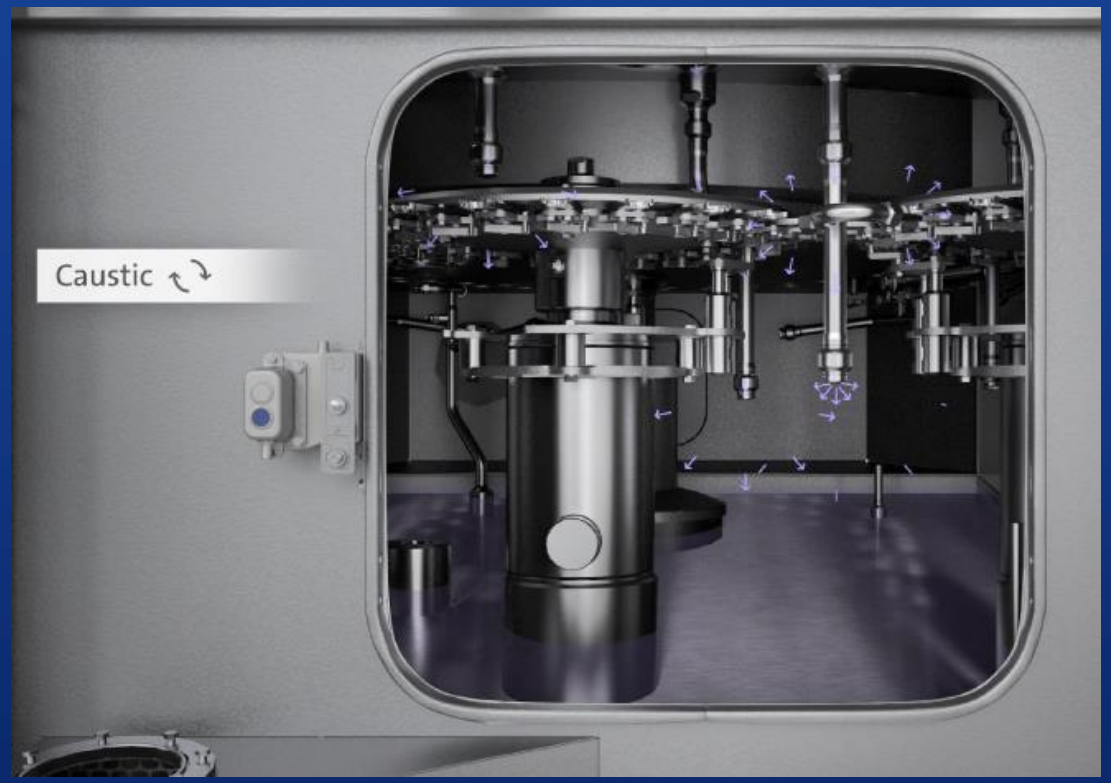
Hot isolator surface cleaning

External SIP with peracetic acid followed by sterile water flush

System needs to withstand heat and caustic treatment

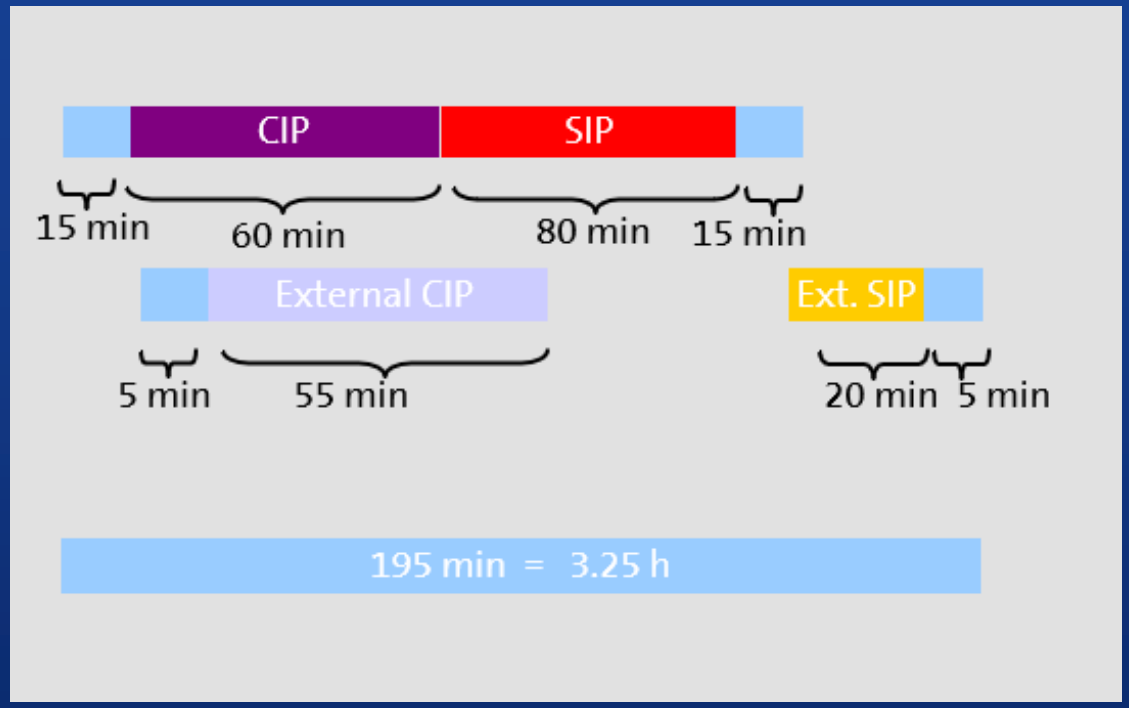
- External caustic cleaning is the enabler for parallel treatment

From foam cleaning to caustic cleaning



- Caustic cleaning is more efficient than foam cleaning

Procedure using a dedicated CIP-unit



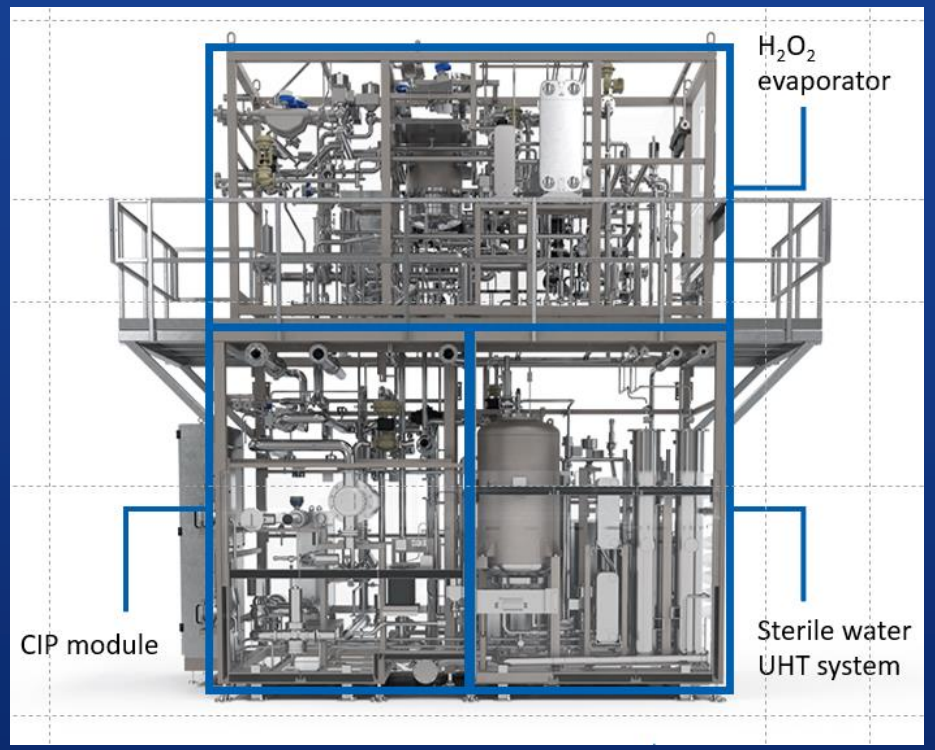
CIP media direct from CIP-Unit

no displacement of CIP media from CIP module to sterile tank

System needs to be able to heat up caustic quickly

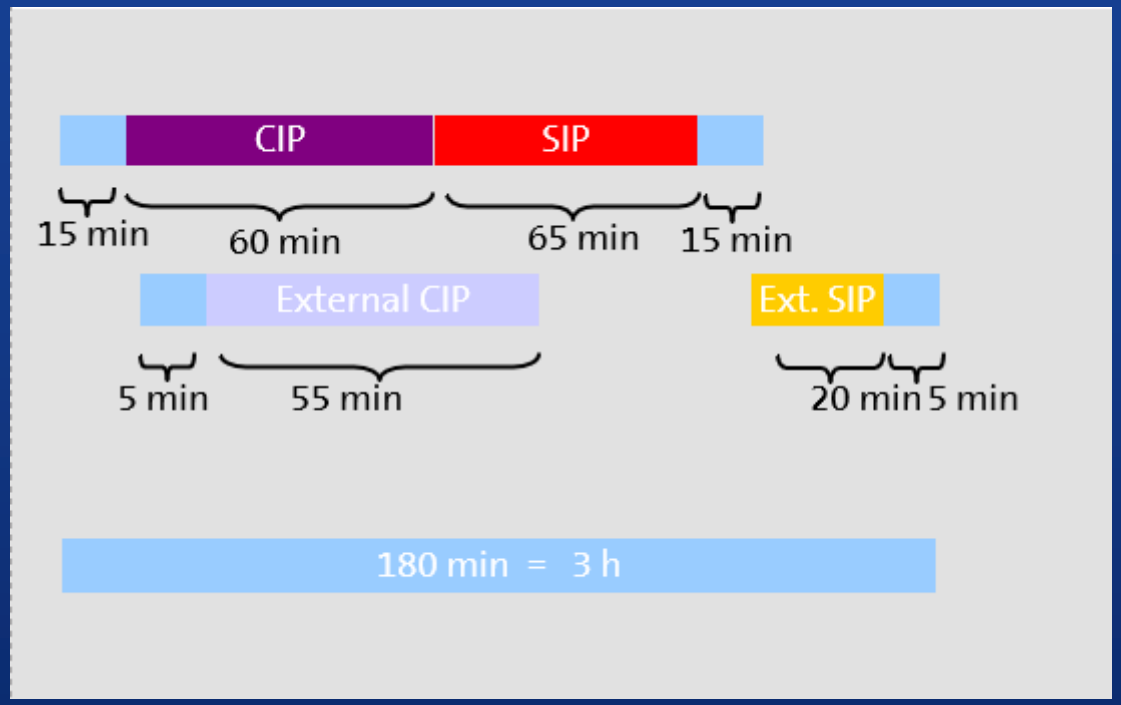
- Shortening preparation time by reducing system size

From existing CIP-plant to dedicated CIP-module



- Reducing system size and pipe length saves time and energy

Procedure using H_2O_2 and steam sterilization



SIP with steam

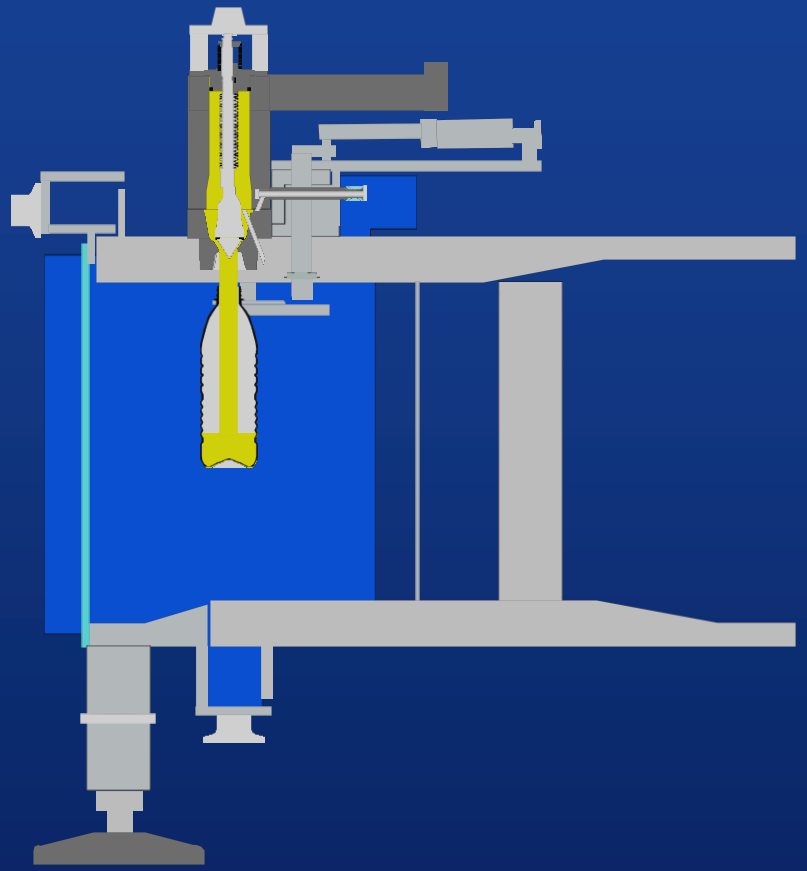
microbiological benefit

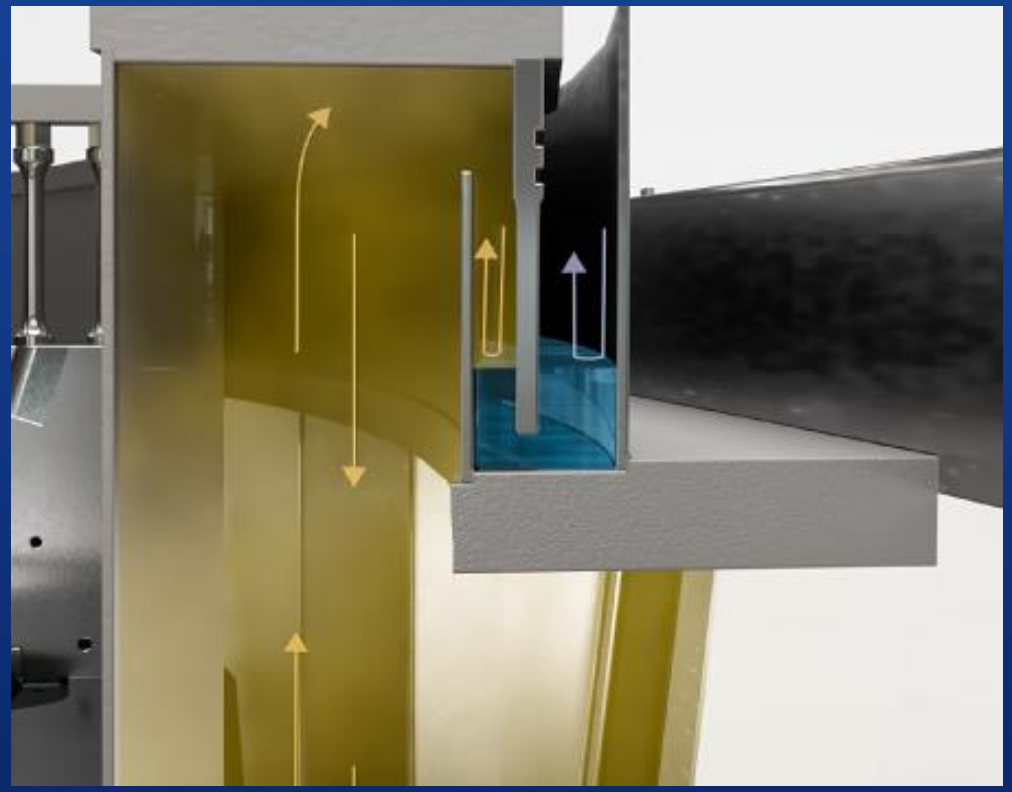
Gaseous external SIP with vapourized H_2O_2

Hygienic design for effective external sterilation necessary

- Reduced downtime with steam sterilization and gaseous ext. SIP

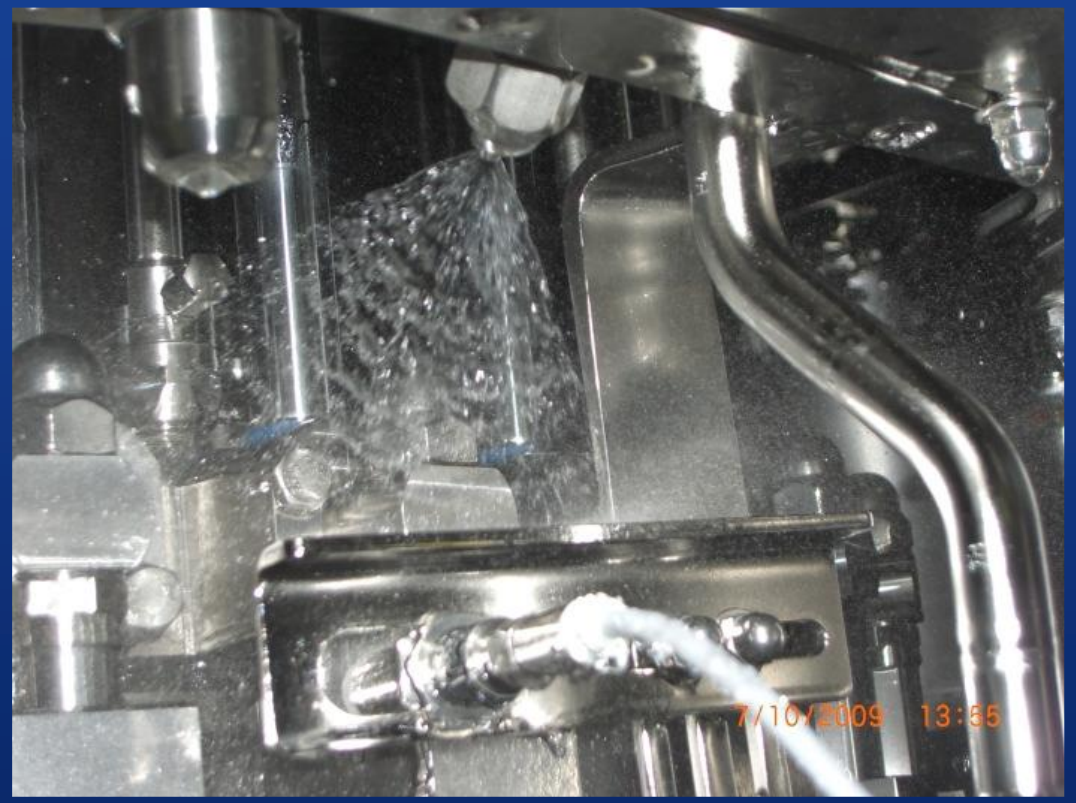
From grey zone to disinfectant lock

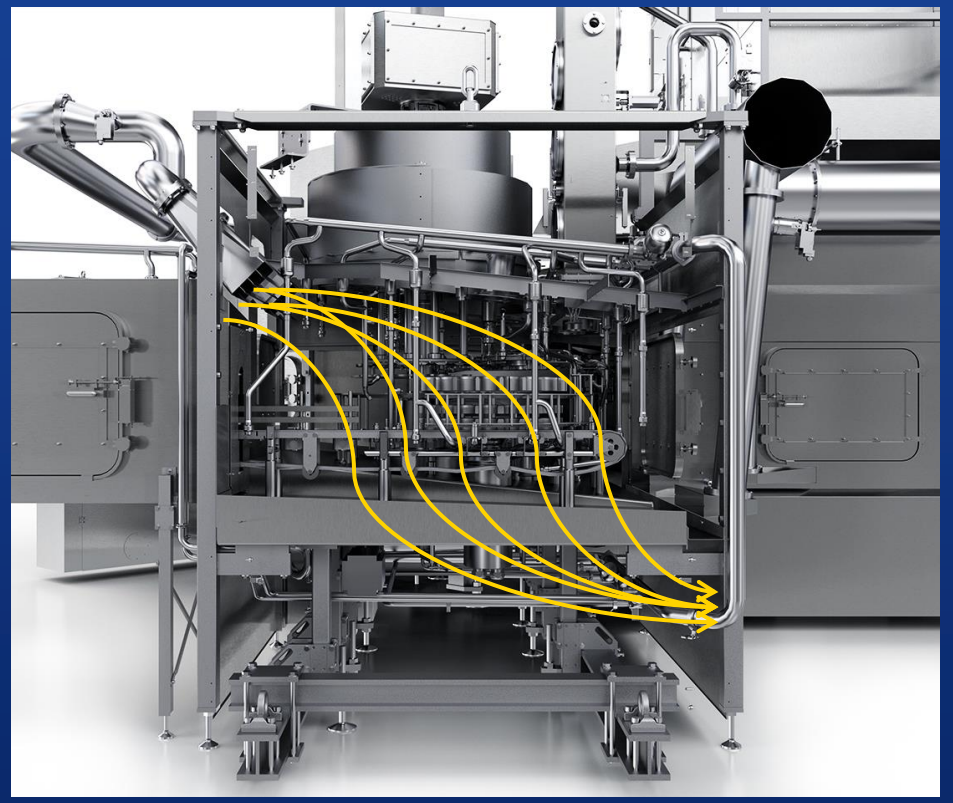




- A closed system reduces air flow and allows for quicker heating

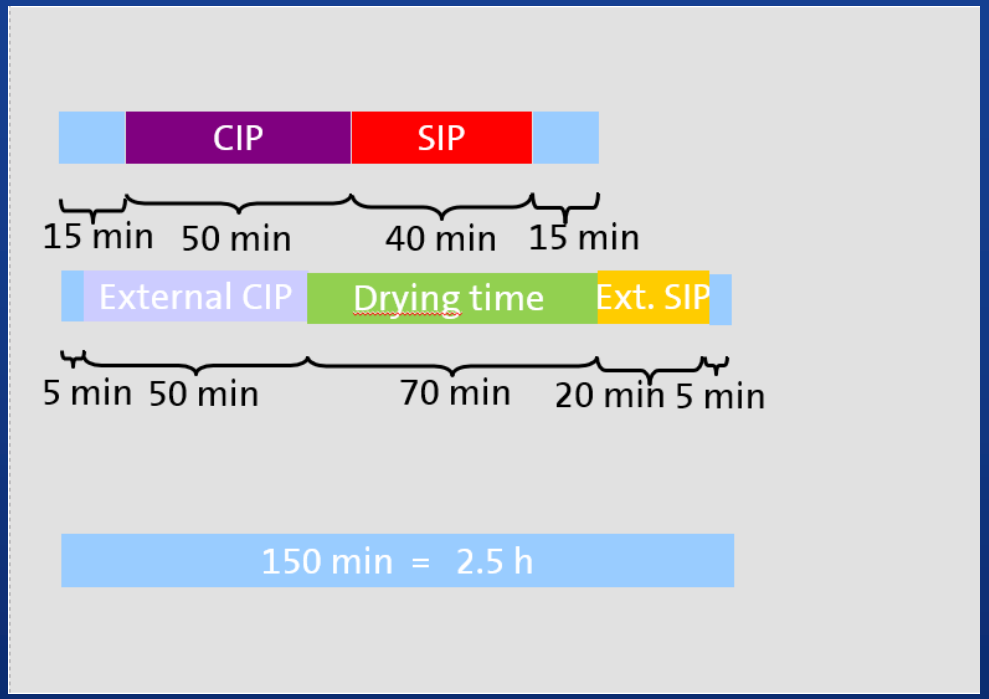
From wet to dry external sterilization





- Dry external sterilization needs freely accessible surfaces

Actual procedure for low acid products



Drying time is largely influenced by hygienic design of surfaces

Slanted and freely accessible areas dry within 5 minutes

Horizontal hydrophobic areas take up to 45 min. to dry (capper handling parts)

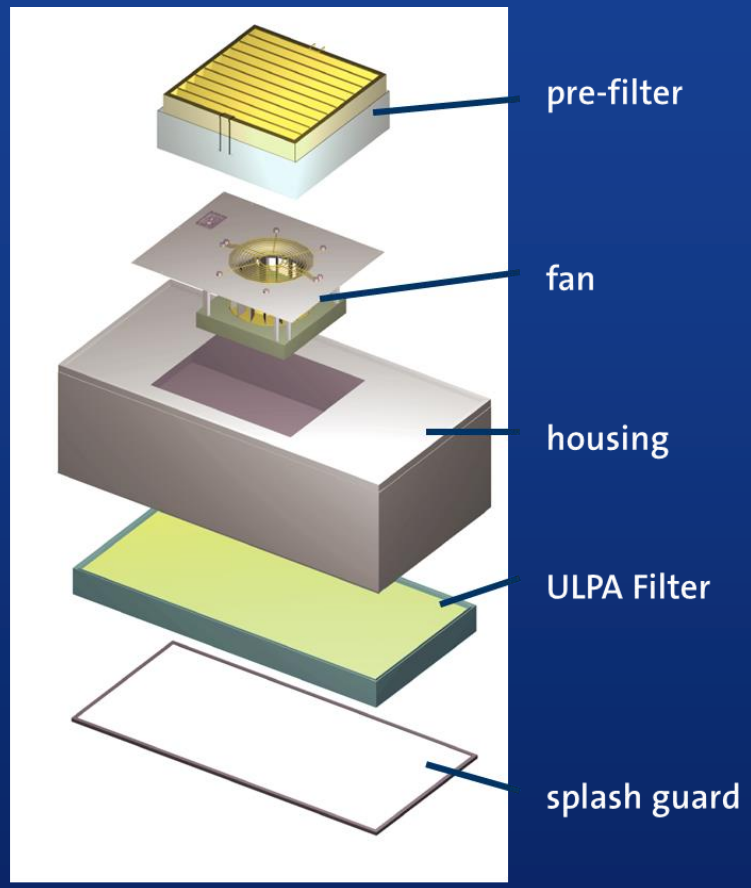
Further reductions possible

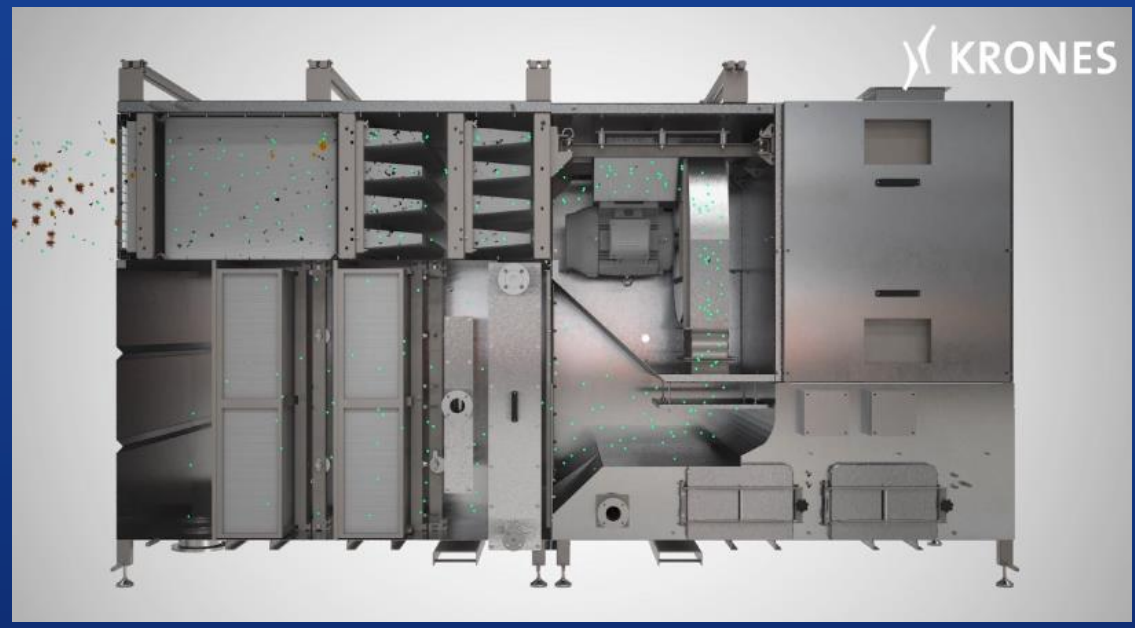
- Hygienic design determines the speed of drying to a large degree

From decentral to central air management

- Central air management allows for filter sterilization

From non-sterilizable to sterilizable filters





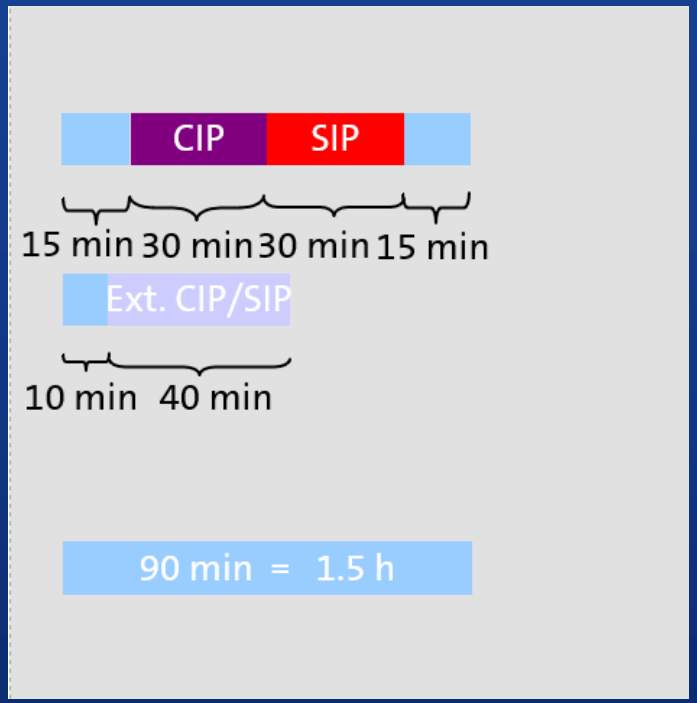
Preliminary filtration
Air treatment system
HEPA filtration
Exhaust air

- Removing another weak point in the system

From CIP-cups to SIP-cups

- SIP-cups for backpressure to increase sterilisation temperature

Actual procedure for CSD



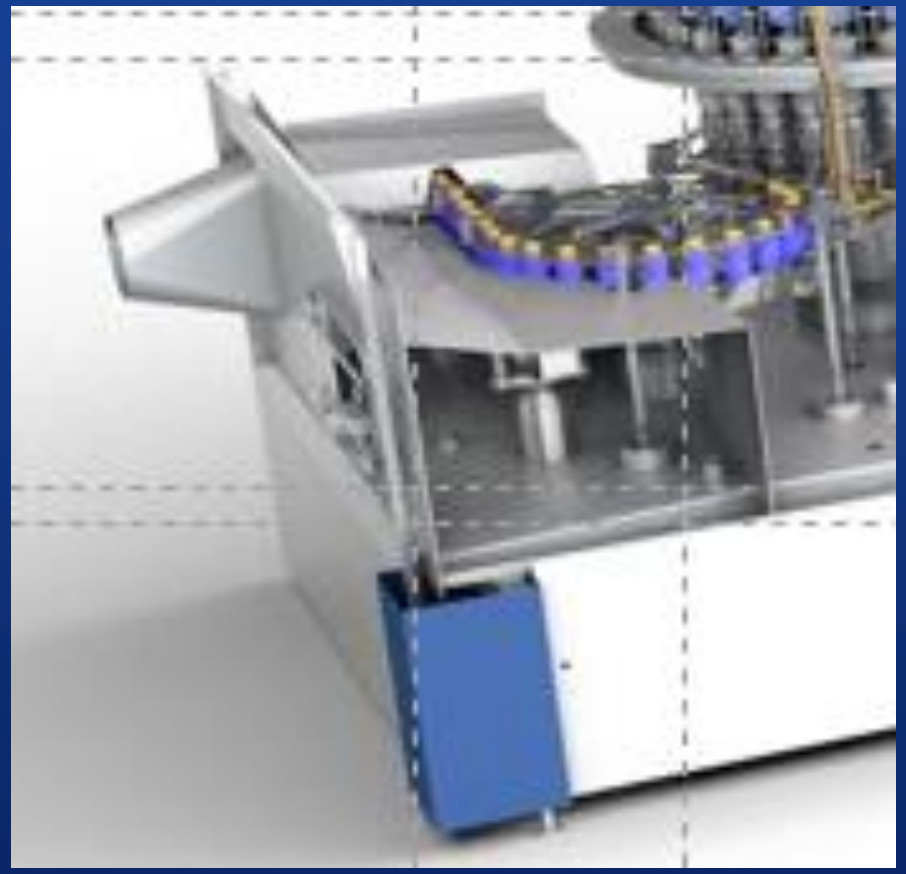
For carbonated softdrinks, where no moulds can grow, the procedure may even be reduced.
No extra external sterilization necessary, heating the system once with hot caustic is sufficient.
These products are sometimes filled on conventional lines with proper hygiene management.

- With hygienically designed systems, even less effort is necessary

From drives in the cleanroom to bellows

- The capper is the most critical part in the system

Reducing risk in the discharge area



- The conveyor belt does not leave and enter the sterile zone anymore

Conclusion

- Hygienic design helps to reduce planned downtimes to a large degree, increasing product safety at the same time
- The system design needs to be adapted to modern cleaning and sterilization regimes
- Still potential to reduce drying time is accessible through hygienic design
- Poor hygienic design accounts to over 50.000 € lost profit per week in the shown example