ISPE D / A / CH

BAUSCH+STRÖBEL

Robotic Gloveless Fill & Finish Platform “GENEX”

MARCEL WEIZEL

RAYA 2025 Finalist Event

“ 50% of deviations in aseptic manufacturing are caused by human error according to an internal survey of the BioPhorum

? Can we eliminate human errors in traditional fill&finish processes?

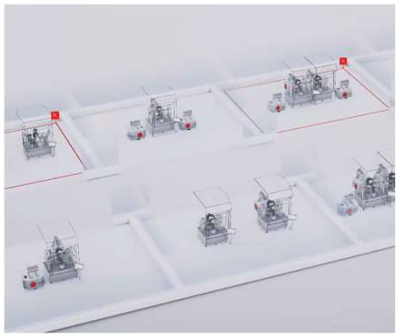
ANNEX 1

APPROPRIATE TECHNOLOGIES

Robotic systems – The journey

Robotics for transportation or de-lidding, de-nesting, ...

Using advanced technologies for aseptic interventions in gloveless isolators



Using autonomus robotic systems to reduce operation actions in cleanrooms

Past — Today → Future

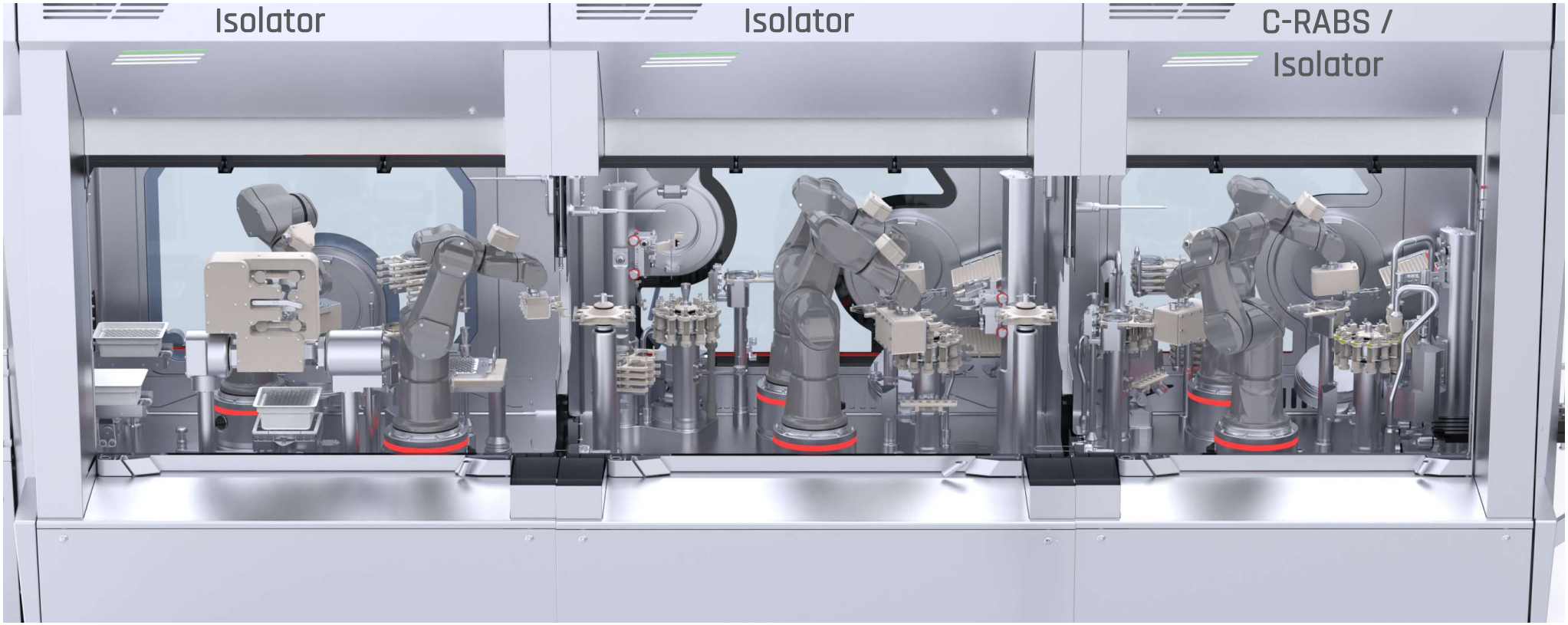
Robotic gloveless fill&finish platforms are the next leap for sterility assurance, product/operator safety and enabler for lights-out-facilities

- Line st-up
- Container transport
- Surface monitoring
- Size changeover
- Line clearance
- Closure handling
- Material transfer
- Trouble-shooting

The X-Factor in aseptic processing is robotic and gloveless

GENEX functional overview

Delidding & Denesting | **Filling & Stoppering** | **Capping**

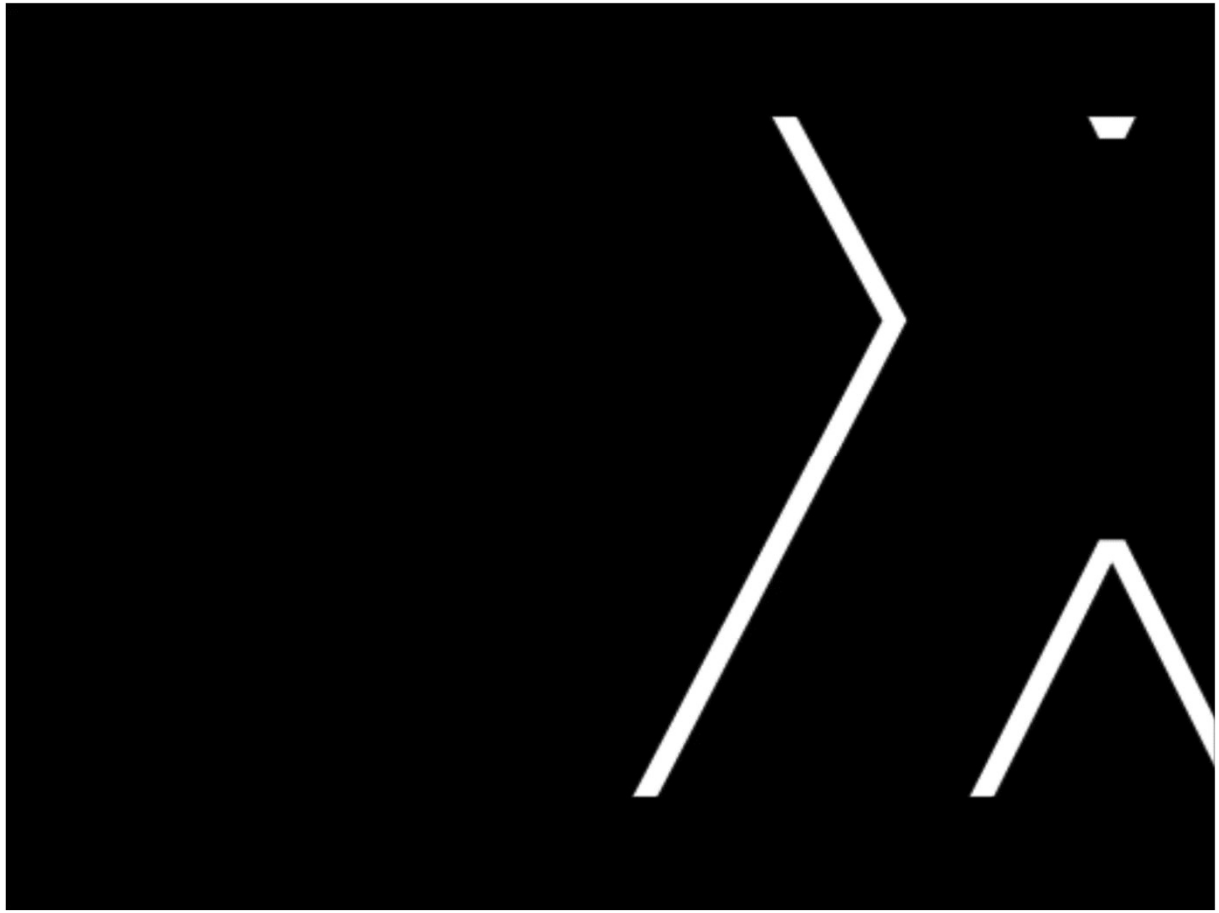


ANNEX 1

APPROPRIATE TECHNOLOGIES

GENEX

Gloveless preparation & operation



ANNEX 1

APPROPRIATE TECHNOLOGIES

Robotic systems

What are their added-values?

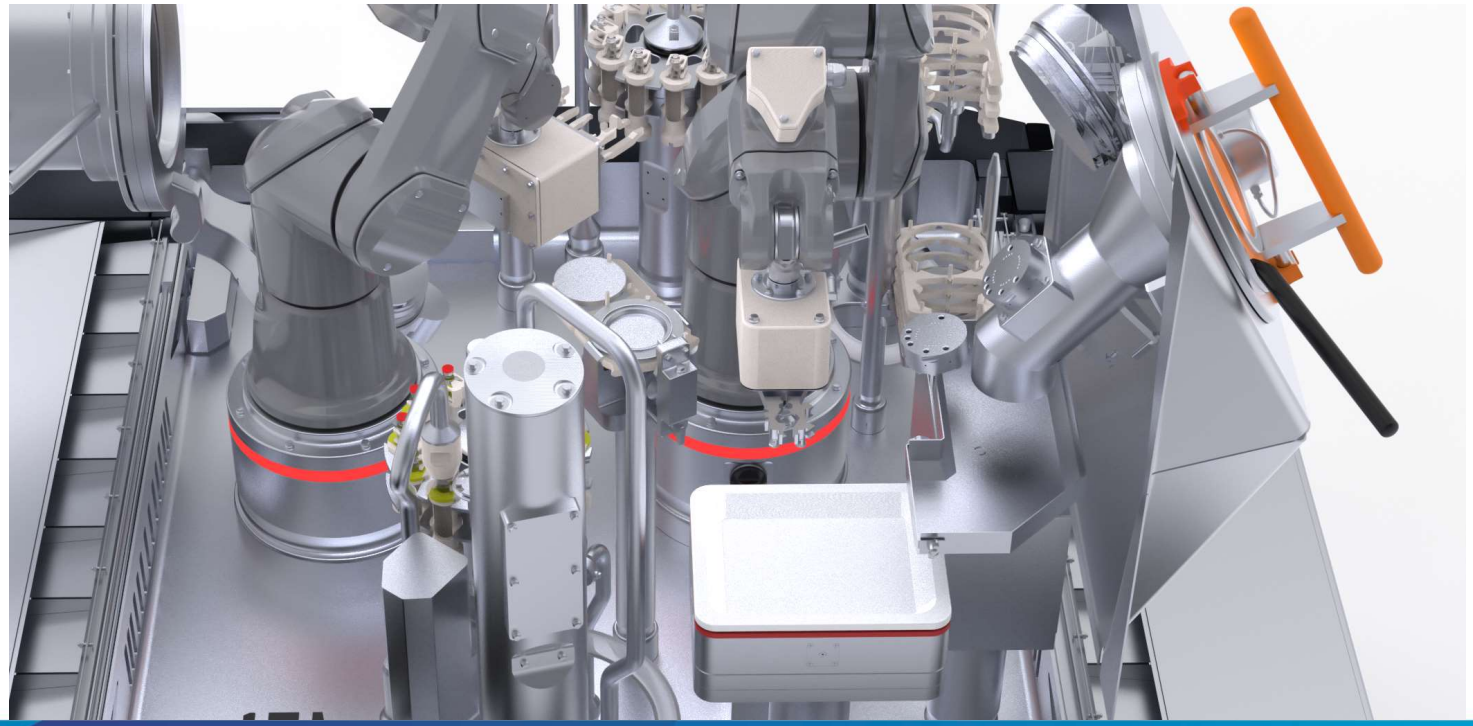
ANNEX 1

APPROPRIATE TECHNOLOGIES

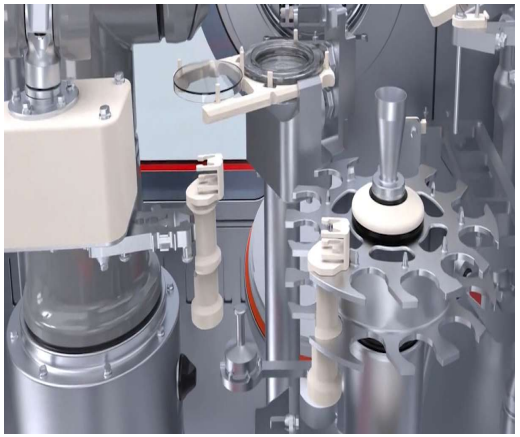
GENEX

Elimination of human intervention

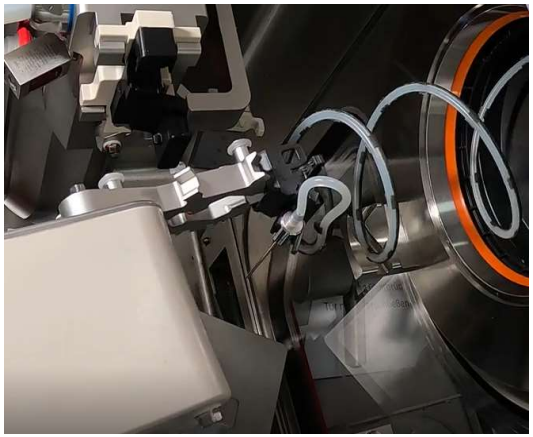
Robotic supported installation of autoclaved direct and indirect product contact parts after Biodecontamination of the isolator



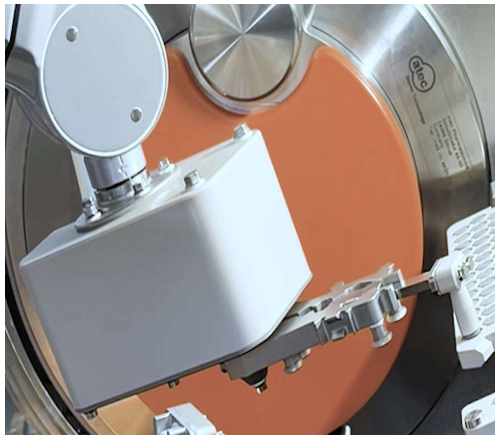
GENEX Robotic supported installation of autoclaved direct and indirect product contact parts



Installation of autoclaved format size parts

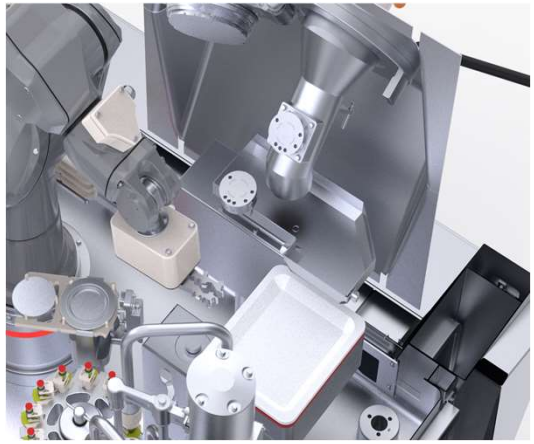


Robotic product path set-up

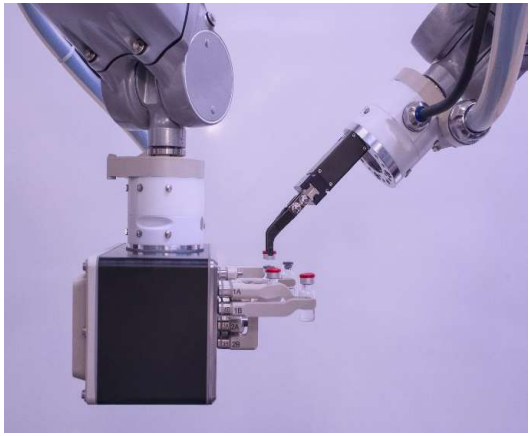


Individual closure handling

GENEX Robotic supported installation of autoclaved direct and indirect product contact parts



Installation of indirect product contact parts



Robotic tool changer

Surface Monitoring at any sample point possible (filling needle included)

GENEX Robotic Environmental Monitoring

Biomonitoring settle plate storage

Automated settle plate handling

Automated surface monitoring

ANNEX 1

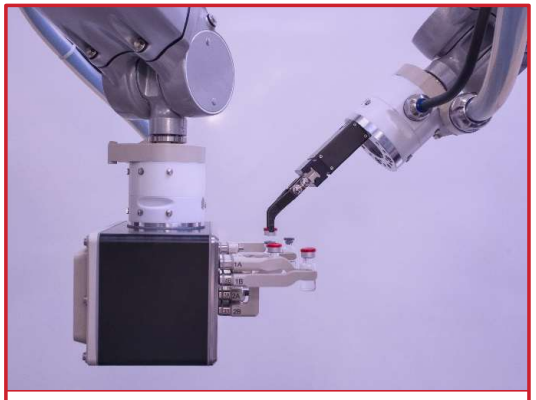
APPROPRIATE TECHNOLOGIES

Robotic systems – Benefits

Enabler for corrective and unplanned interventions in a gloveless isolator

Corrective intervention – An intervention that is performed to correct or adjust an aseptic process during its execution. These may not occur at a set frequency in the routine aseptic process. Examples include such as clearing component jams, stopping leaks, adjusting sensors, and replacing equipment components.

Telemanipulation (Source: Stäubli Robotics)



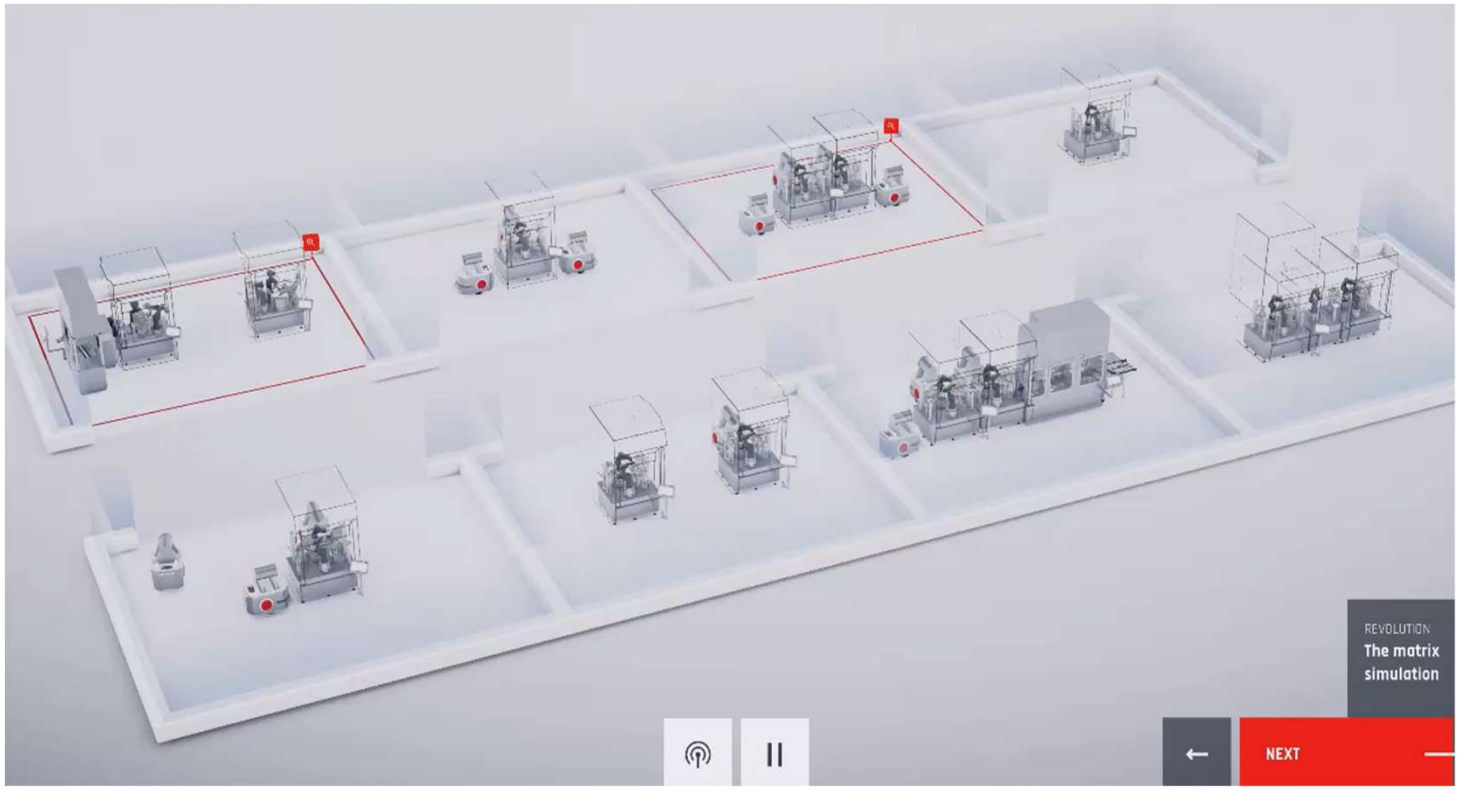
Robotic tool changer

Rescue glove (Source: Getinge)

Robotics as a key enabler for matrix production

GENEX THE MATRIX APPROACH

Autonomous production by using mobile robotics for material transfer in sterile containers



GENEX

FEATURES

SCALE **OUT**

NEXT LEVEL
HYGIENIC DESIGN

ELIMINATE HUMAN
INTERACTION

PROCESSING
VARIOUS PACKAGING
MATERIALS

ZERO REJECT

GMP, **FDA**, **ANNEX 1**
CONFORMING MACHINE
DESIGN

SHORT
DECONTAMINATIONS
CYCLE

INTEGRATED
SYSTEM