

# Processing of cells and tissues

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# INTRODUCTION

- Company BLOCK has been founded in 1991 in the Czech Republic
- Main activities are in pharmaceutical industry, biotechnology, R&D, microelectronics and health service
- Producer of clean rooms and equipment like walls, doors, ceiling system, SS furniture and isolators
- More than 450 employees in group
- Main target markets are CZ, SK, RU and DACH



# Sterile production

*What is the sterile production?*

- The most difficult production in pharmaceutical industry
- Production covered by clean rooms in required conditions with appropriate filtration class in accordance with EN ISO 14644
- Production preventing microbiological and particle contamination
- Solutions for sterile production
  1. Terminal sterilization (in final packaging)
  2. Aseptic production (for whole or part of the production)



# Sterile production

## *Requirements*

- Production in dedicated cleanliness classes:
  - „A“ for filling process
  - „C“ for compounding, weighing, etc.
  - „D“ for material preparation or manipulation
- People and material enter clean rooms via material/personal airlocks
- All clean rooms must be under control of:
  - particle measuring
  - microbiological monitoring
- Big potential for isolator technology



# Sterile production

## *Isolator technology*

- Minimized microbiological contamination
- Minimized personal innervation into the process
- Aseptic processes covered by class „D“
- One of the biggest risk of contamination is material transfer into the isolator
- Whole process validated before the start up
- Tightness class of the isolator in accordance with ISO 10648-2 and regularly checked
- Regular tests also for glove's tightness



# Handling of cells and tissues

- Working with cells and tissues has increased in recent years
- Biological material must be processed in sterile conditions
- Material comes from:
  - genetically modified cells
  - tissues from donors
- Used for biological kind of treatment
- Main activities with those materials
  - cell removal
  - filtering
  - separation
  - centrifuging
  - cultivation



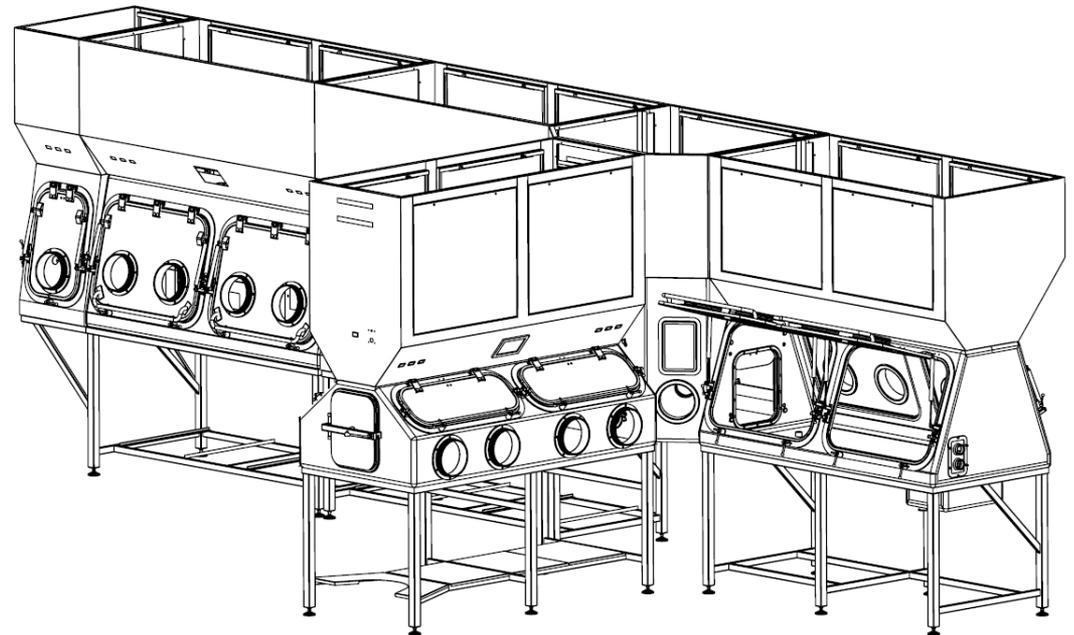
# Isolator technology for cells and tissues

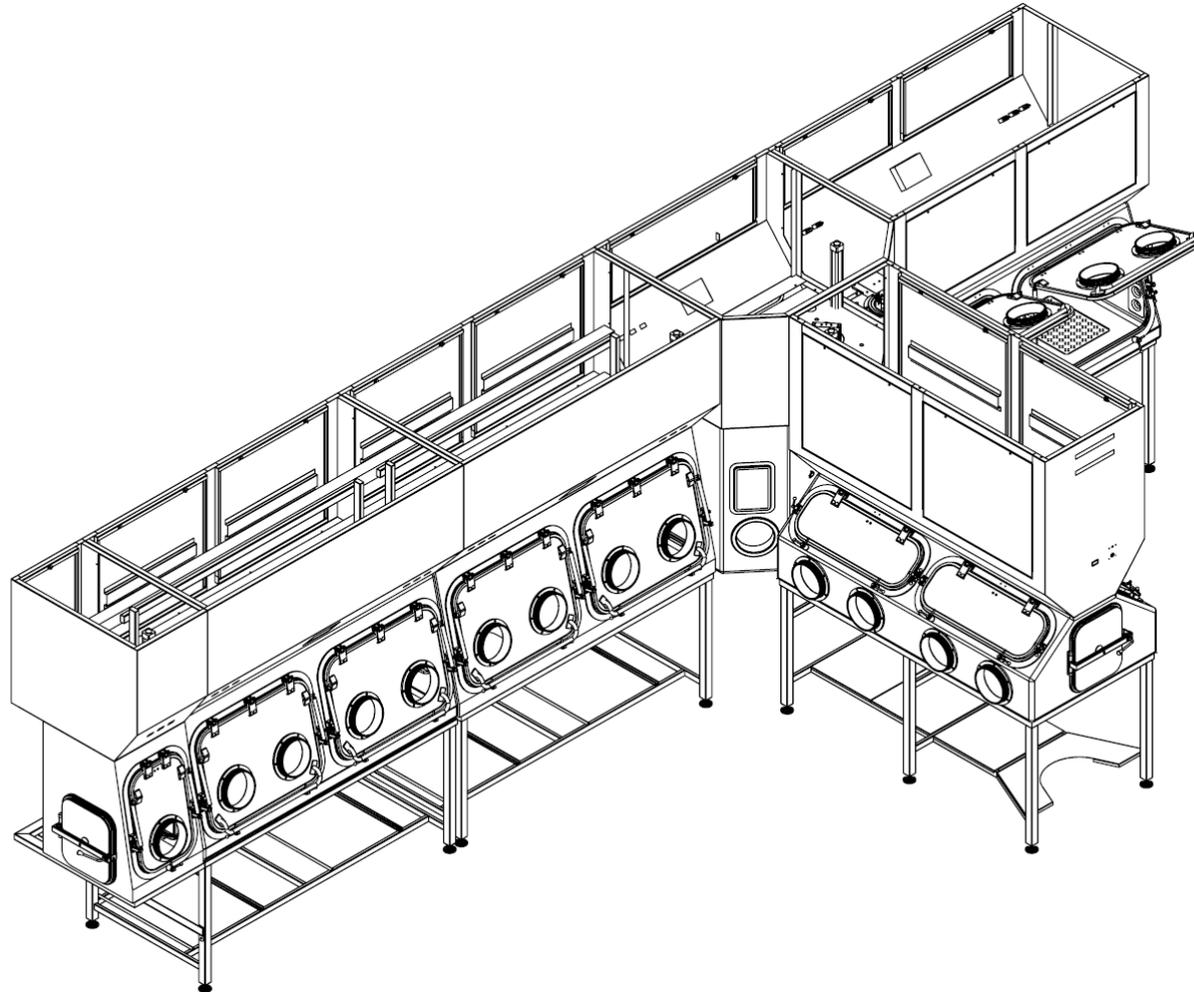
- Design is one the most important part of the sterile isolators
- Required integration of supportive devices
- Decontamination provided by VHP generators
- Required positive pressure inside of the isolator's chambers for product protection
- Each chamber equipped with isokinetic probe for particle measuring
- Microbiological monitoring is required:
  - petri dish located in chamber
  - active microbiological monitoring with automatic system
- Whole process validated and revalidated for future purpose according to GMP rules



# Isolator for tissues

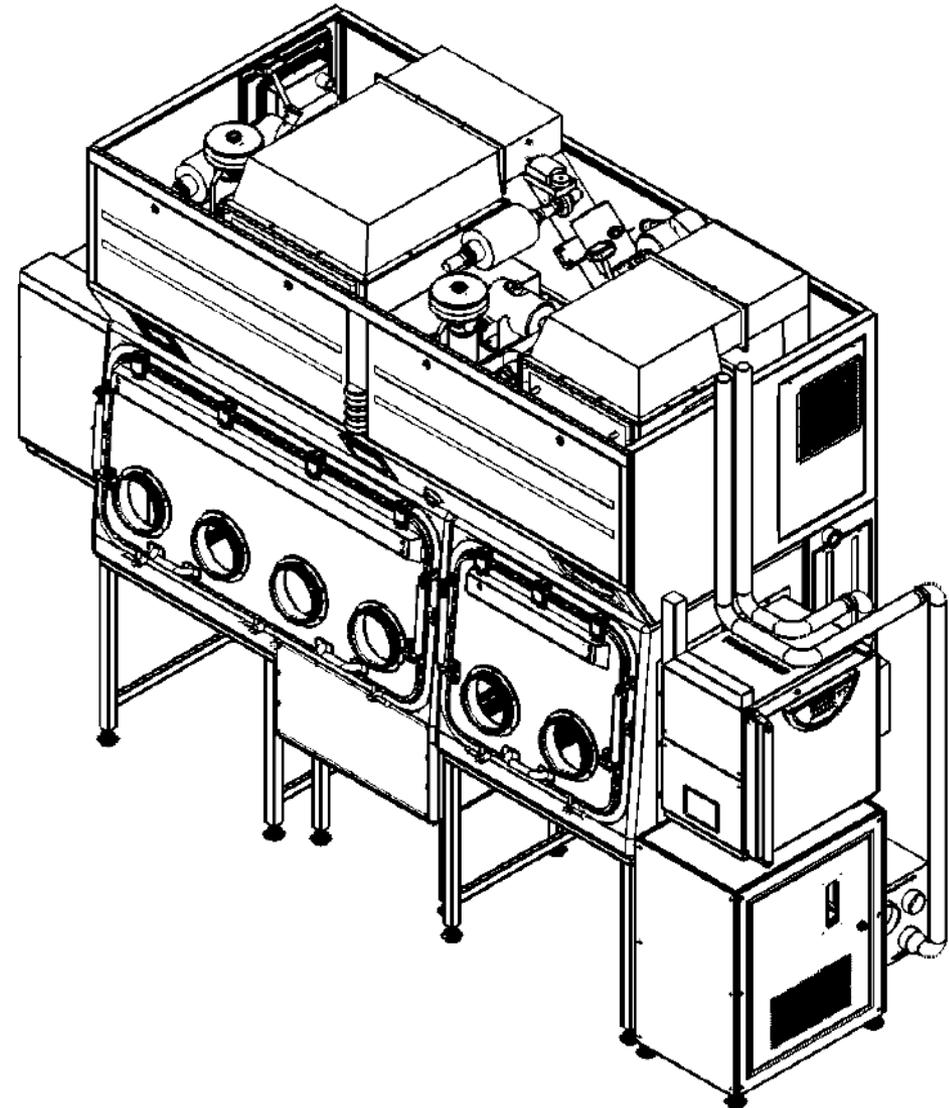
- Processing of human's materials
- Class „A“ with laminar flow
- Positive pressure
- Sterilization by VHP generator



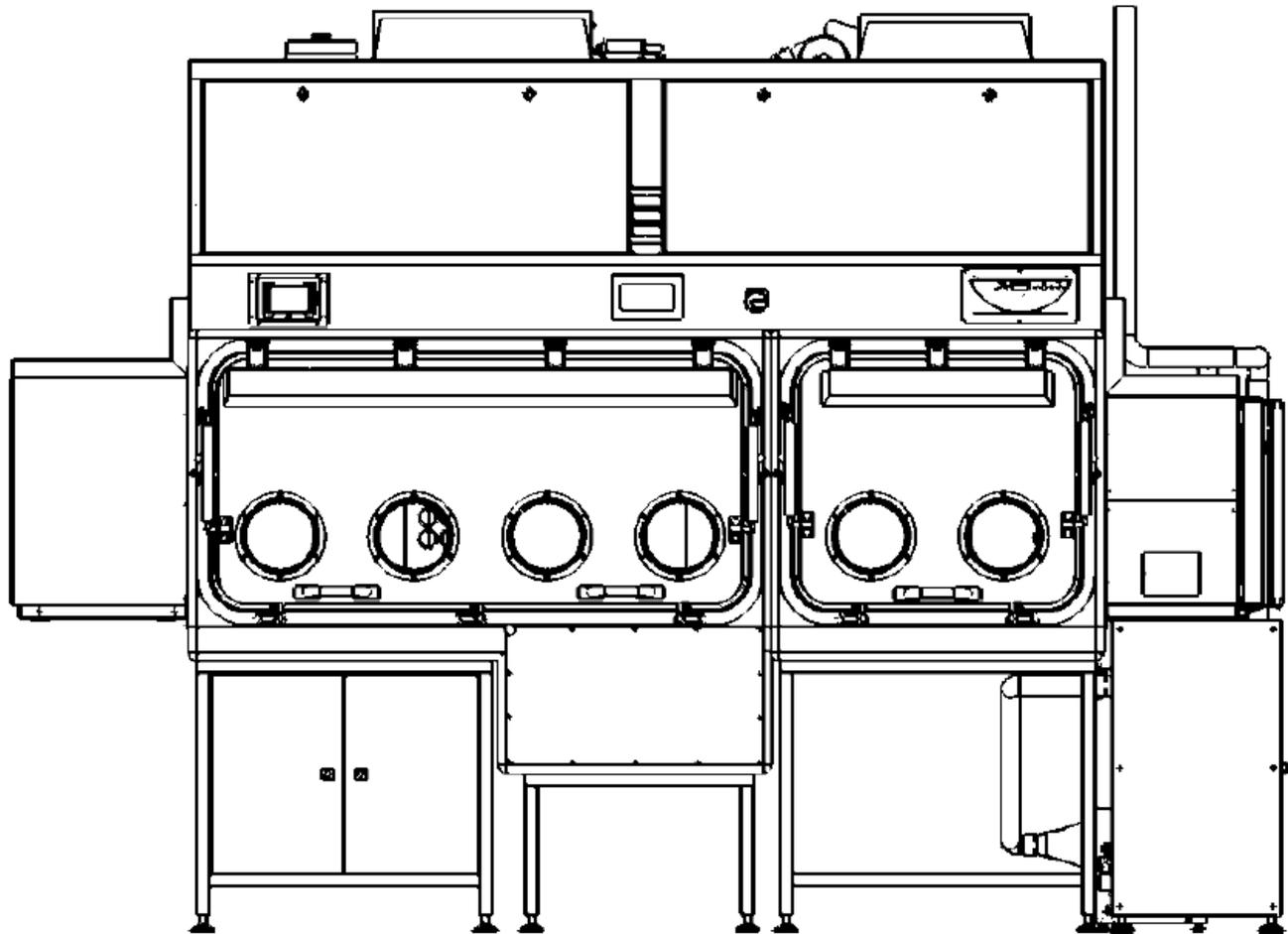


## Isolator for cells

- Processing of animal materials
- Class „A“ with laminar flow
- Positive pressure
- Sterilization by VHP generator
- Integrated steam sterilizer
- Integrated CO<sub>2</sub> incubator
- Integrated centrifuge



## Isolator for cells







**THANK YOU  
FOR YOUR ATTENTION**

