



#sharing challenges  
and solutions in practice

# Disposable Isolator

Advantages, weaknesses, limits, recycling and sustainability

Part of PharmaCongress – Düsseldorf/Neuss, 31 May–1 June 2022

# Usage, Setup and implementation of Disposable Isolator for sterile manufacturing

- GTP Nano
- Why a disposable Isolator
- Clinical products and Orphan drugs
- API nano vectors creation
- Advantages
- Pitfalls and weakness
- Limits
- Recycling and planet sustainability
- Conclusion



GTP Nano

#sharing challenges  
and solutions in practice

Part of PharmaCongress – Düsseldorf/Neuss, 31 May–1 June 2022

# Worldwide unique sterile platform using HPH in GMP conditions

HPH equipment dedicated to GMP manufacturing of nanodrugs

- Preparation under isolator (with H<sub>2</sub>O<sub>2</sub> sterilisation)
- HPH going up to 1500 bars
- From 5 liters to 60 liters
- Top down processes
- Bottom up processes
- Nanonization processes
- Full CIP/SIP system



## UNIQUE CAPACITIES

- Aqueous phase liquid
- Highly viscous bulk
- Automatic filling process
- Dose control
- Disposable isolator for filling and stoppering
- Semi manual capping station





## Disposable Isolator ?

#sharing challenges  
and solutions in practice

Part of PharmaCongress – Düsseldorf/Neuss, 31 May–1 June 2022

# Isolators vs RABS and Standard environment



- Main issues for aseptic filling
  - Containment
  - Sterility assessment
  - MFT
  - Critical area in Grade A
  - Cleaning efficiency
  - Cross contamination
- Alternatives
  - RABS / Grade A
  - 6 Log SAL
  - Sterile Hold times extended
  - Human in critical area
  - No Cleaning
  - No cross contamination



## Clinical Products and Orphan Drugs

#sharing challenges  
and solutions in practice

Part of PharmaCongress – Düsseldorf/Neuss, 31 May–1 June 2022

# Small is beautiful

- Targeted therapies
  - Small to hypersmall quantities
  - Flexibility
  - Efficiency
- Innovative drugs
  - Reactive process
  - Easy change overs
  - Specially designed filling lines
- Adaptative filling processes
  - Nano encapsulation
  - Vector preparation
  - Highly potent products
  - Active vaccines
  - Inactivated vaccines
  - ATMP production
- What is the next step
  - Correlation between patient and therapy
  - Highly effective process flow
    - Patient collection
    - Cell modification and selection
    - Halo-injection





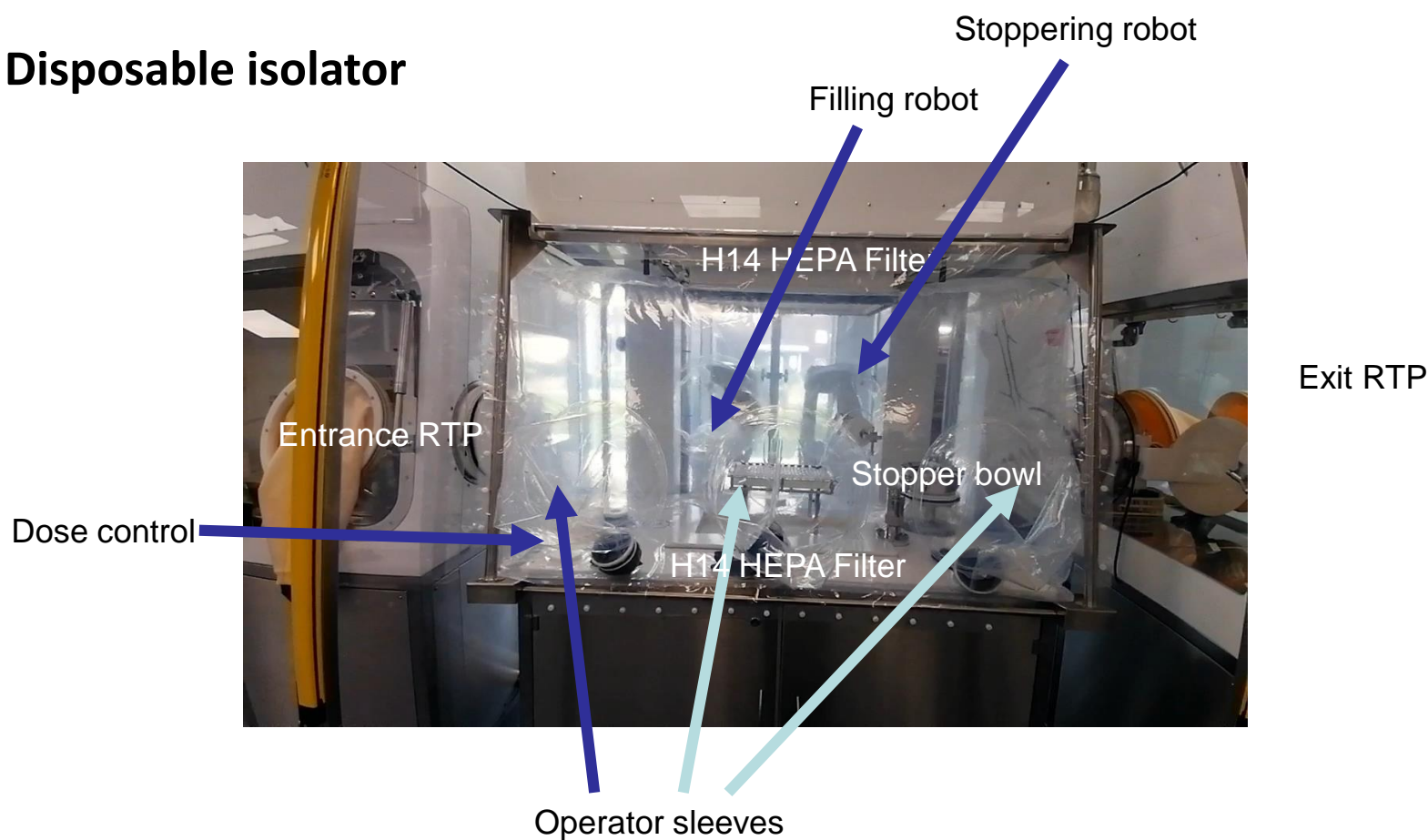


## Advantages of Disposable isolators

#sharing challenges  
and solutions in practice

Part of PharmaCongress – Düsseldorf/Neuss, 31 May–1 June 2022

# Disposable isolator





## Pitfalls and weakness

#sharing challenges  
and solutions in practice

Part of PharmaCongress – Düsseldorf/Neuss, 31 May–1 June 2022

# Peatfalls and weakness

- Highly automated environment
- High skilled staff
- Masterize
  - Sterility environment
  - Filling and stoppering activities
- Part of non disposable environment
- Formulation activities not involved
- Increased solid wastes





## Recycling

#sharing challenges  
and solutions in practice

Part of PharmaCongress – Düsseldorf/Neuss, 31 May–1 June 2022

# Plastic recycling

- Disposable but recycling is possible
- Incinerated in case of Cytotoxic manufacturing
  - Solid waste increase
  - Liquid waste decrease drastically
- No recycling flow yet for such devices





## Conclusion

#sharing challenges  
and solutions in practice

Part of PharmaCongress – Düsseldorf/Neuss, 31 May–1 June 2022

# New manufacturing environment

- Highly efficient and reliable
- Low throughput but increased SAL
- Recycling stream to be initiated
- SMED ready
- No format parts anymore by using 3 axis robots







#sharing challenges  
and solutions in practice

Thanks for your attention

Question & Answers

Part of PharmaCongress – Düsseldorf/Neuss, 31 May–1 June 2022