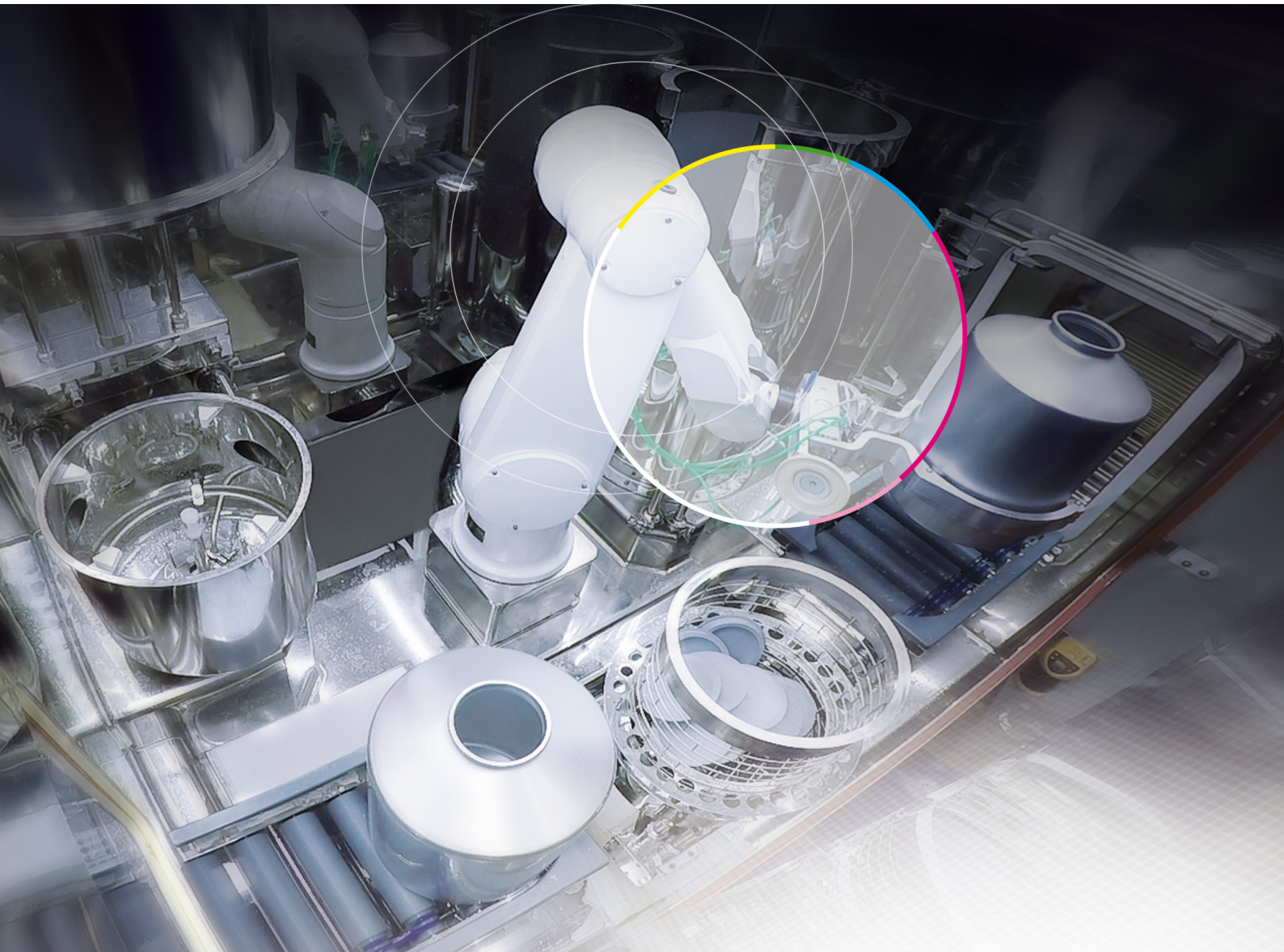


# ASEPTIC HANDLING AND FILLING

## OF BULK API POWDER IN PHARMA



CUSTOM SOLUTION FOR **YOUR BULK STERILE MANUFACTURING**



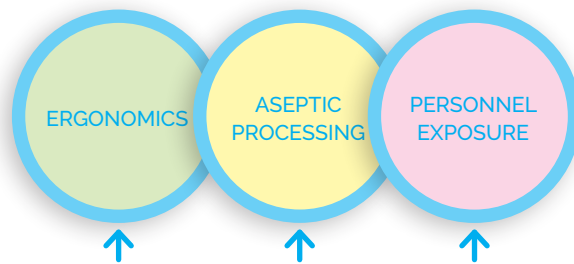
**COMECER**

an  company

# ASEPTIC HANDLING AND FILLING

## OF BULK API POWDER IN PHARMA

### Challenges with bulk sterile powder



### Several types of containers

Comecer solutions for Bulk API Powder Aseptic Handling and Filling in Pharma are compatible with all different types of containers.



ALU KEG



BOTTLE SHAPED BAG



PE KEG



RTP BAG

### Isolator or RABs?

An ISOLATOR is a *barrier systems well defined (physical) that can be validated to provide significant risk reduction of bio-contamination*. An isolator provides an uncompromised, continuous, Grade A isolation of its interior from the surrounding environment.

A RABS is a *combinations of physical and aerodynamic barrier over the aseptic process zone*. RABS is an alternative contamination control methodology designed to be used in a higher classification cleanroom (EU Grade B – ISO 7 minimum) and based on systems of less engineering complexity.

#### Why Comecer prefers the isolator?

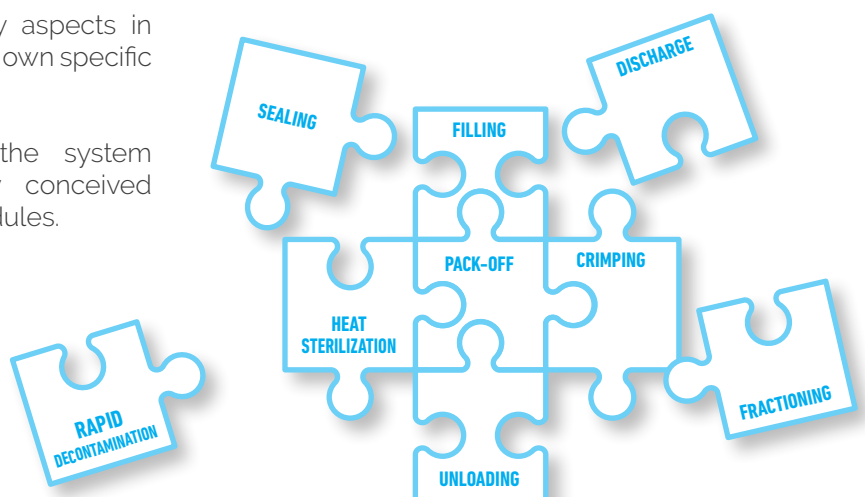
Given the complete separation between the operators and the aseptic area, the isolator solutions are more likely implemented together with a certain level of automation when the batch sizes are significant. Same when the API

has in some extent containment need the solution with isolator is a must. On the other hand RABs can be adopted when an extremely manual operation is carried out and no issue of containment is involved.

### Process ad hoc design

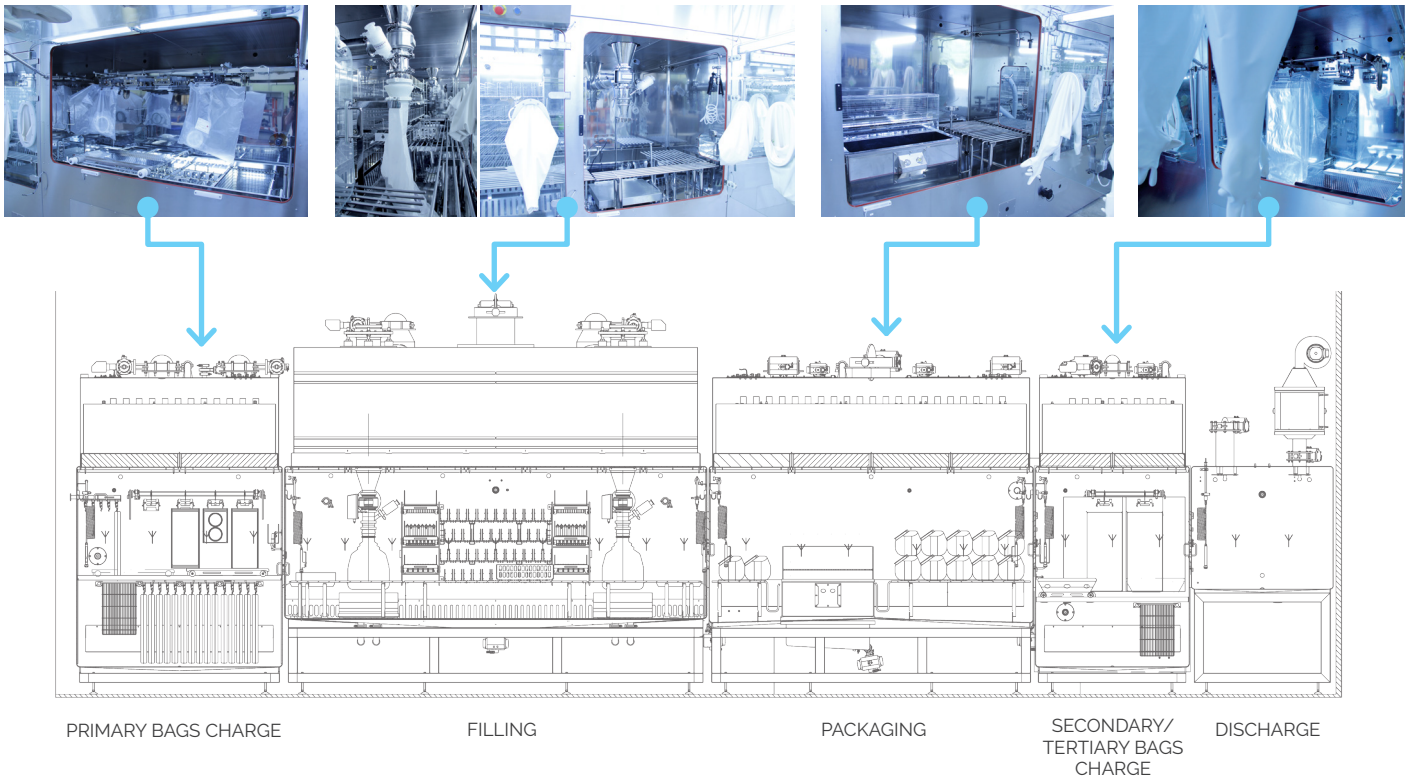
All the Bulk Sterile processes have many aspects in common, however every application has its own specific requirements and constraints.

For this reason Comecer re-designs the system configuration ad hoc integrating newly conceived solutions to already adopted functional modules.

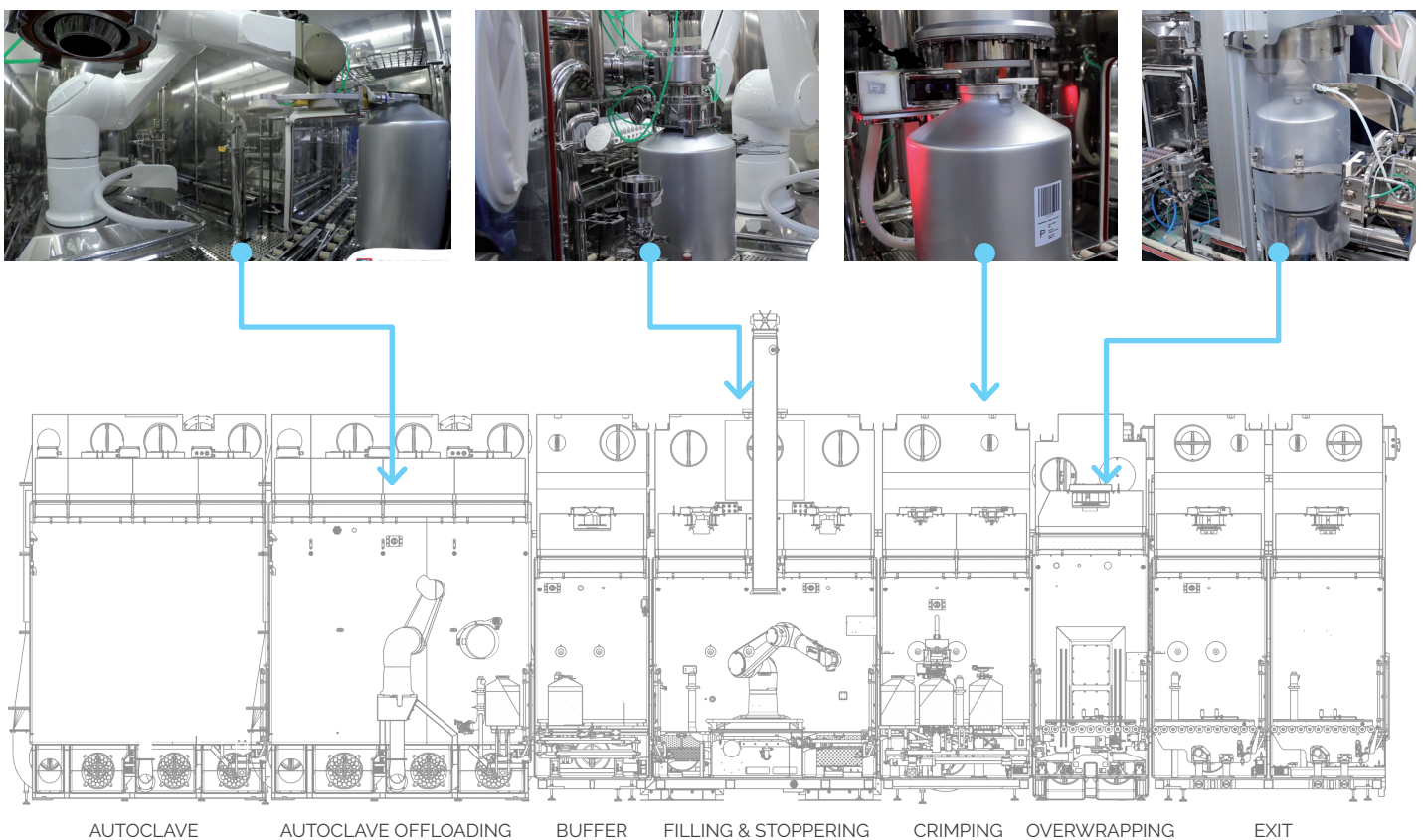




## Example of manual solution for bags within isolator



## Example of automated solution for kegs within isolator



## STATE-OF-THE-ART FEATURES

- Stainless steel AISI 316L enclosure with external Scotch-Brite and internal Mirror-Brite
- Complete custom aseptic multi-chamber isolator and custom fitting
- Custom container (different types of kegs or bags)
- Laminar airflow on working area with highest recirculation rate
- Integration of dosing and weighing system with automatic valve and scale feedback control
- Integration of primary and final packaging system with thermal welder
- Integrated bio-decontamination systems using the hydrogen peroxide solution
- Automatic discharge station under aseptic condition
- Automatic washing and drying in isolator
- Autoclave offloading with anthropomorphic robot under Grade A isolator
- CIP and SIP automatic setup on all product contact parts

## APPLICATION: QUALITY CONTROL FOR API BULK POWDER



- Media transfer into isolator with thru the wall aseptic port
- Manual conveyor for assisted ergonomic transfer of product sample
- Integration of peristaltic pumps for media dilution
- Automatic oscillating mixer to implement dilution recipe
- Autoclave integration for incubation customized plate



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