PSL – Microsphere summit 2025

Robotic Transport and Filling of Microspheres: Ensuring Sterility and Product Integrity

Philippe Sporen – ROMACO Macofar

ROMACO: Who are we?

one stop solutions
processing and packaging equipment

ROMACO beyond technology

INNOJET Herbert Hüttlin | KILIAN | TECPHARM | NOACK | SIEBLER | PROMATIC | MACOFAR

Drying & Coating, Granulating Systems	Tablet Presses	Tablet Coating Equipment	Blister Machines	Heat Sealing & Tube Filling Machines	Secondary Packaging	Powder Filler & Liquid Filler

Headquartered in Germany
– Delivering value locally, worldwide

ROMACO beyond technology

Romaco Processing

GERMANY
STEINEN
50 Employees

MANUFACTURING:
- Drying, Coating & Granulating Systems

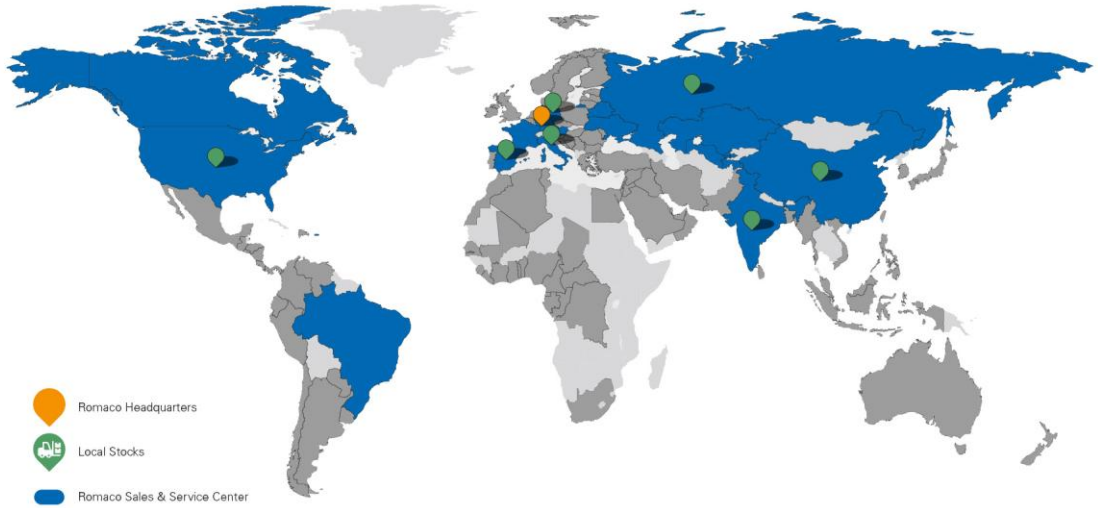
GERMANY
COLOGNE
200 Employees

MANUFACTURING:
- Tablet Presses

SPAIN
BARCELONA
70 Employees

MANUFACTURING:
- Tablet Coating Equipment

Romaco Worldwide



Ownership

TRUKING

CHINA
CHANGSHA, HUNAN

Romaco Packaging

GERMANY
KARLSRUHE
270 Employees

MANUFACTURING:
- Blister Packaging Lines
- Strip Packaging & Tube Filling Lines for Effervescent Tablets

ITALY
BOLOGNA
200 Employees

MANUFACTURING:
- Liquid & Powder Filling Lines
- Cartoning & End-of-Line Equipment

CHINA
CHANGSHA
70 Employees

Total > 950 employees

Sales and Service Center
– Delivering value locally, worldwide

GERMANY
KARLSRUHE

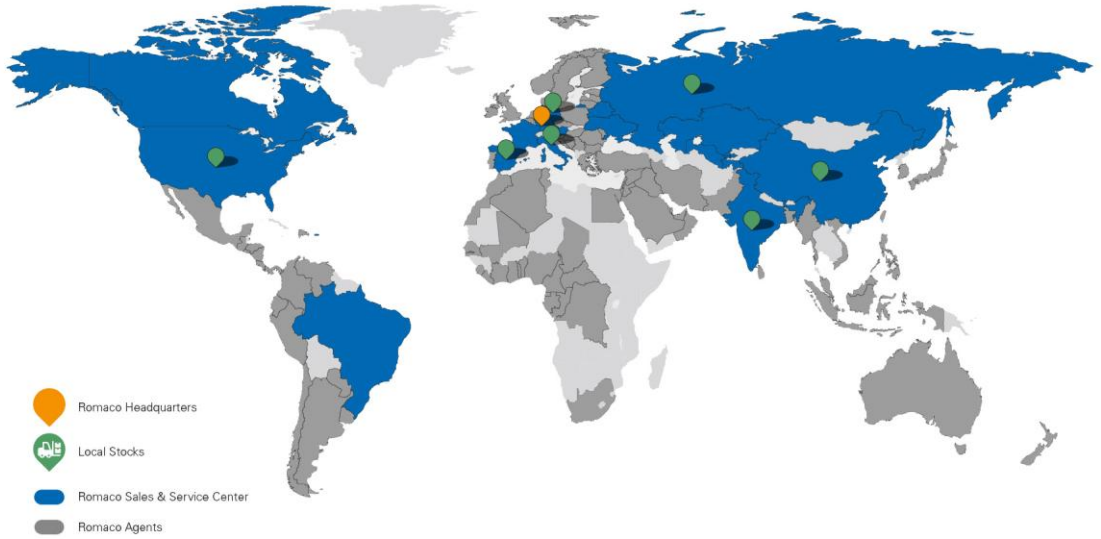
Germany & Austria

Romaco Worldwide

ITALY
Bologna

SPAIN
BARCELONA

FRANCE
AGEN



BRAZIL
SAO PAOLO

USA
HAMILTON

INDIA
MUMBAI

CHINA
SHANGHAI

RUSSIA
MOSCOW

Total
> 950
employees

Robotic Transport and Filling of Microspheres: Ensuring Sterility and Product Integrity

MicroRobot
General Information

Micro dosing
for powder or liquid

MicroRobot

Transport system and operations
carried out by means of robots

Small footprint monoblock aseptic filling and closing machine suitable to handle microspheres and high potent drugs (powder or liquid) under isolator up to 2.000 vph.

Production range

MicroRobot 50

• Single shot up to 2.000 vials/hr (regardless from vials' format)

Dimensions of acceptable vials

➢Diameter:	min. 16 mm	max. 52 mm
➢Height:	min. 35 mm	max. 110 mm

Vials ISO-DIN 8362 1-4 as standard dimensions, but also different glass vials could be handled after evaluation

Dimensions of acceptable closures

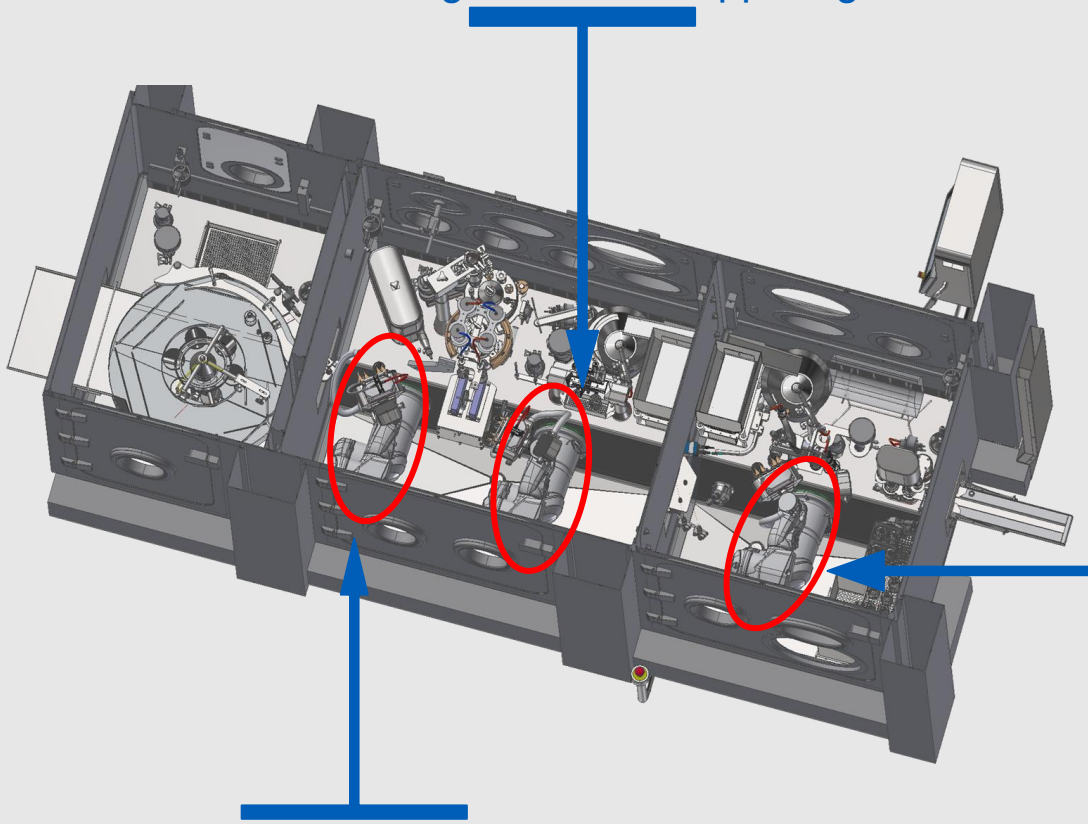
➢ISO/DIN stoppers and Alu-cap up to Ø 32 mm

Powder and liquid filling range

➢Powder dosing starting from 20 mg

➢Liquid filling starting from 0,5 ml

MicroRobot
Robotic transport

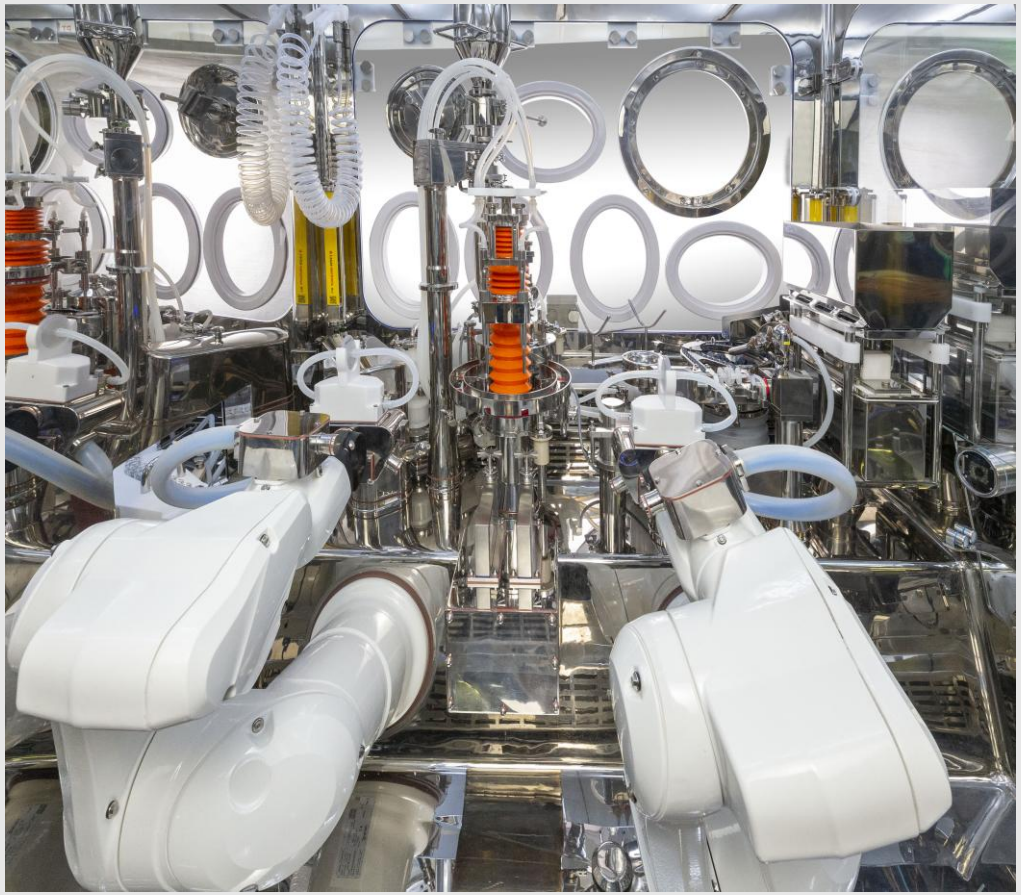


Filling station to stoppering

Stoppered vials to capping and outfeed

Infeed mouse-hole to filling station

MicroRobot
Robotic transport

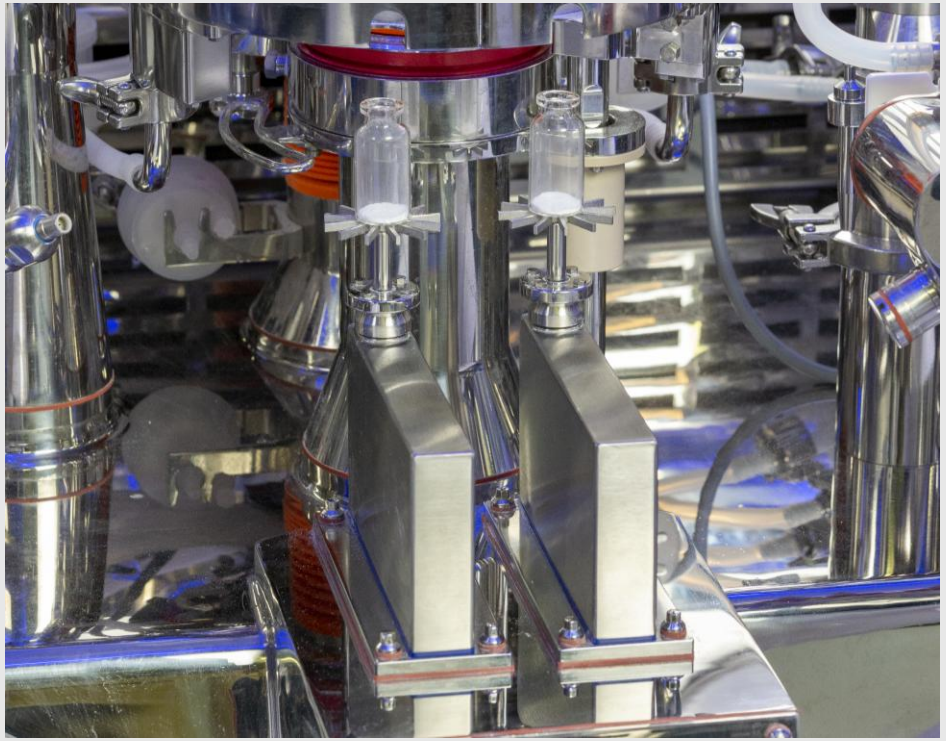


Key benefits of robotic

- Transfer system works according to zero loss logic cutting down rejections,
- Reduces number of size parts and changeover time,
- Grants easy cleaning and gives the possibility to create validated cleaning procedures

MicroRobot
Robotic transport – Infeed and filling

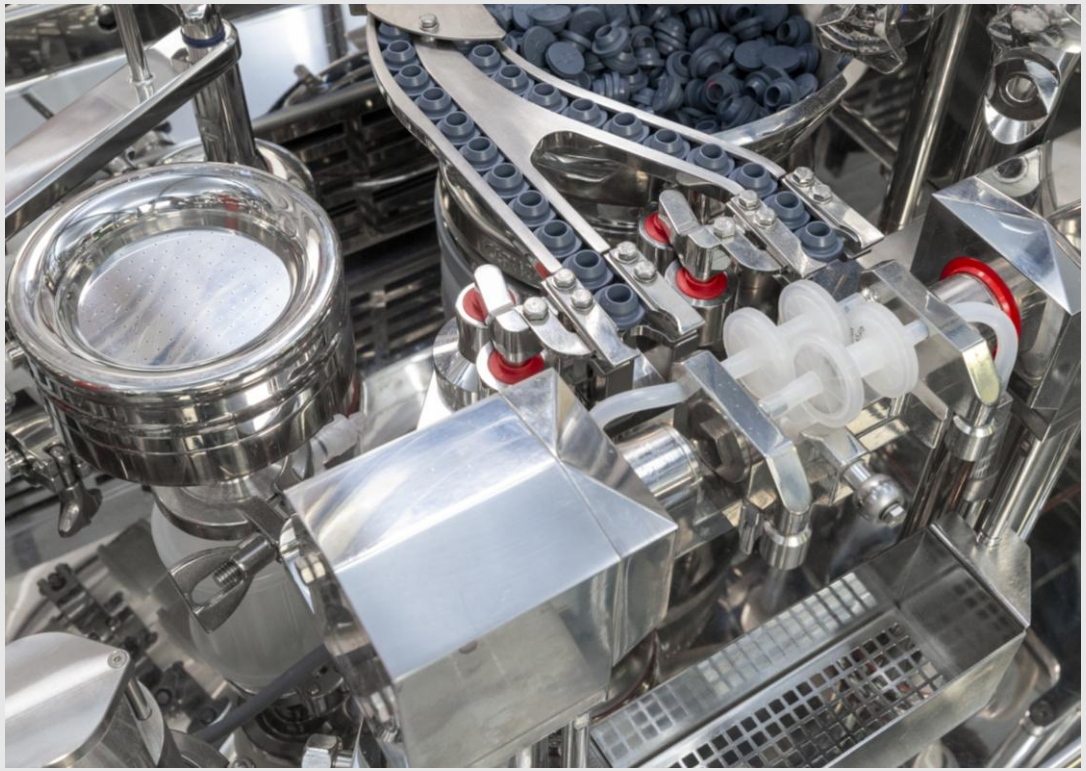
Empty vial pick-up and transport to filling station



Vial filling station with 100% weight-check

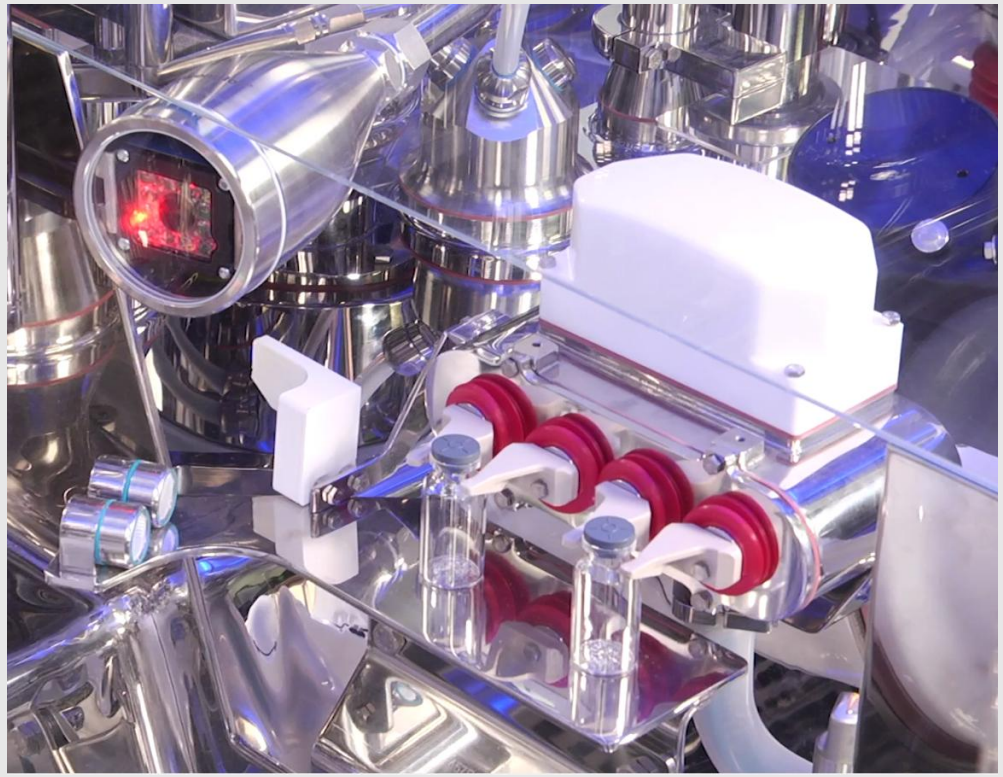
MicroRobot
Robotic transport – Stoppering

Stopper sorting and inserting station



Vision system to check stopper presence

Universal grippers on robots' arms – no size parts changeover needed.



MicroRobot
Robotic transport – From stoppering over capping to outfeed

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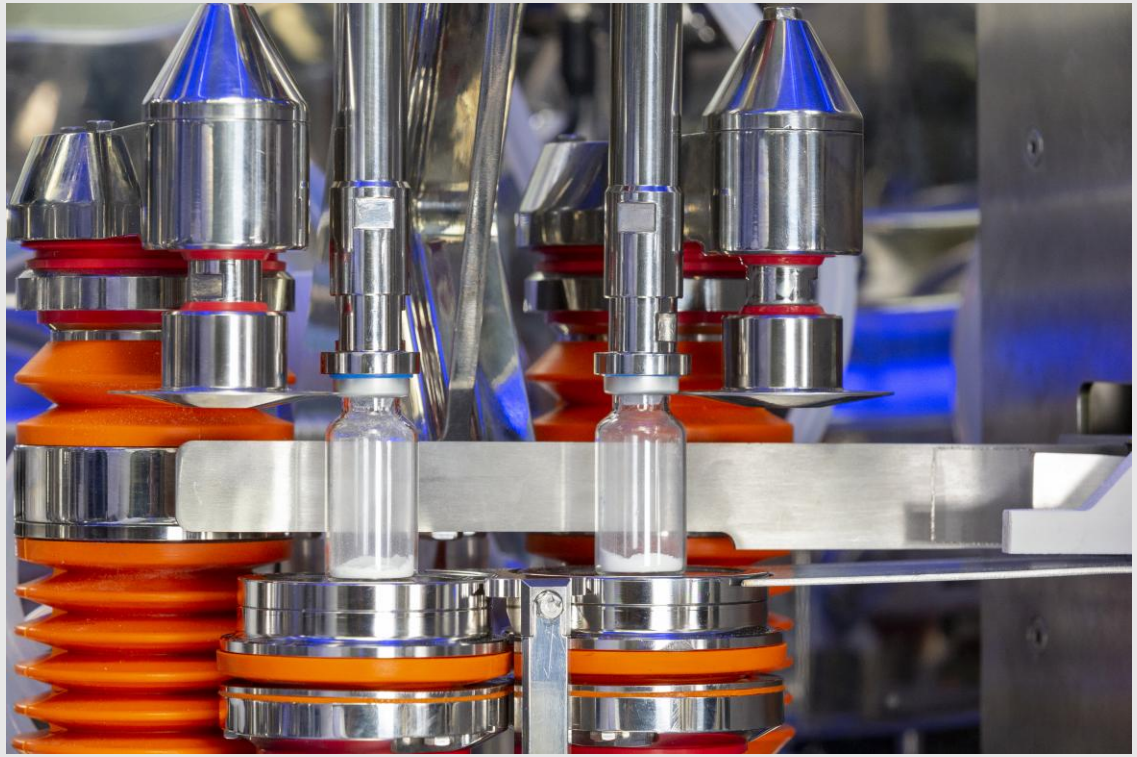
Final processing station with crimping by discs



Special robot arm to push finished vials in exit channel

MicroRobot
Robotic transport

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- **Minimised format parts**
  + Reduces direct handling of parts and therefore the risk of introducing contaminants
  + Improves cleanability and disinfection process
  + Reduces change-over time

- **Safe transportation**
  + Reduces frictions thus particle emission
  + Reduces scratch or damage risks on vial through no glass/glass or glass/metal contacts

- **Consistent, Repeatable Movements**
  + Reduces turbulence and airborne particle movement that might happen with hurried or sloppy manual handling.

- **Cleanability**
  + Reduces format parts

- **First air**
  + Opened vial transport always under first air influence, fully conform to Annex1

⇨ **Robots ensure sterility because they reduce exposure to human-generated contamination, maintain controlled transport pathways, and operate with precision and repeatability in compliance with sterile requirements**

MicroRobot
Product integrity - Powder Filling Unit

Powder filling unit composed by:

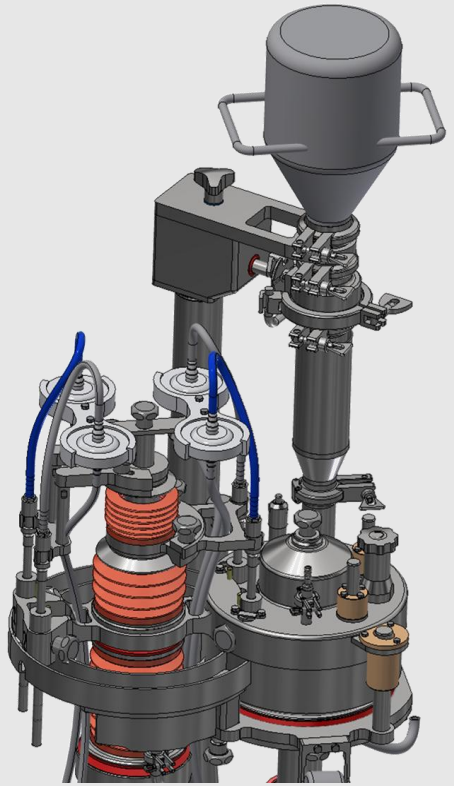
- Connection and support for customer's powder bag/canister inside machine hood
- Rotovalve feeding the powder in the hopper
- Rotating ring-shaped powder hopper with elical scraper and n. 2 cavities for end of batch procedure
- N. 4 vacuum-assisted needles working alternatively

MicroRobot
Product integrity - Powder Filling Unit

B

A

A) rotating «ring-shaped» hopper
B) rotating pick & place system with 4 dosers

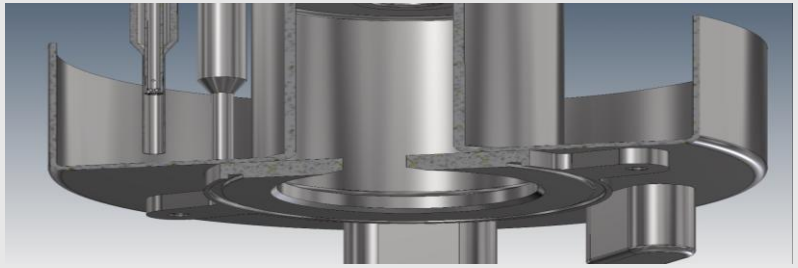


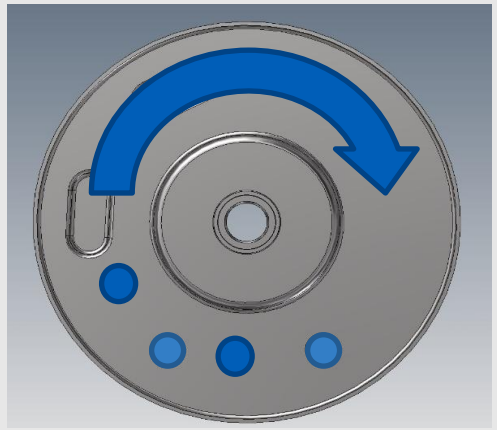
MicroRobot
Product integrity - Powder Filling Unit

While two dosers are filling into the vials, the opposite two dosers are sucking up the quantity necessary for the following dosage.

To prevent the dosers from plunging into the hole created by the previous filling step, during the rotation of the Pick & Place also the hopper rotates by a defined angle (approx. 20-30°).

The helical scraper-compactor group eliminates the holes created by the dosing, flattening and evening the powder bed.





END OF BATCH PROCEDURE

Thanks to the two cavities inside the hopper, MicroRobot end of batch procedure will leave minimum residual at the end of production, cutting product waste.

MicroRobot
Tests on microspheres

- Powder residual at the end of batch of about 90g.
- Dosing with no mechanical expulsion but only with pressure → avoids friction and breakage of the microsphere;
- Target fill weight ranged between 45 to 85 mg and limits inside 10%. About 10 tests have been performed and results on «worst case» test (Endurance test on lowest dosage) showed a std dev. of 2 mg and a Cpk below 1. These results should be intended as «capability study» between powder dosing system installed on MicroRobot 50 and customer powder.
- Speed of the machine – filling accuracy – rejection rate are related to each other and final tuning
- Nearly no adherence on the SS surfaces, avoiding coating

- All microspheres at the end-of-batch sample have a “normal” appearance

- The “Donut” powder filling system installed on MicroRobot does not cause any damage to the microspheres and it can safely be used for commercial production.

Summarised capabilities on Microspheres

- High accuracy → up to 2 mg std dev
- Low powder residual after production → target below 50 g
- Low rejection rate → target < 1%
- Easy to manage under isolator and reproducibility → small components, everything can be adjusted from HMI
- Ensure the batch completion → even with half dosers, customer will always finish the batch
- Different solution in terms of containers managed by MicroRobot → versatitility of containers

Thank you for your interest!

philippe.sporen@romaco.com
+49 174 2767058