



FILL & FINISH MACHINE FOR GENE THERAPY (ATMP)

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RAYA 2023 Finalist Event



CUSTOMER'S REQUIREMENT



Batch size

Tiny / micro batch size (from 50 ml to 5 l)



Outputs

50 to 1000 vials / shift (Up to 5 000 vials in commercial phase)

Machine output = 150 to 400 vials/h – (1.5 to 5 tubs / h)



Filling target

Fill volume: 250 μ l – 5 ml

Accuracy \pm 1%



Filling RTU containers in Nest

2 ml hybrid (polymer + glass) vials

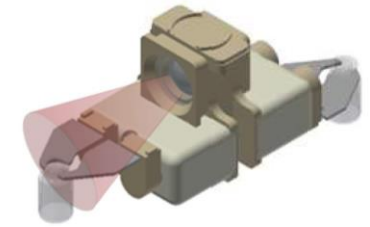
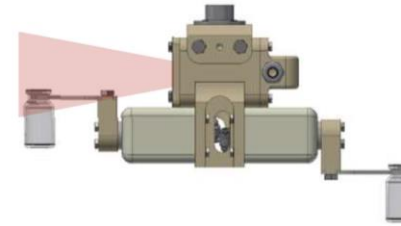
10 ml hybrid (polymer + glass) vials

LINE OVERVIEW

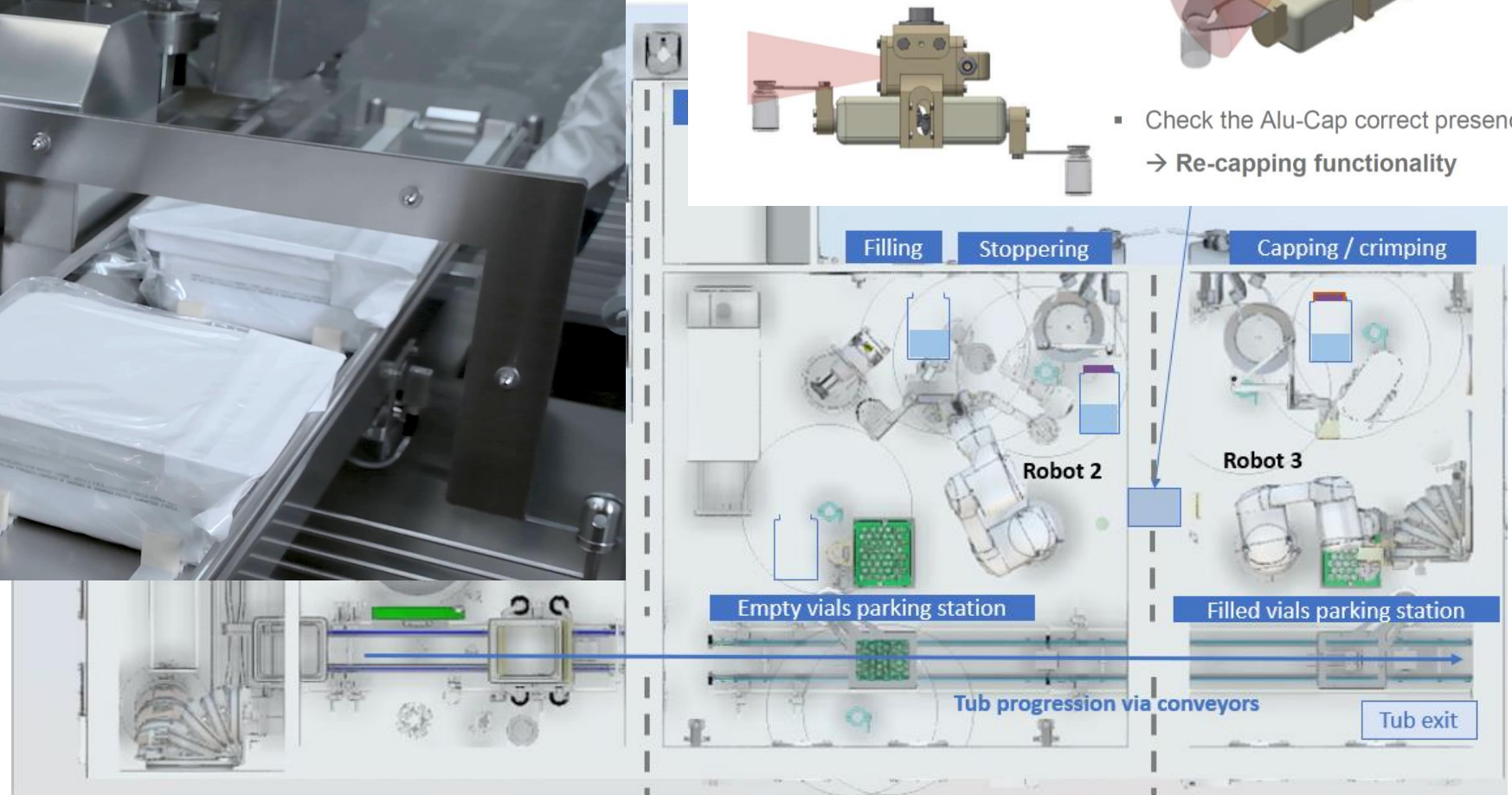


New grippers integrated design

- Check the stoppers correct presence
→ Re-stoppering functionality



- Check the Alu-Cap correct presence
→ Re-capping functionality



ATTRACTIVITY

- Minimized product loss**
 - Re-Filling, Re-Stoppering, Re-Capping
 - 100% weighing IPC
 - Production start “Zero loss”
- Fully automatic for critical operations**
 - Limit the operator interventions to prevent human mistakes
 - Use as much as possible robots
 - Continuous monitoring of critical operation
- Agility**
 - Ability to process different containers (vials, syringes, cartridges)
- Compact footprint**

COST EFFECTIVENESS

HIGH VALUE PRODUCT
Re-Filling, Re-Stoppering, Re-Capping
100% weighing IPC
Production start “Zero loss”



**MINIMIZATION OF
PRODUCT LOSS AND
PRODUCTION REJECT**

Fully automatic for critical operations
Limit the operator interventions to prevent human mistakes
Use as much as possible robots



**OPTIMIZATION OF
PRODUCTIVITY**

Agility
Ability to process different containers (vials, syringes, cartridges)
Short time format change



**MINIMIZATION OF
FORMAT CHANGE
TIME**






Compact footprint

AREA OF APPLICATION

- Batch size**
Tiny / micro batch size (from 50 ml to 5 l)
- Outputs**
50 to 1000 vials / shift (Up to 5 000 vials in commercial phase)
Machine output = 150 to 400 vials/h – (1.5 to 5 tubs / h)
- Filling target**
Fill volume: 250 µl – 5 ml
Accuracy ± 1%
- Filling RTU containers in Nest**
2 ml hybrid (polymer + glass) vials
10 ml hybrid (polymer + glass) vials

**APPLICABLE TO ALL
R&D OR MICRO BATCH
PRODUCTION
APPLICABLES FOR
DIFFERENT PRODUCT
TYPES**

FLEXIBILITY

-  *The machine is suitable for different types of Nest containers (RTU containers) in both glass and polymer.*
-  *The machine manages part of the format change without operator intervention.*
-  *The machine manages load cell calibration without operator intervention.*
-  *The machine handles a wide range of filling volumes (from 250 µl to 10 ml, 1% accuracy)*
-  *Short decontamination time (maximum 150 min). All the parts in contact with the product are disposable: it is possible to manage multiple batches of the same product without cleaning the machine.*

EASYNES TO INTEGRATE

- The tubs are completely managed by the robots*
- All the parts in contact are disposable*
- The pumps are peristaltic (can be adapted to any filling volume)*
- The management of only 1 container at a time allows to manage all the formats and filling volume on the market*

FROM AUTOMATION
AND ROBOTIC POINT OF
VIEW THE MACHINE IS
FULL PLUG&PLAY

CONCLUSION

THE PRESENTED MACHINE IS A THE MACHINE PRESENTED REPRESENTS A SIGNIFICANT INNOVATION IN THE WORLD OF THE PHARMACEUTICAL INDUSTRY.

IN ADDITION TO HIGH FLEXIBILITY, IT OFFERS MAXIMUM REDUCTION OF PRODUCT LOSS AND CONTINUOUS MONITORING OF CRITICAL OPERATIONS, ENSURING THEIR CORRECT EXECUTION, ALSO REQUIRES MINIMAL OPERATOR INTERVENTION, BOTH FOR SET UP AND FORMAT CHANGEOVER.