



Connecting People, Science and Regulation

Manual, Semi- or Fully Automated Inspection - Choices for Adoption

Gaetano Baccinelli,
Sales Manager - OPTREL





Different options for inspecting

| Technology | Handling | Inspection |
|-------------------|-----------------|-------------------|
| Manual | Operator | Operator |
| Semi-Automatic | Automated | Operator |
| Fully Automatic | Automated | Automated |



What Pharmacopeia prescribes

MANUAL




The base
(i.e. European
Pharmacopoeia 2.9.20)
Particle Contamination:
Visible Particles

SEMI-AUTOMATIC



FULLY AUTOMATIC



Validation needed to demonstrate that
the inspection is better than manual
(Article 124, Annex 1)



Pro's Con's of each Technology

MANUAL



High Variability due to Human Factor

SEMI-AUTOMATIC



Small Batches
Low False Reject
Ideal for Expensive Drugs
Ideal for Lyo/Powder
Variability due to Human Factor

FULLY AUTOMATIC



Large Industrial Batches
100% Cosmetic inspection
False Rejects to keep in consideration (Lyo/Powder)

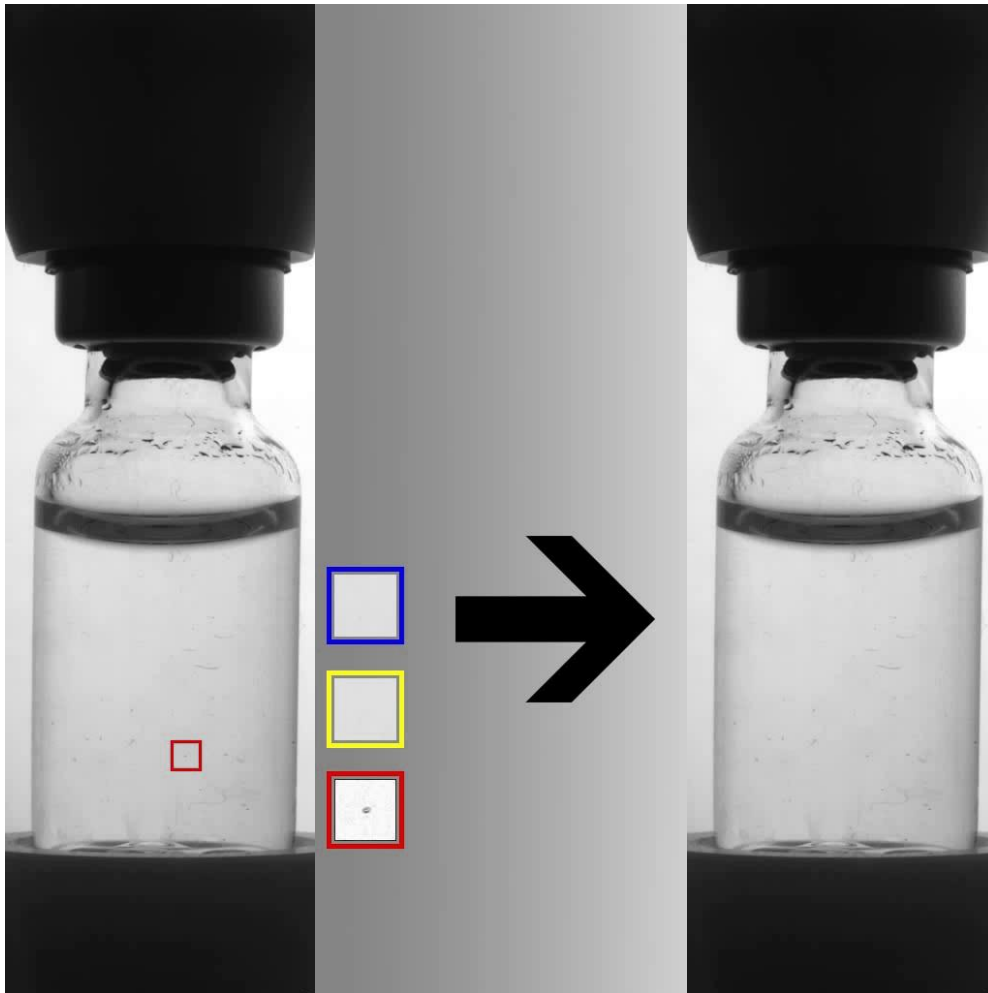


Liquid Inspection: controls available

| | AMPOULES | VIALS | CARTRIDGES |
|-----------------------------|---|--|--|
| PARTICLE INSPECTION | <ul style="list-style-type: none"> • Particle inspection • Fill level • Tip inspection | <ul style="list-style-type: none"> • Particle inspection • Fill level • Alu-seal crimping • Stopper presence | <ul style="list-style-type: none"> • Particle inspection • Fill level • Alu-seal crimping • Stopper presence |
| CONTAINER INTEGRITY | <ul style="list-style-type: none"> • Leak test | <ul style="list-style-type: none"> • Leak Test | <ul style="list-style-type: none"> • Leak Test |
| COSMETIC INSPECTIONS | <ul style="list-style-type: none"> • Tip ring color/OPC • Tip black spot • Printing integrity • Glass surface | <ul style="list-style-type: none"> • Glass surface • Lateral side • OCR and OCV • Reading | <ul style="list-style-type: none"> • Bottom edge • Glass surface • Plunger position and orientation • Plunger integrity and defects • Bead presence |



Dynamic Analysis For Particle Inspection

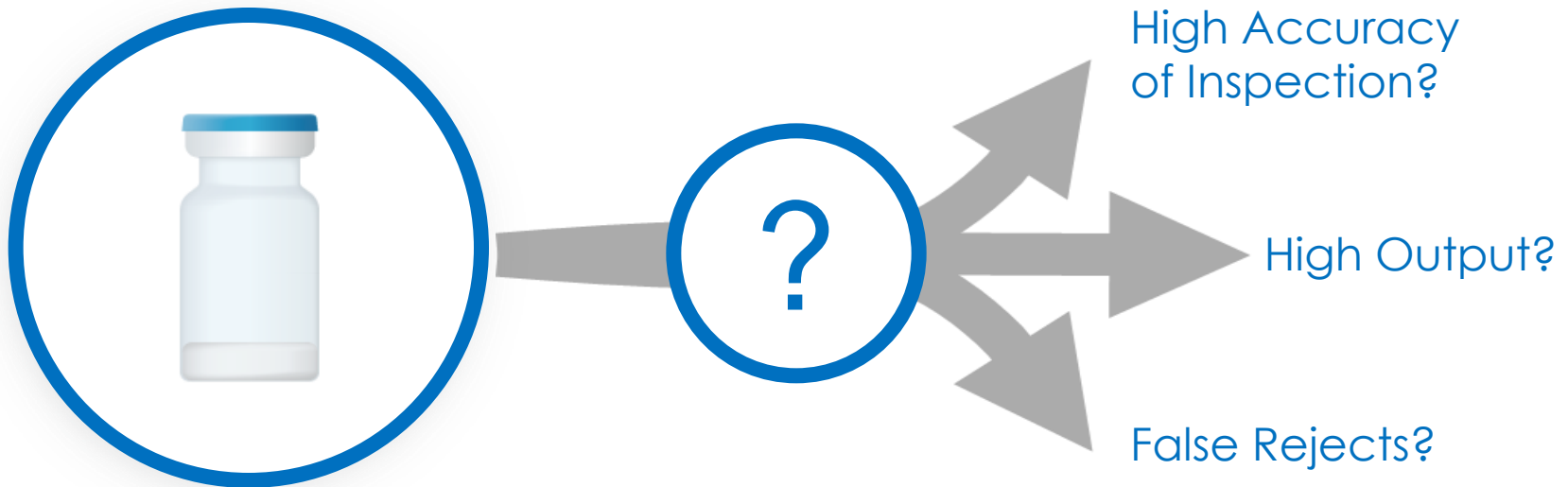


FALSE REJECTION REDUCTION

- Particle trajectory reconstruction using the Kalman filter
- Trajectory post analysis filtering – lower false reject
- Analysis of the meniscus – floating particle inspection
- Analysis of the container bottom – heavy particle inspection

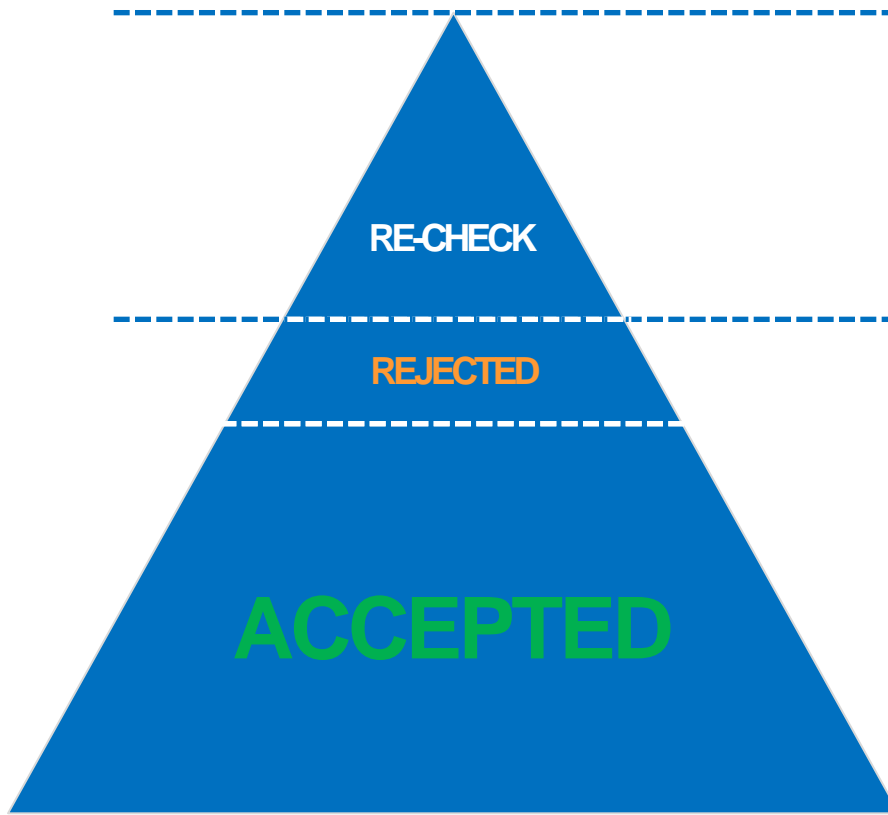


Lyo/Powder: A big Question Mark





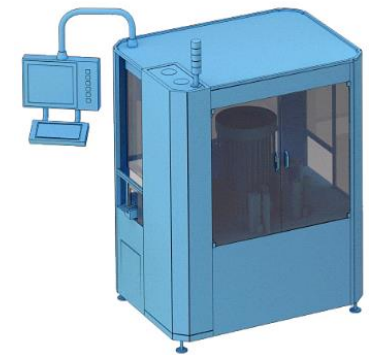
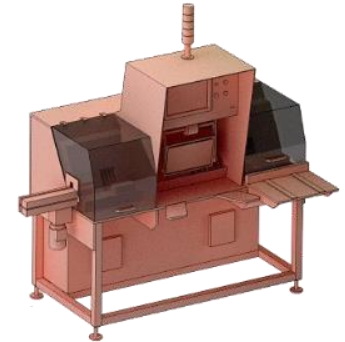
Lyo/Powder: Changing the Approach



Second Inspection

First Inspection

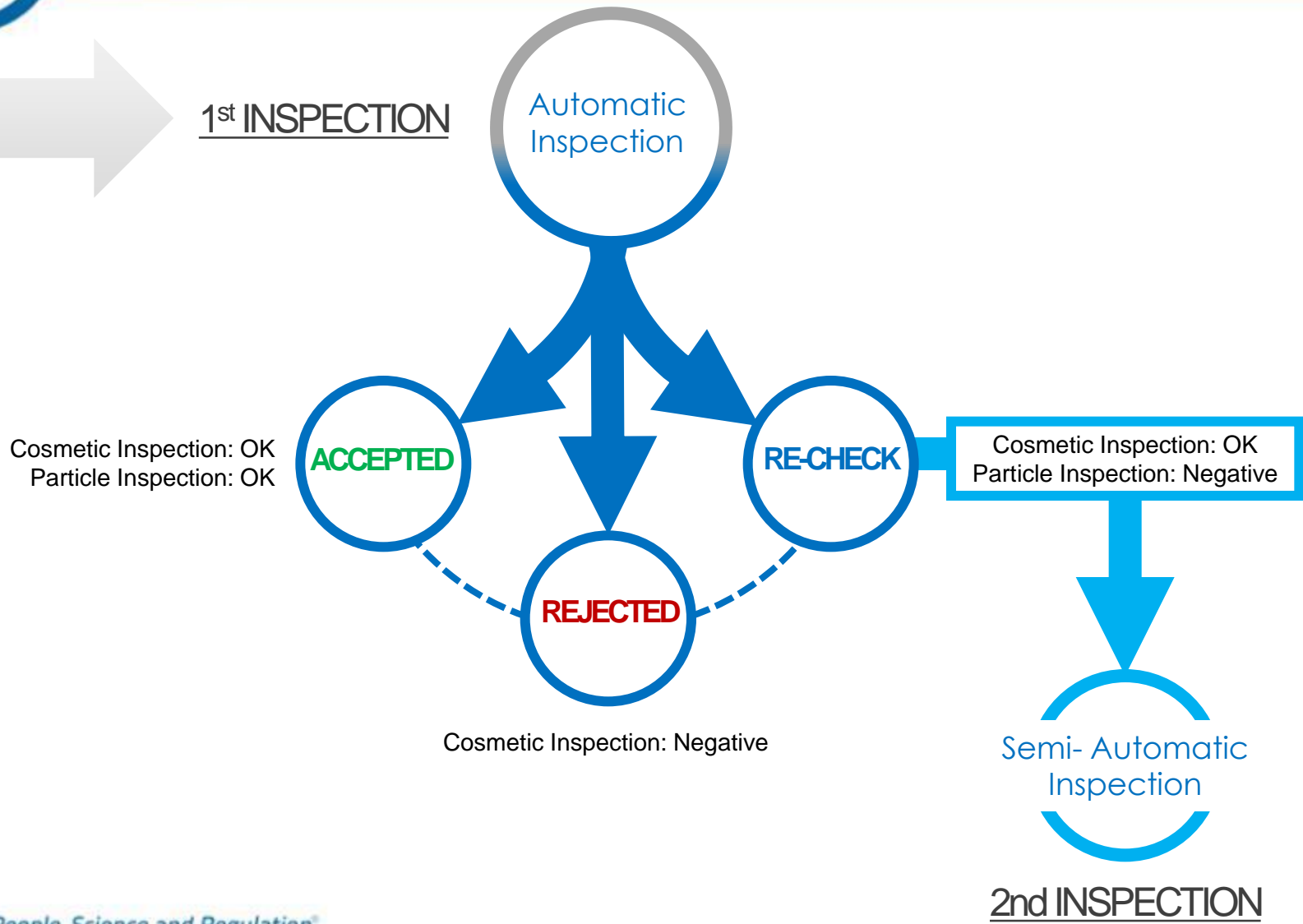
Semi-Automatic Inspection



Automatic Inspection



Lyo and Powder: Changing the Approach

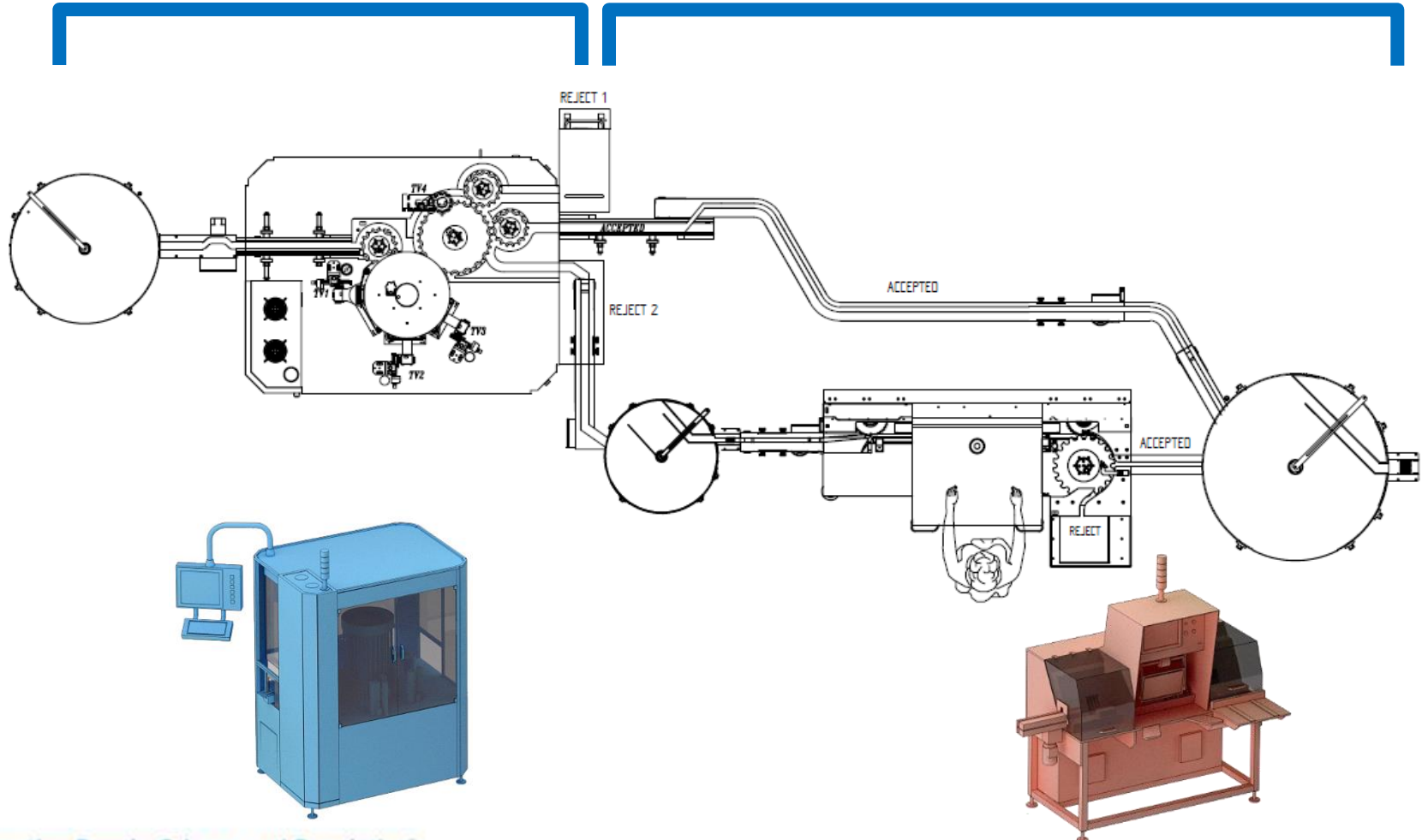




Combo Line: Auto + Semi-Auto

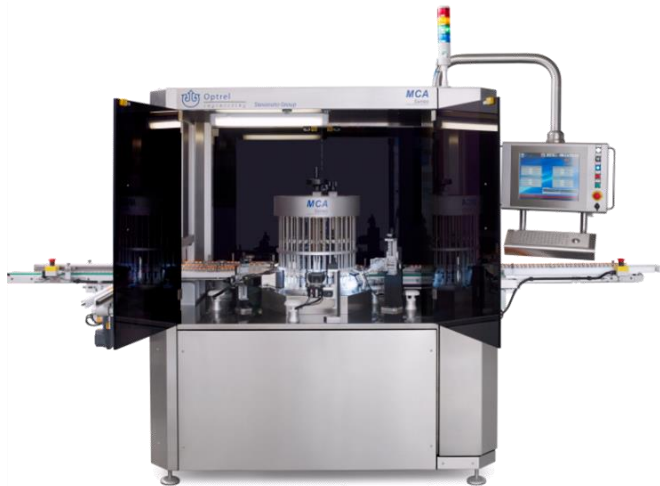
1st Step:
Automatic Inspection

2nd Step:
Semi-Automatic Inspection



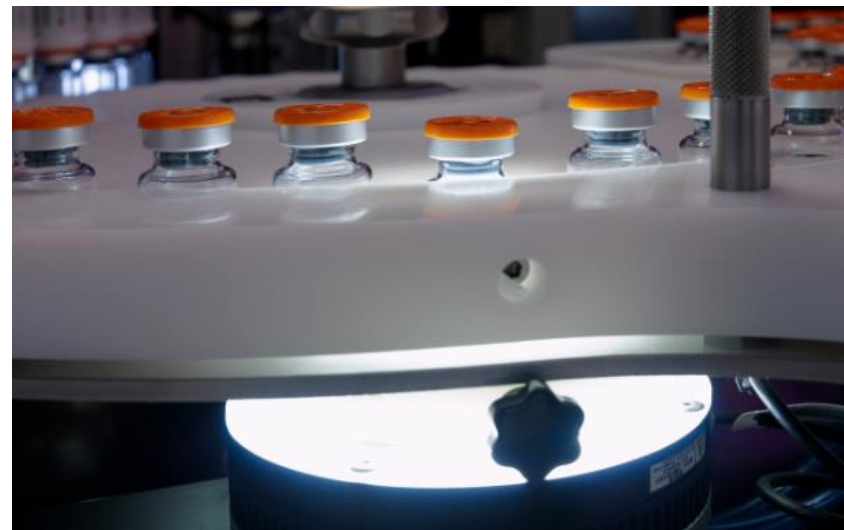


Combo Line: Automatic Inspection



Inspection
Configuration

- inspection of the cake (top cake, bottom cake)
- inspection station for alu seal control
- container glass surface





Connecting People, Science and Regulation®

Contact us directly for more details:

Gaetano Baccinelli,
Sales Manager
OPTREL
gaetano.baccinelli@stevanatogroup.com

