



**MANAGING
COMPLEXITY,
DELIVERING
VALUE**



**EZ-Fill® Platform to fasten
Scale-up of Fill & Finish Manufacturing
capacity for Vaccines**

DVCMN webinar

21st August, 2023

Stevanato Group Speakers



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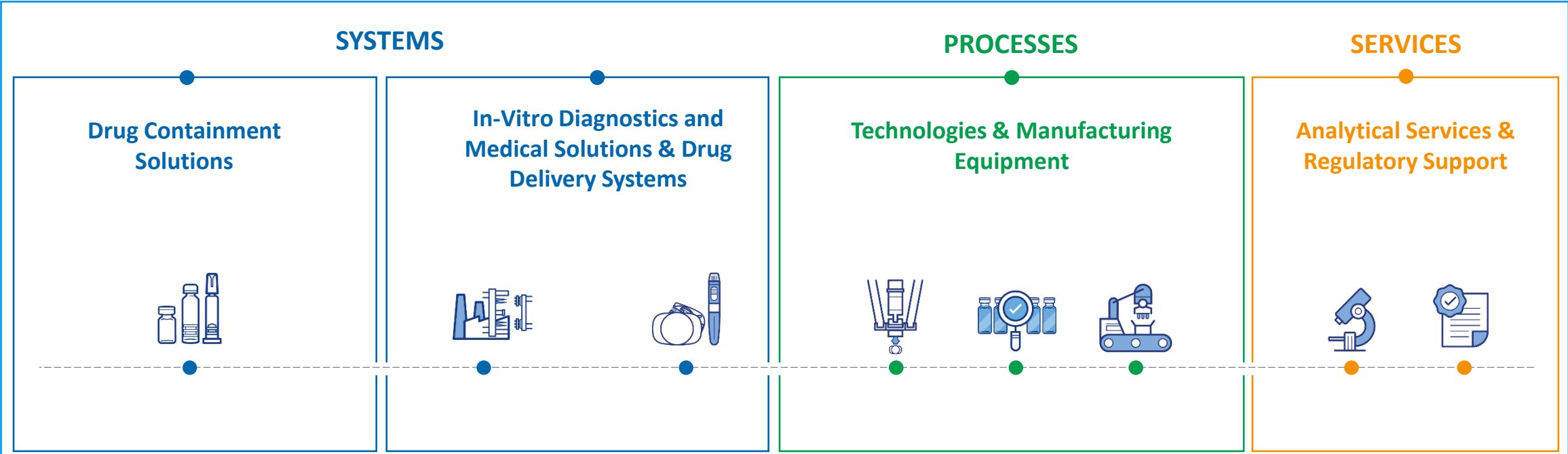
[Flavia Batista - LinkedIn](#)

- **Stevanato Group at a glance**
- **Development Countries and Pharmaceutical Landscape**
- **EZ-fill® Vials - Ready-to-Use platform**
- **Benefits of EZ-fill® Vials on Fill & Finish Process**
- **Q&A**

- **Stevanato Group at a glance**
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Stevanato Group at a glance

What we proudly do



Unique combination of integrated capabilities addresses pharmaceutical customer needs through developmental, clinical and commercial phases

Reduced Time to Market

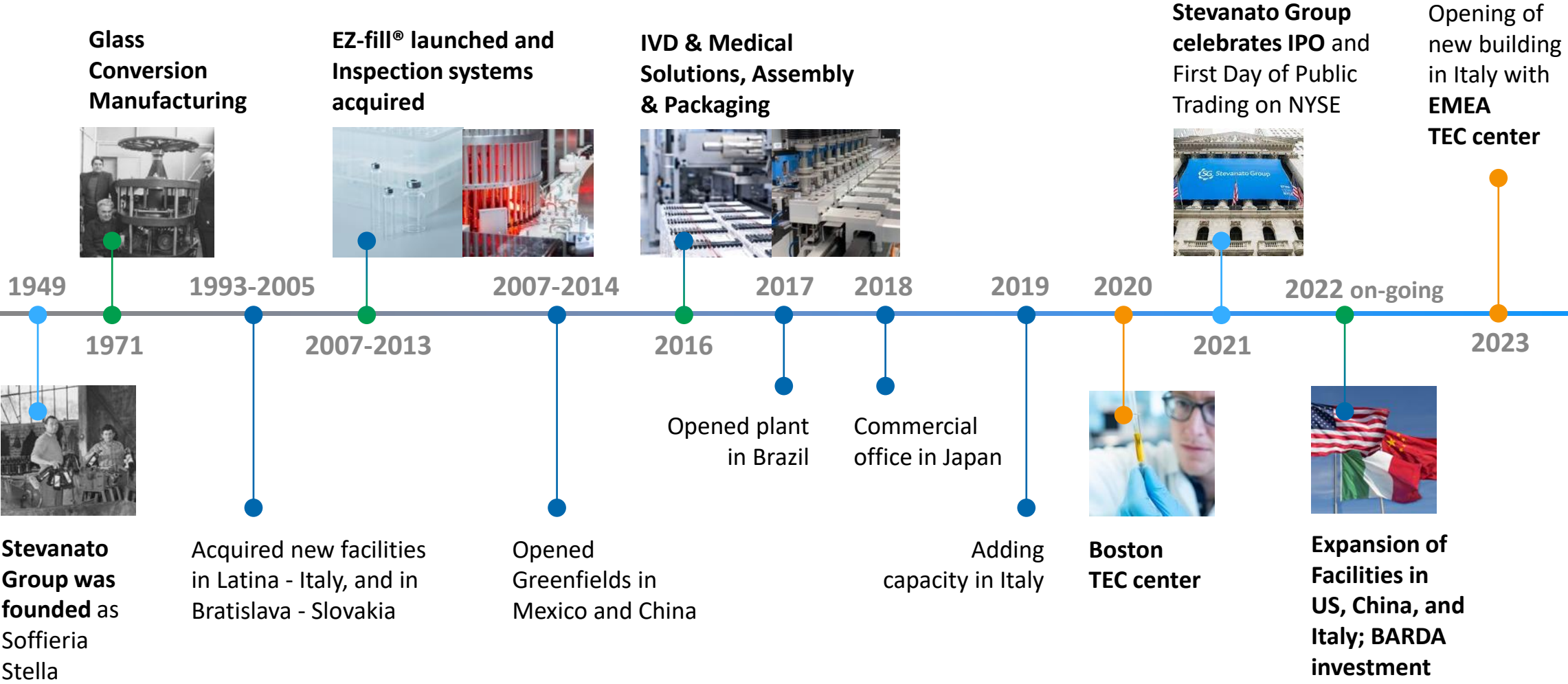
Reduced Supply Chain Risk

Reduced Total Cost of Ownership

Consistent Quality

70 years of Expansion, Acquisition, Integration

The story we can tell



Stevanato Group Today, 70+ Countries Served

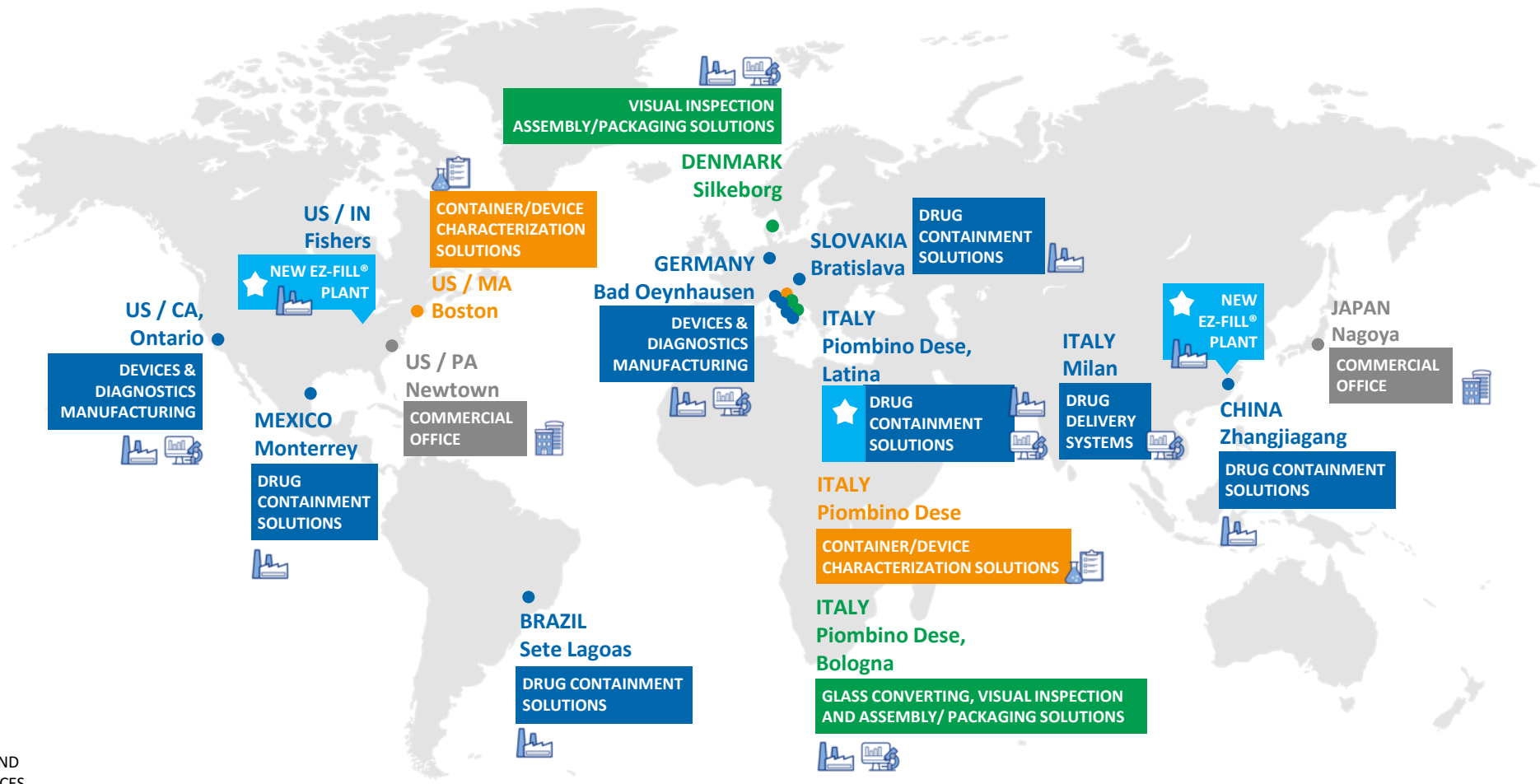
Our present

16 sites

9 countries

☆ 3 sites

investments underway for EZ-fill® / Engineering



-  OFFICE
-  R&D
-  PLANT
-  ANALYTICAL AND TESTING SERVICES

SOURCE: SG INTERNAL DATA

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New Trends are Driving Pharmaceutical Industry



Challenging Trends for Developing Countries

Market Trends

Cost Explosion in Manufacturing



Growth in Emerging Markets



Increasing Regulatory Quality & Compliance



Pharmaceuticals Needs for Fill & Finish



NEED TO REDUCE TOTAL COST OF OWNERSHIP (TCO)



REDUCE TIME TO MARKET



NEED TO INCREASE QUALITY



REDUCE COMPLEXITY



NEED TO INCREASE FLEXIBILITY

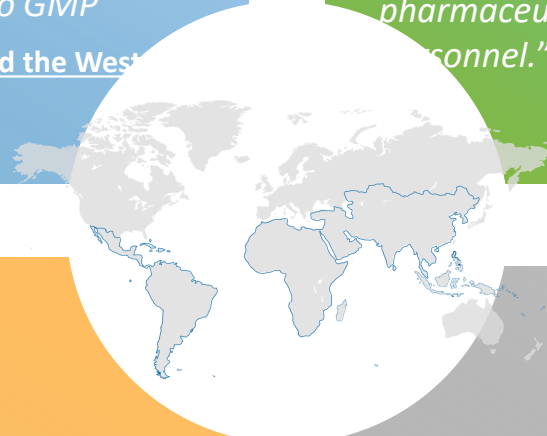
COVID-19 Pandemic highlighted the major need to access to infrastructures...

"[...] In terms of vaccine manufacturing capacity and efficiencies, considerations for facility sharing of fill and finish activities are in place and so is the provision of technical guidance on personnel competency improvement and personnel's understanding of regulation related to GMP"

Vaccine manufacturing workshop for South-East Asia and the West Pacific regions: meeting report, 21-22 February 2022

"[...] support from development financial institutions together with the private sector is crucial in supporting Africa's industrial and sustainable development and countries need to be supported to expand their fiscal space during the ongoing pandemic. [...] development partners need to actively promote human resource capacity and knowledge for the pharmaceutical manufacturing sector which requires highly skilled personnel."

Strengthening Africa's pharmaceutical industry: learning the lessons from COVID-19 | UNIDO



"[...] The Latin America and Caribbean (LAC) region relies heavily on imported COVID-19 vaccines [...], having the second lowest level of domestic supply after Africa."

Expanding Emergency Vaccine Manufacturing Capacity in Latin America and the Caribbean

"[...] Clearly, the cost of setting up production would make the products locally produced in Africa more expensive than those imported from existing suppliers. But sustainable supply for years to come is worth the short-term cost."

Scientists call on AU leaders to prioritise mRNA vaccine technology | Nation

Key importance in Developing Countries to develop and strengthen local Capacity and related capabilities in order to ensure access to vaccination

...which requires Pharmaceutical Companies to face new challenges in their growth



Access to trained workforce for R&D and Operations activities



Consistent access to utilities and WFI



Access to Fill&Finish Capacity and Capabilities



Efficiency in manufacturing and Fill & Finish to improve Return on Investments



Proactive incorporation of regulatory guidelines

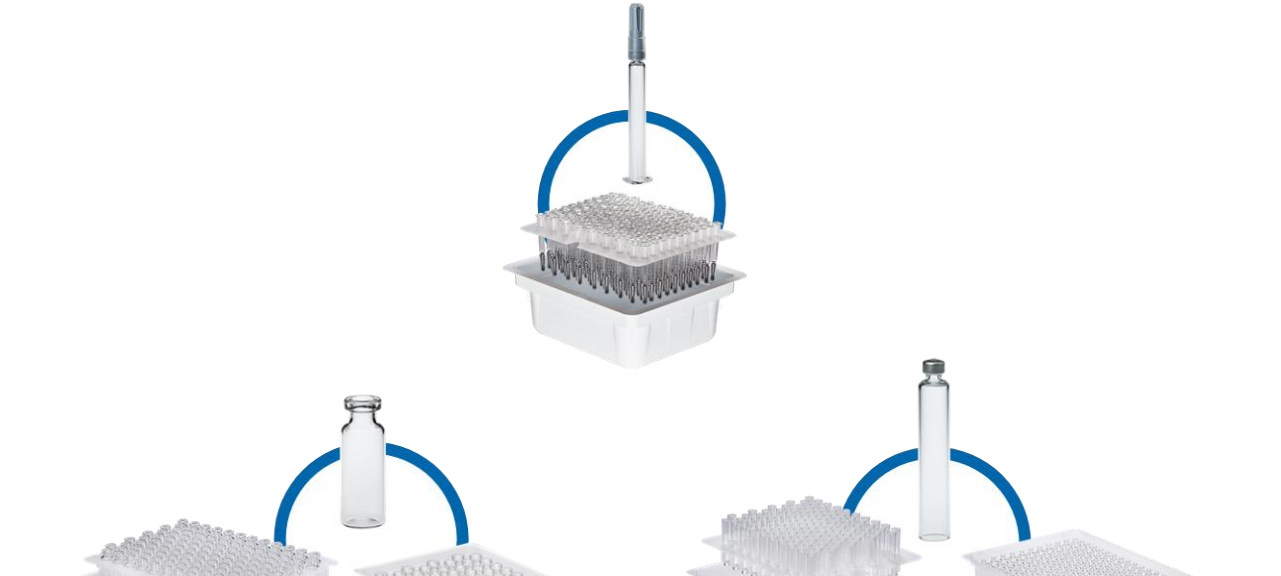


Quick industrial scale-up to reduce risk of dependance from external sources

How Stevanato Group can support Pharmaceutical Companies in Developing countries to overcome these challenges

Pharmaceuticals Needs for Fill & Finish

-  **NEED TO INCREASE FLEXIBILITY**
-  **REDUCE COMPLEXITY**
-  **NEED TO INCREASE QUALITY**
-  **REDUCE TIME TO MARKET & QUICK INDUSTRIAL SCALE-UP**
-  **NEED TO REDUCE TOTAL COST OF OWNERSHIP (TCO)**



The diagram illustrates the EZ-fill vial filling process. At the top, a syringe is positioned above a multi-well tray containing numerous small vials. A blue circular arrow indicates the flow of material from the tray to a single vial. Below this, another blue circular arrow shows the material being dispensed into a larger vial. The entire process is set against a blue background.

EZ-fill® Vials, Ready-to-Use Configuration

the proven advantages have turned the technology into an **industry standard**

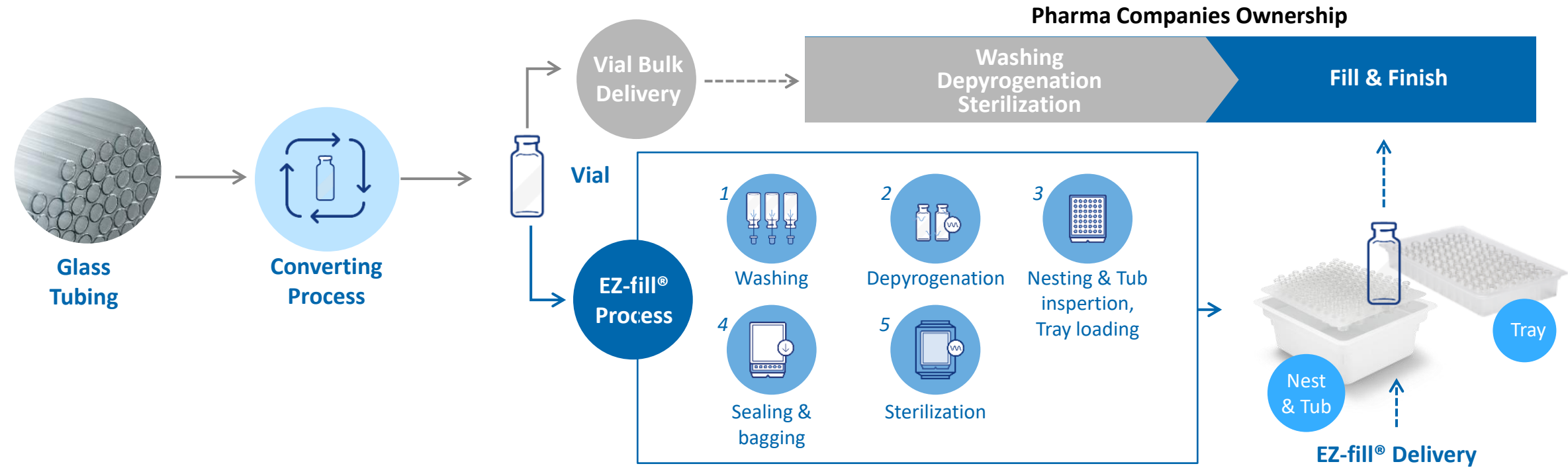
- Stevanato Group at a glance
- Development Countries and Pharmaceutical Landscape
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- Benefits of EZ-fill® Vials on Fill & Finish Process
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EZ-fill® vials Platform At a Glance | Producing Significant Value for Pharma Companies



- **EZ-fill® vials** are pre-washed, pre-sterilized and ready-to-fill vials available in both nested and tray configurations
- **No Glass-to-Glass packaging** (Nest & Tub or Tray) to minimize possible scratches or other glass defects during shipment, aligned with ISO 21881
- **EZ-fill® Nest & Tub** configuration is compatible with multi purpose fill & finish lines
- **EZ-fill® Tray** is compatible with a wide range of fill&finish process, from manual to automatic, up to high speed fill&finish lines
- EZ-fill® packaging, both Tray and Nest & Tub, can be packed with either single or double steribag
- EZ-fill® platform is an open platform, currently used by other primary packaging suppliers



Stevanato Group Process: from Bulk to EZ-fill®



Ready-to-Use Secondary Packaging configurations can support a wide range of Pharmaceutical Needs

EZ-fill® Vial in Tray



-  **INCREASE QUALITY**
-  **REDUCE COMPLEXITY**
-  **INCREASE FLEXIBILITY**



Courtesy of Syntegon

EZ-fill® Vial in **Nest&Tub**



- Configuration to fill vials, cartridges, syringes with a unique filling machine (combi lines)



Courtesy of Optima

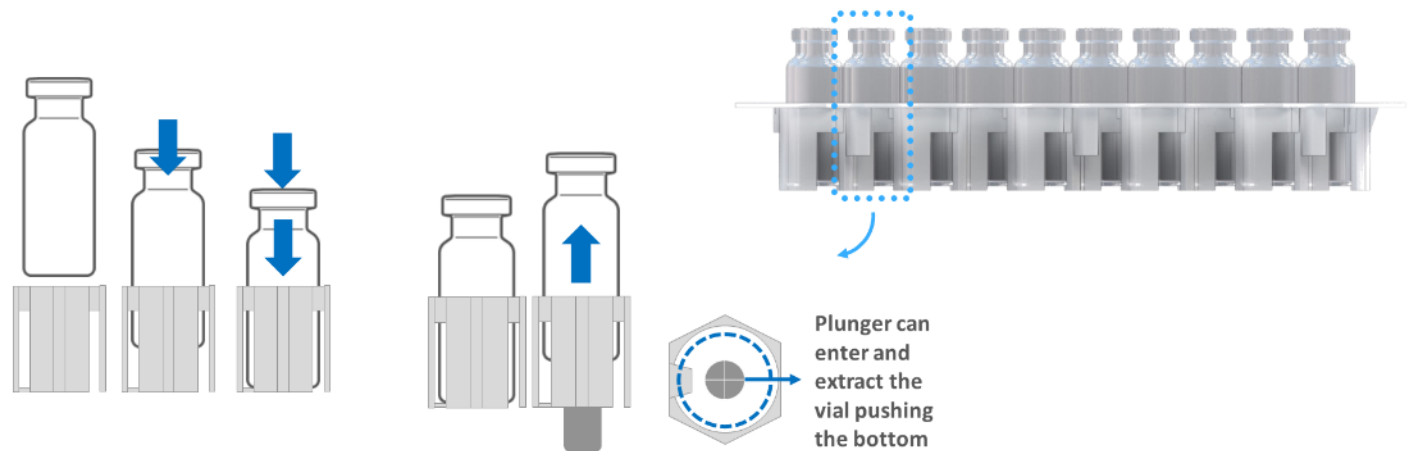
EZ-fill® is suitable for filling applications from LOW to HIGH SPEED

Advantages of EZ-fill® Nest

Mechanical Support of Glass Containers

Mechanical support from the bottom

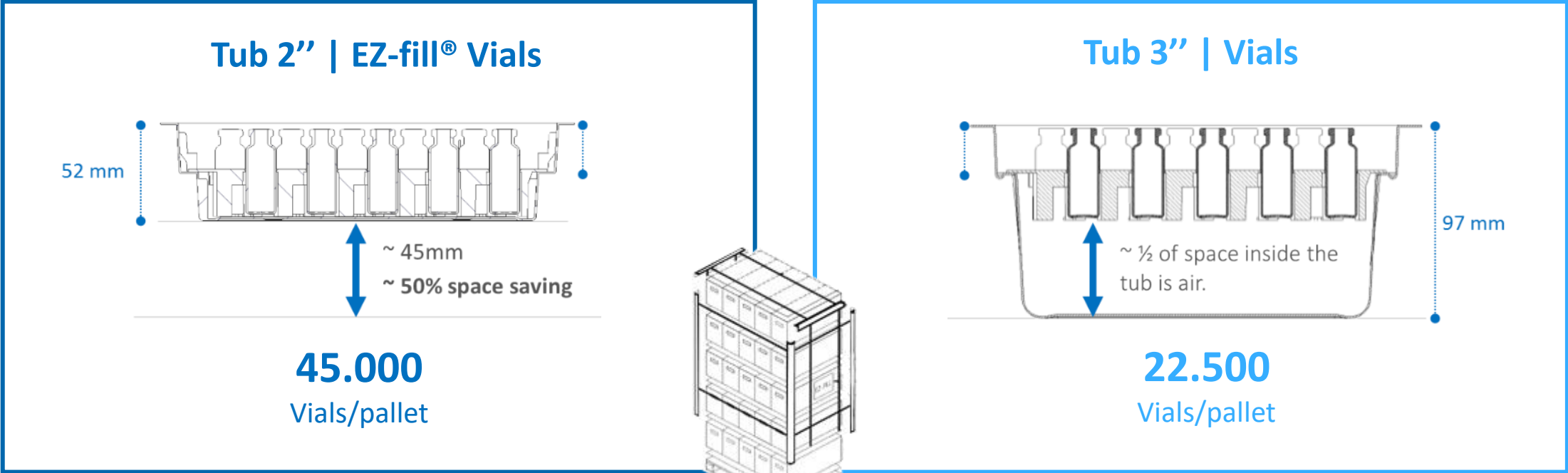
- No stresses generated on glass
- Possibility of removal and re-insertion of the container on the same secondary packaging without risks or waste of product
- No particle generation due to friction



Advantages of EZ-fill® Tub

Optimized Tub Dimensions

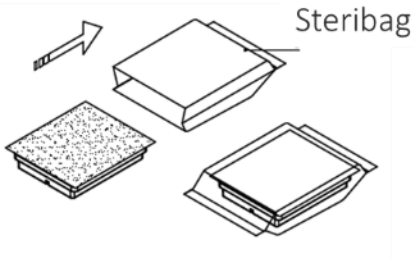
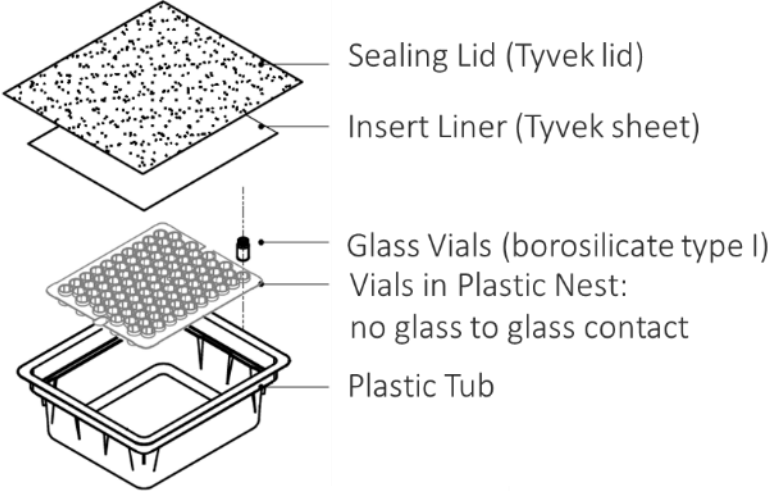
Optimized Tub to increase pallet density with low transportation and warehouse costs



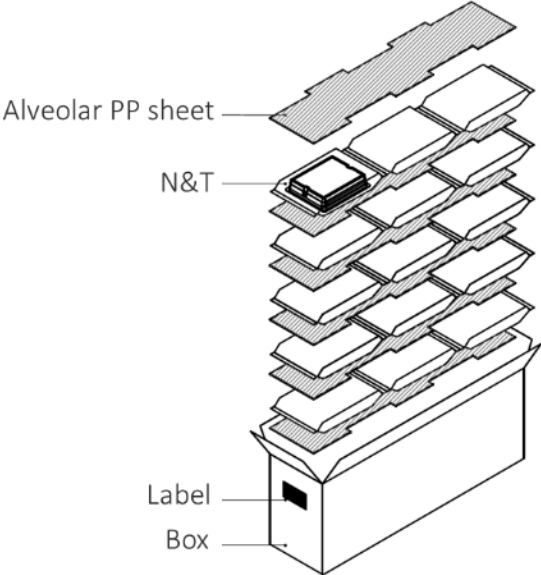
Stevanato Group solution is currently validated in existing RTU filling lines

EZ-fill® Vials in Nest & Tub

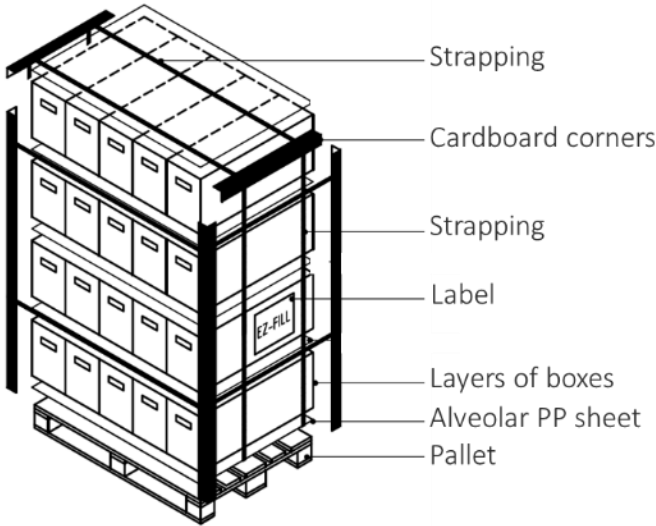
Secondary Packaging Configuration



Tub protected by a single or double protective bag/s (Steribag/s)



Box composition



Pallet composition

Ready-to-Use Secondary Packaging configurations can support a wide range of Pharmaceutical Needs

EZ-fill® Vial in Tray



- Manual filling at laboratory scale
- Industrial lines filling RTU Vials according to existing process (manual/automatic)



Courtesy of Syntegon

EZ-fill® Vial in Nest&Tub



REDUCE TIME TO MARKET & QUICK INDUSTRIAL SCALE-UP



REDUCE TOTAL COST OF OWNERSHIP (TCO)

with

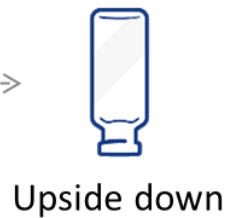


Courtesy of Optima

Stevanato Group EZ-fill® is suitable for filling applications from LOW to HIGH SPEED

Advantages of EZ-fill® Tray

Vial Different Orientations According to Filling Requirements

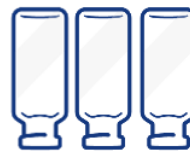


Neck-up Vial Solutions for Laboratory Scale



Direct filling of vials inside Tray under laminar flow

Upside-down to load in a line with conventional filling system



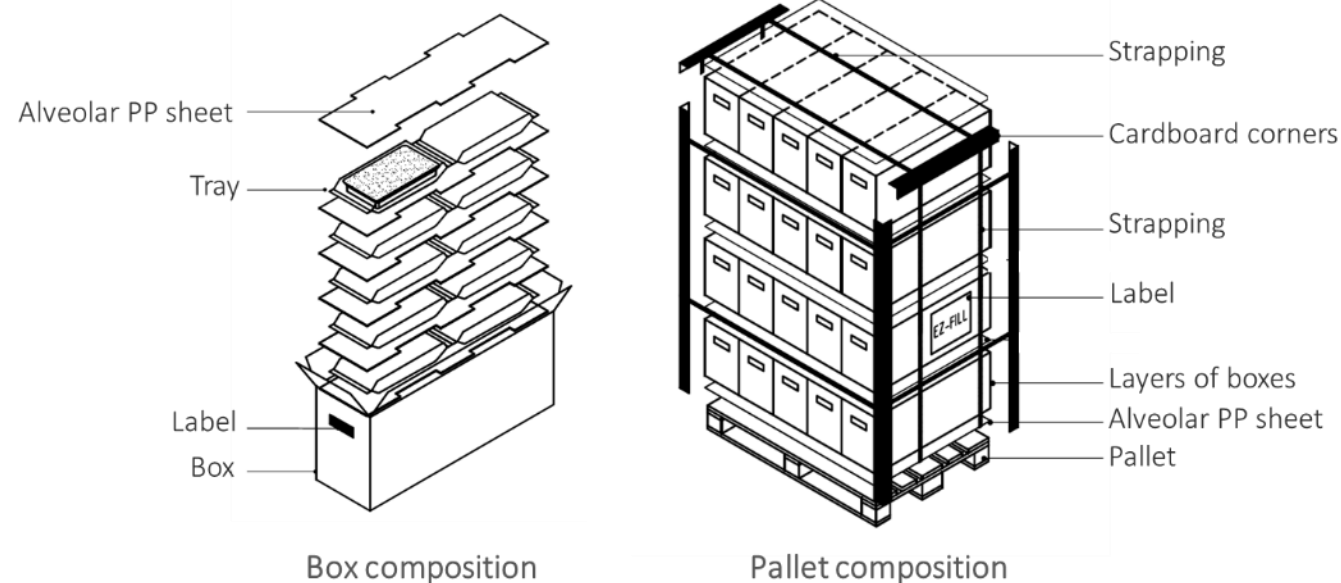
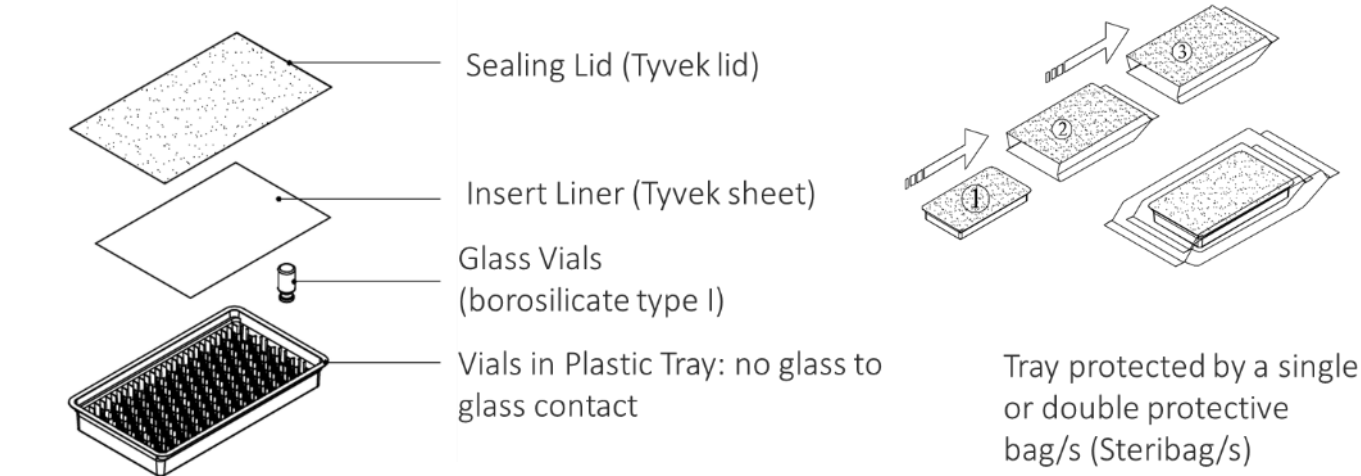
De-traying



Filling

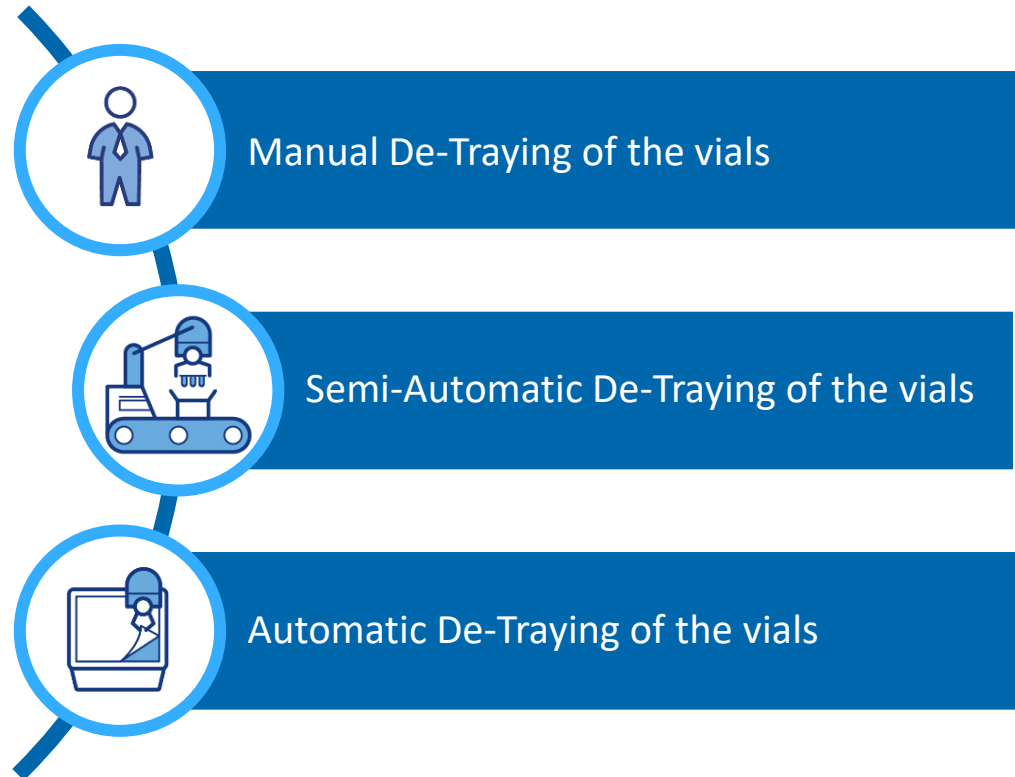
EZ-fill® Vials in Tray

Secondary Packaging Configuration



Proven technologies available in the market to guarantee processability of EZ-fill® Vials in Fill & Finish

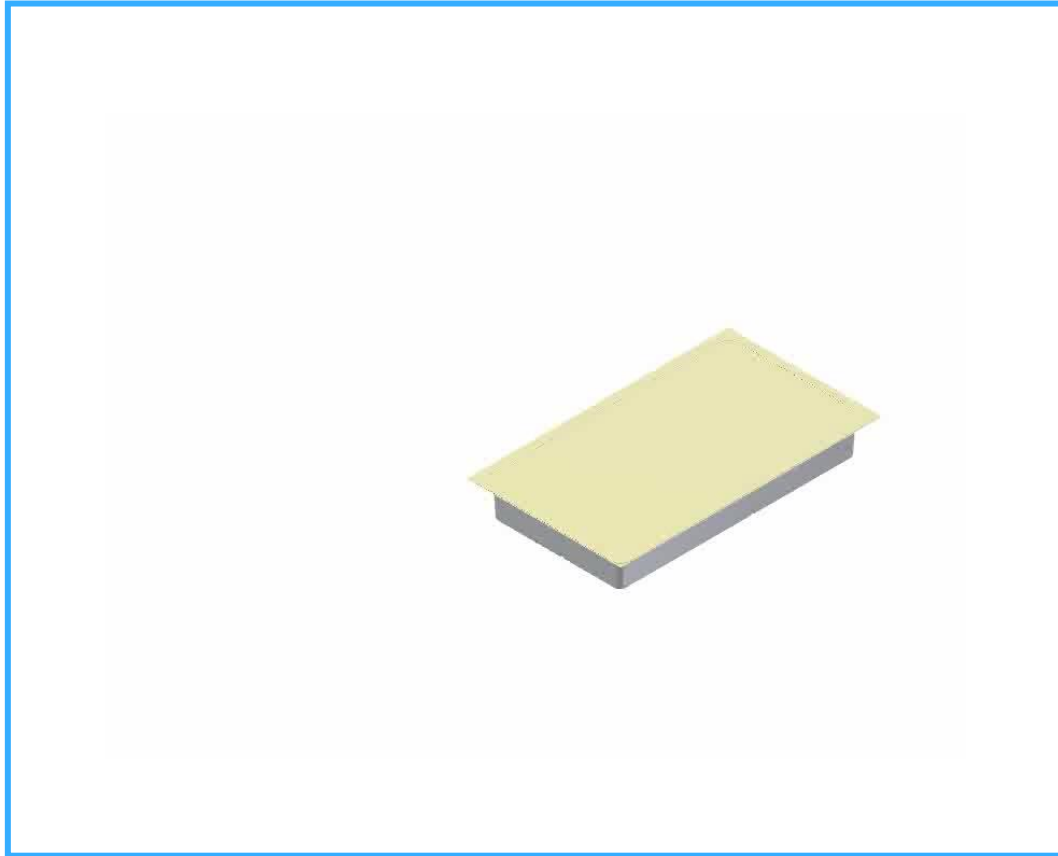
The technology used for the infeed of the packaging can impact the timeline and costs for the adoption of EZ-fill® vials platform



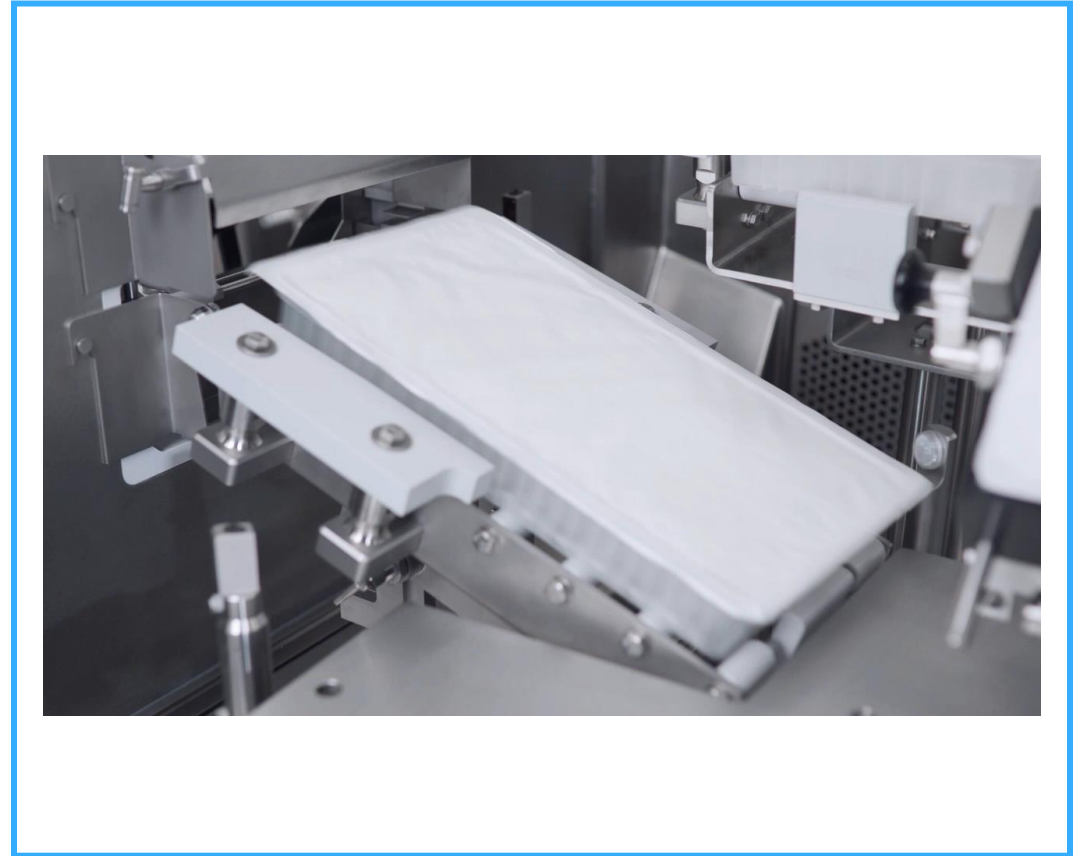
Stevanato Group can support pharmaceutical industry in both approaches, leveraging the benefits of EZ-fill® vials to reduce the risk of particles generation and human intervention

Note: SG EZ-fill® Tray packaging is the preferred solution for retrofit; Nest & Tub packaging can be used as well, impacting timelines, costs and throughput of the process.

Some examples of de-traying of EZ-fill® vials



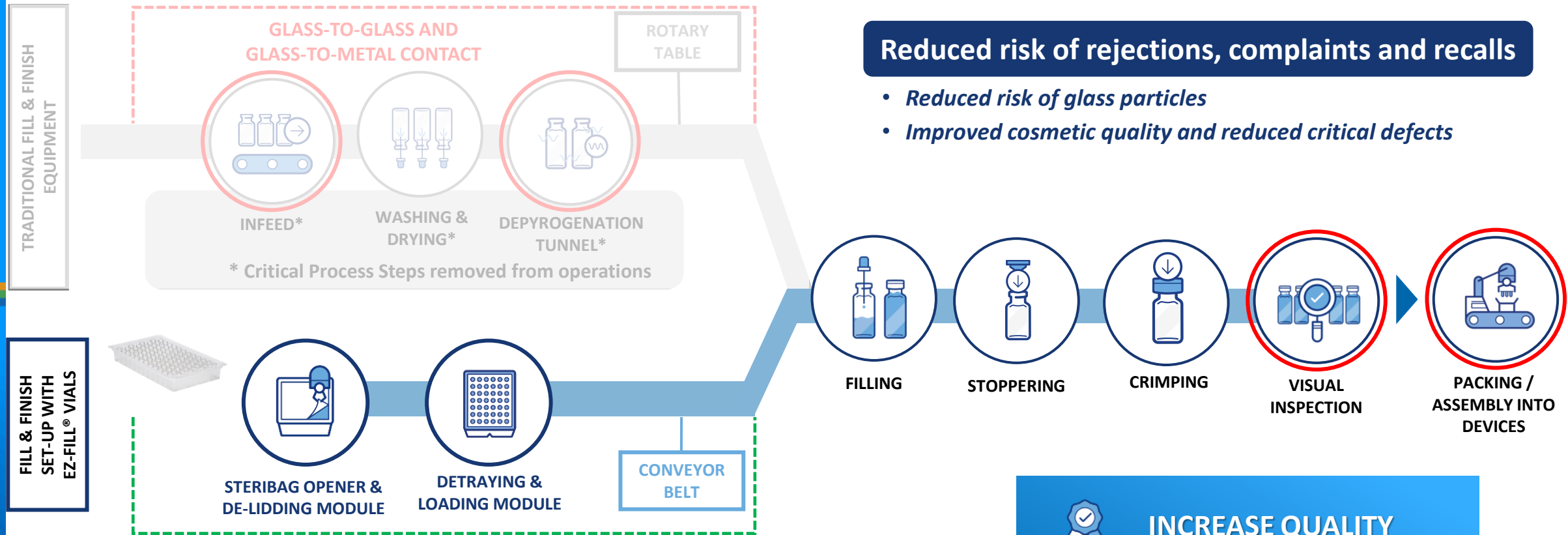
**MANUAL DE-TRAYING WITH
DEDICATED TOOL**



SEMI-AUTOMATIC DE-TRAYING

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Benefit of EZ-fill® vials | Improved integrity and safety of the medicine



Reduced risk of rejections, complaints and recalls

- Reduced risk of glass particles
- Improved cosmetic quality and reduced critical defects

Reduced risk of contamination

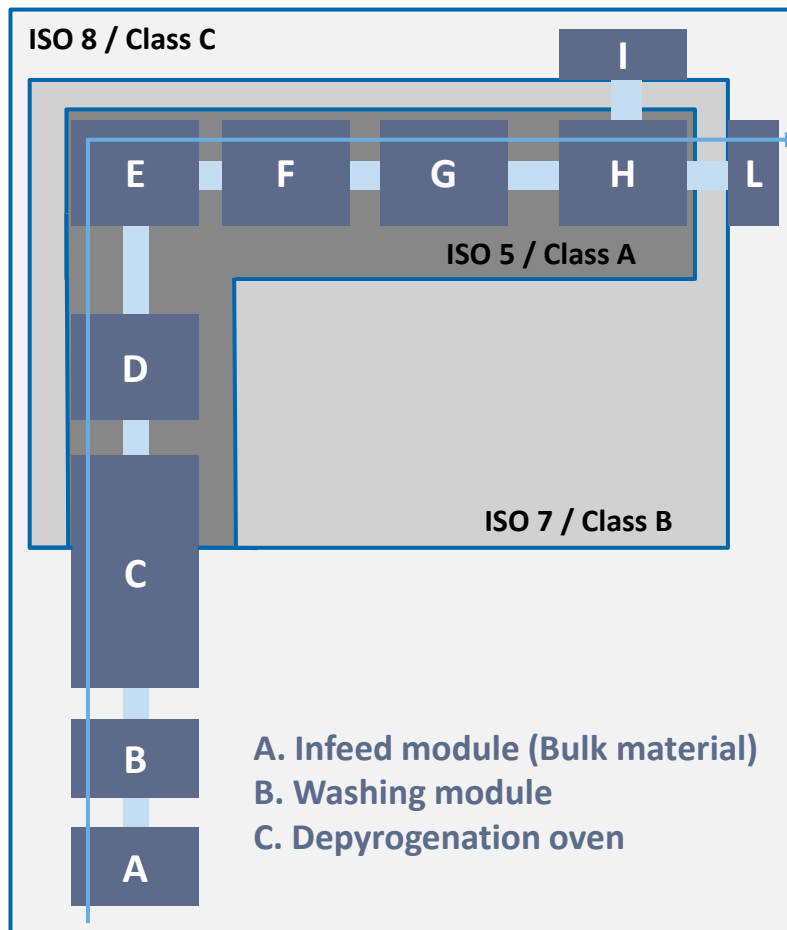
- Low particles contamination, lined up with the updated regulatory guidance
- Improved mechanical resistance (mitigation of glass breakage)
- Higher process efficiency (lower scrap rate after AVI)

- INCREASE QUALITY
- INCREASE FLEXIBILITY
- REDUCE COMPLEXITY

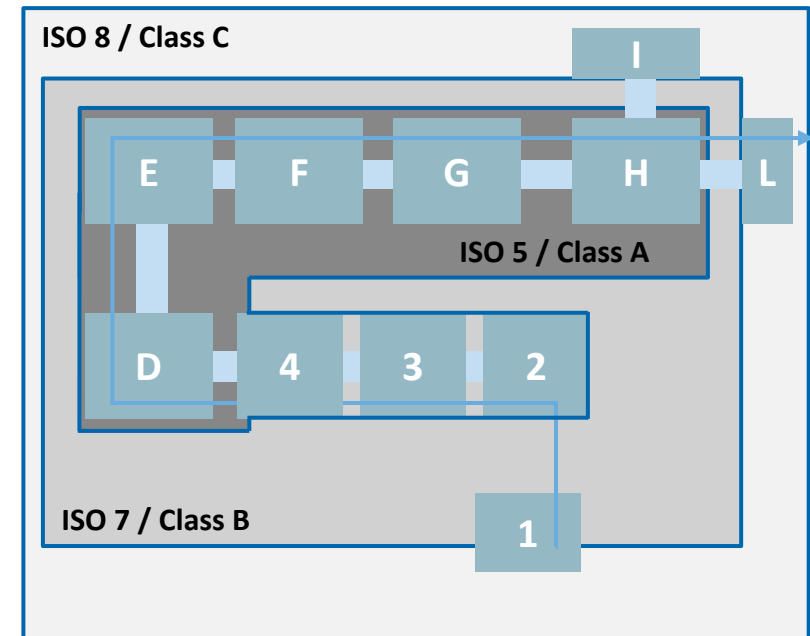
Benefit of EZ-fill® vials |

Fill & Finish process design to reduce footprint and improve quality

Bulk Traditional Process



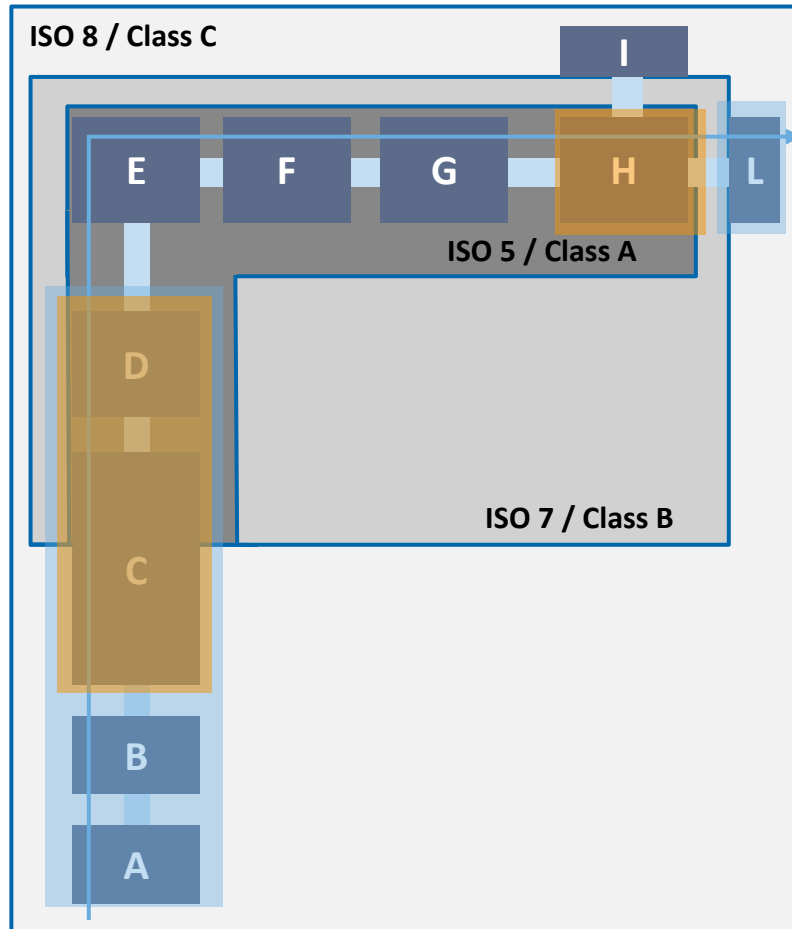
EZ-fill® Aseptic Process



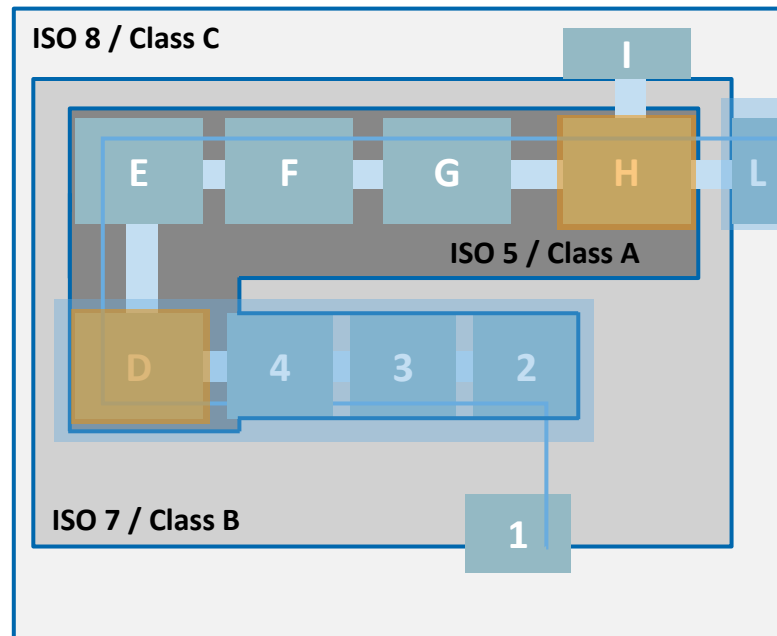
EZ-fill® Vials Benefit can be evaluated focusing on the infeed of primary packaging on the process

Benefit of EZ-fill® vials | Reduction of risk of breakages/rejections and improved efficiency

Bulk Traditional Process



EZ-fill® Aseptic Process



- Reduction of **risk of breakages and rejections** given the **impact of Depyrogenation on cosmetic quality**.
- **Potential increase in the throughput of the line** by **removing the complexity** generated in handling **washing and depyrogenation** modules.



REDUCE COMPLEXITY



NEED TO INCREASE QUALITY

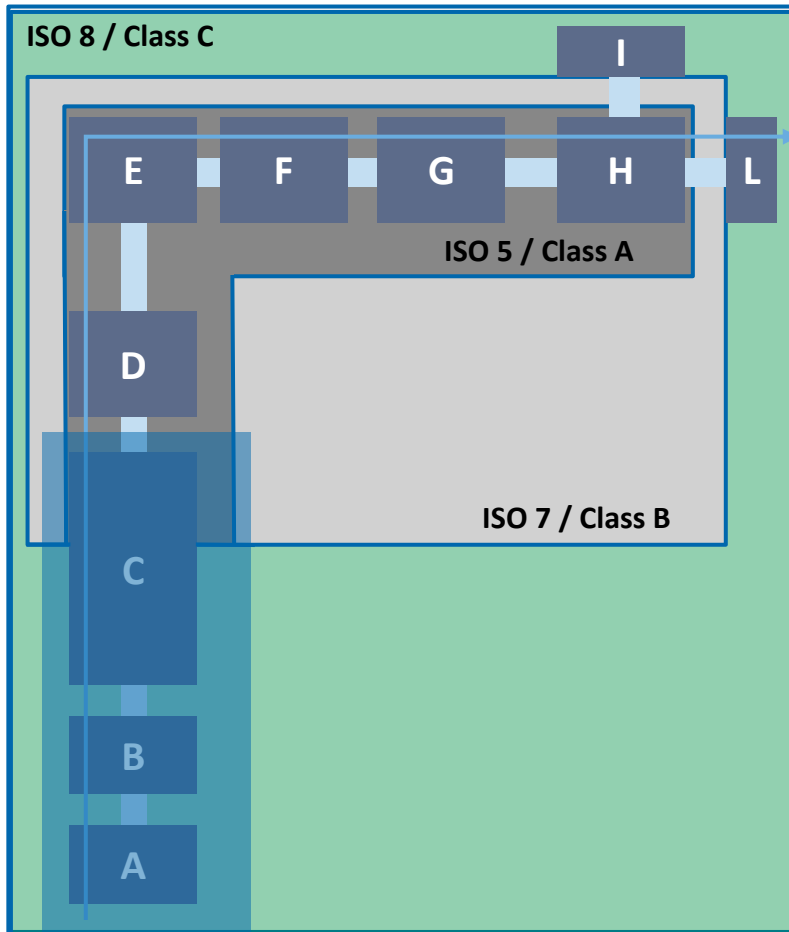


NEED TO REDUCE TOTAL COST OF OWNERSHIP (TCO)

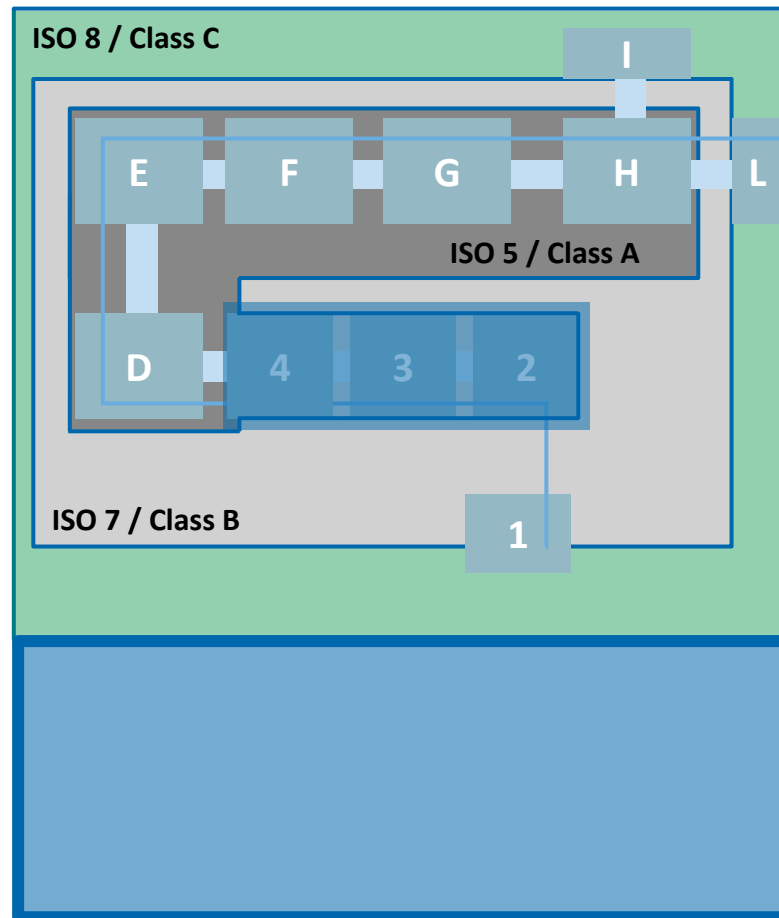
Benefit of EZ-fill® vials |

Reduction of Clean Room area and no need for Washing and Depyrogenation

Bulk Traditional Process



EZ-fill® Aseptic Process



- By **reducing Clean Room area** required in Grade C and Grade B and **removing** the need of **Washing & Depyrogenation**, it is possible to **reduce initial investment** as well as the **time for start-up**.
- Less **Clean Room area** and **no washing and depyrogenation** reduces **validation activities** (cost and timeline) and **utilities consumption**.



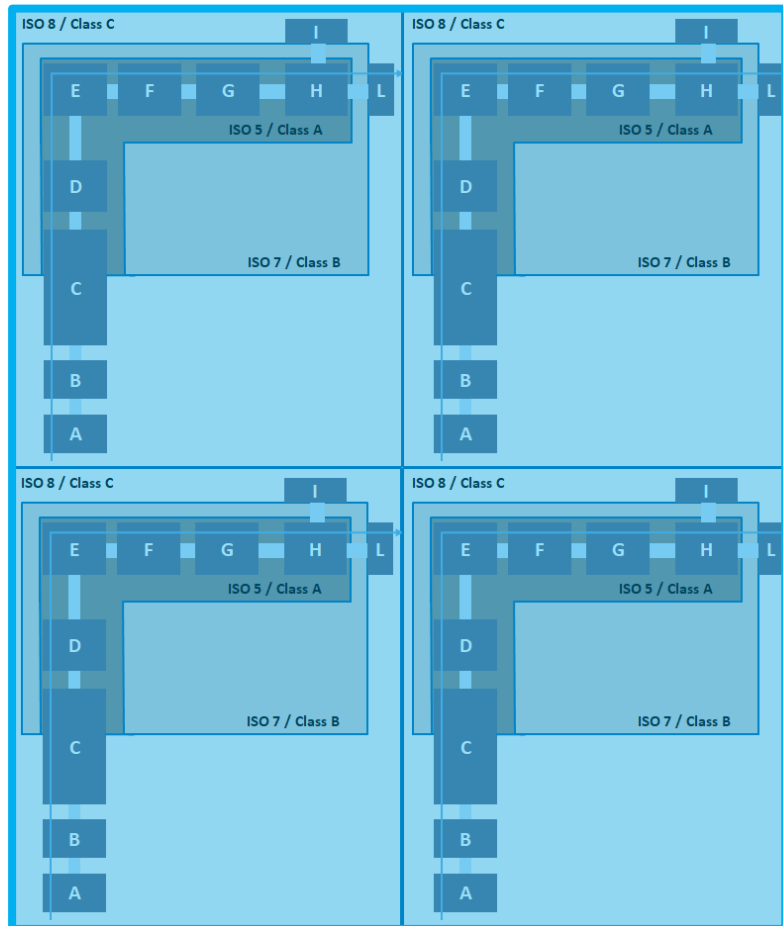
REDUCE TIME TO MARKET & QUICK INDUSTRIAL SCALE-UP



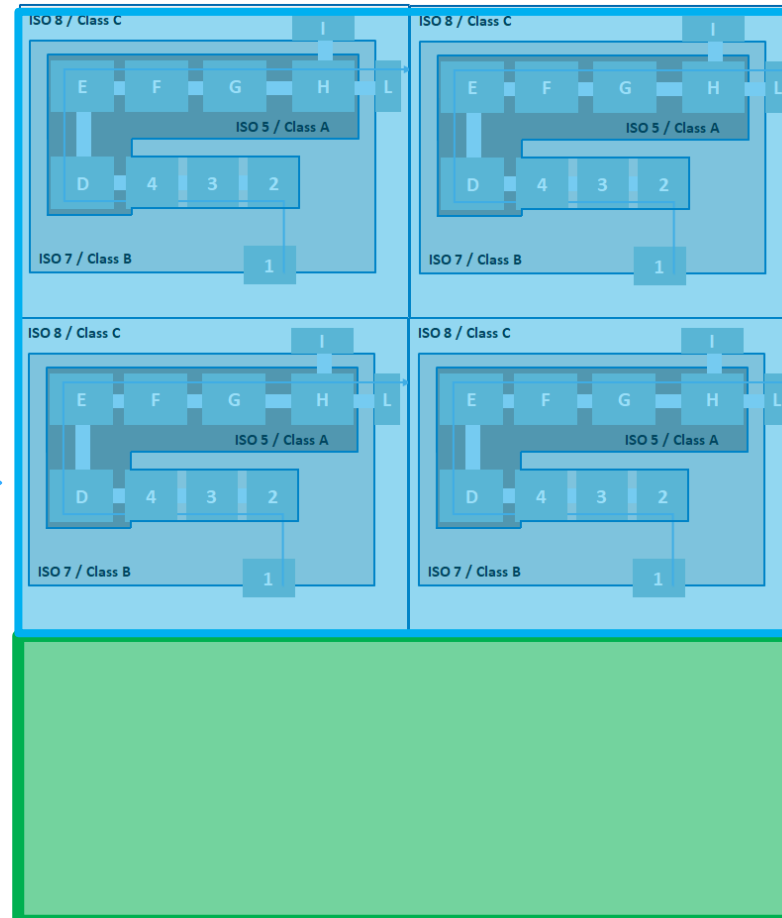
REDUCE TOTAL COST OF OWNERSHIP (TCO)

Benefit of EZ-fill® vials | Benefits of EZ-fill® can be evaluated also at Manufacturing site scale

Bulk Traditional Process



EZ-fill® Aseptic Process



- Depyrogenation oven impact highly the space required for Fill & Finish operations*.
- **Reduction** of the **footprint of Fill & Finish department** due to lower footprint of equipments and clean room areas.
- **Reduction** of the **timeline** for the **department set-up** and of the **space & investments** required.



REDUCE TIME TO MARKET & QUICK INDUSTRIAL SCALE-UP



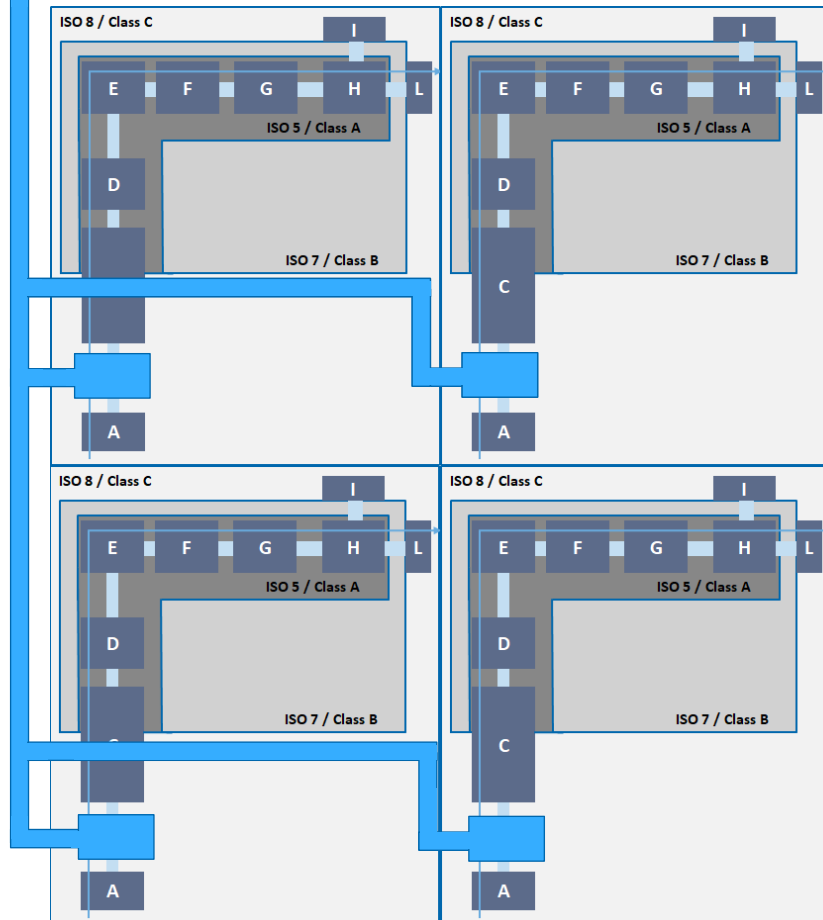
REDUCE TOTAL COST OF OWNERSHIP (TCO)

*The difference in terms of footprint is based on (i) F&F Equipment supplier, (ii) Industrial Set-up (washer and tunnel connected to the filler or not connected to the filler), (iii) Type of RTU F&F equipment

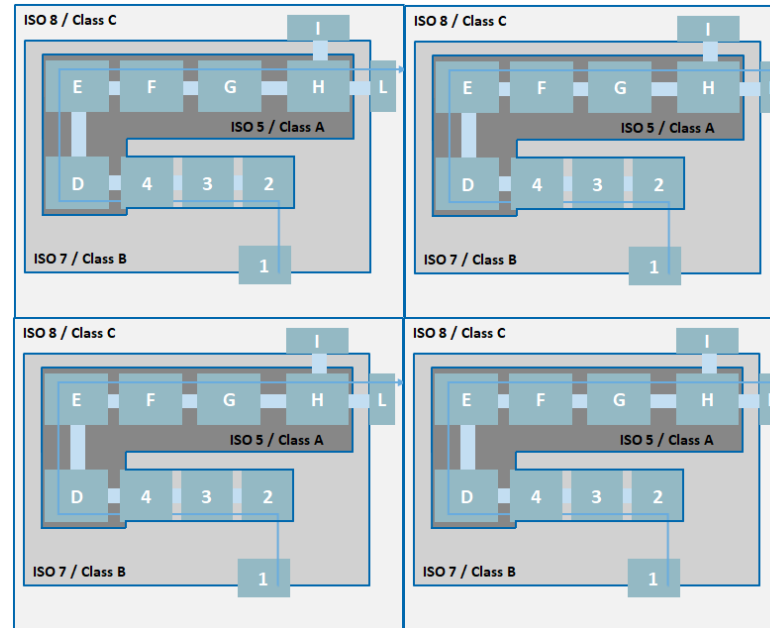
Benefit of EZ-fill® vials | No need for Water For Injection loop for Fill & Finish equipments

WFI

Bulk Traditional Process



EZ-fill® Aseptic Process



- **WFI Loop** and **infrastructure** related to Fill & Finish can be **reduced**.
- **Reduction of WFI** results in reduction of **water waste**, reduction of **initial investment** and **utilities costs**.
- **Reduction** of the **timeline** for the **department set-up** and of the **space & investments** required.



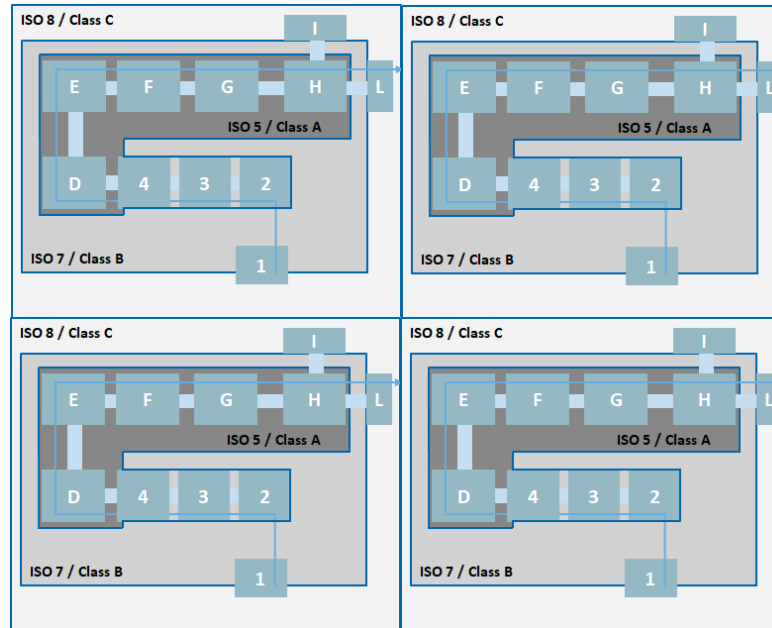
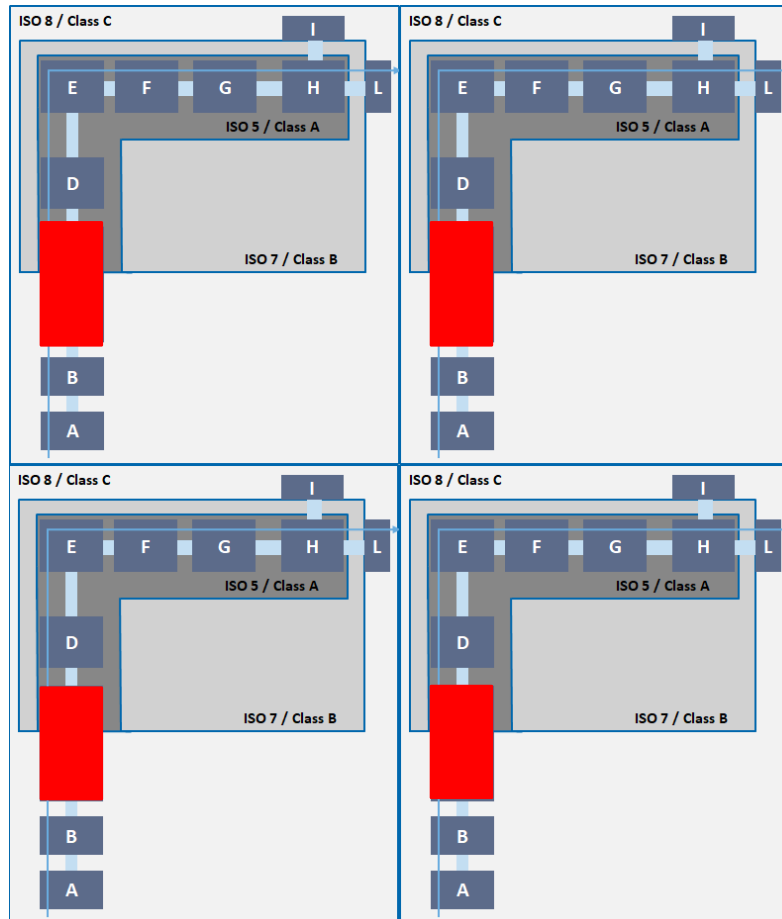
REDUCE TIME TO MARKET & QUICK INDUSTRIAL SCALE-UP



REDUCE TOTAL COST OF OWNERSHIP (TCO)

Benefit of EZ-fill® vials |

No need for oven Start up in production for Fill & Finish equipments



- Production start-up for the depyrogenation oven to reach correct temperature curve can take **up to 4 hrs**
- **Avoiding depyrogenation** oven results in reduction of **initial investment** and **utilities costs**.
- **Reduction** of the **timeline** for the **department set-up** and of the **space & investments** required.



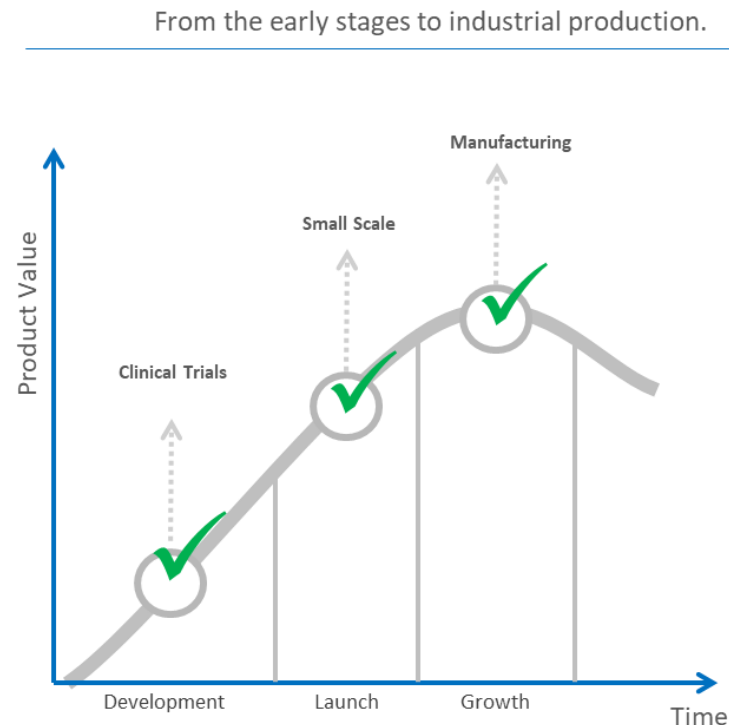
REDUCE TIME TO MARKET & QUICK INDUSTRIAL SCALE-UP



REDUCE TOTAL COST OF OWNERSHIP (TCO)

Benefit of EZ-fill® vials |

Same packaging configuration across different stages of Fill & Finish design



- **Same Fill & Finish Equipment across from Clinical to Commercial Manufacturing**

- **No change on the primary packaging from Discovery to Commercial**

- **Same Fill & finish procedures from Clinical to Commercial Manufacturing**

- **Possibility to plan resources and workforce in advance before Commercial Manufacturing**

- Reduced investment in Fill & Finish Equipment

- Streamline container characterization and validation activities

- Reduced training required for operators

- Reduced risk related to lack of trained workforce available

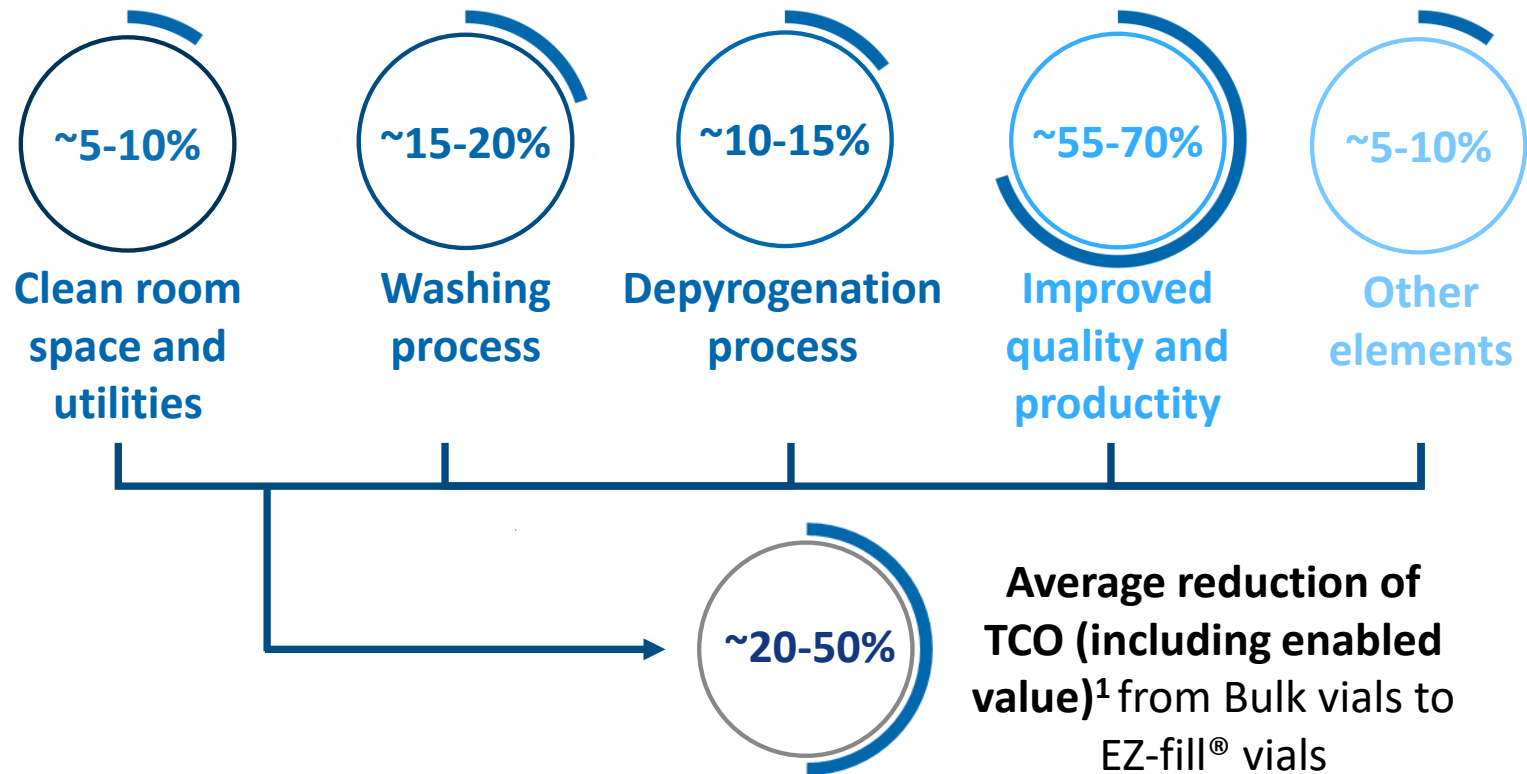


REDUCE TIME TO MARKET & QUICK INDUSTRIAL SCALE-UP



REDUCE TOTAL COST OF OWNERSHIP (TCO)

The advantages to Fill & Finish operations by EZ-fill® vials impacts positively not only on set-up time, but also on Total Cost of Ownership



Stevanato Group can support Pharma Companies in evaluating how using EZ-fill® vials configuration can reduce cost of upstream operations as well as timelines for Fill & Finish capacity with dedicated tools

Note: 1) Average data collected by Stevanato Group; the variance is due to factors such as (i) productivity rate, (ii) breakages and rejections rate, (iii) filling line utilization, (iv) volumes, (iv) country, (v) Industrial Set-up (washer and tunnel connected to the filler or not connected to the filler)

Key Takeaway on EZ-fill® vials platform

EZ-fill® vials is the solution for **fasten the industrial scaled-up** for Fill&Finish solutions considering the following topics



Reduction of risk of contamination



Reduction of breakages, rejections and improved cosmetic quality



Improve the overall process effectiveness



Reduction of utilities consumption



Reduction of initial CAPEX



Reduce Time To Market & Quick Industrial Scale-up



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- **Q&A**

We're looking forward to meeting you at DVCMN Annual Meeting – Booth 5

DCVMN Annual Meeting

19 - 21 September 2023

Cape Town - South Africa



Don't miss the opportunity to meet us during the [DCVMN Annual Meeting](#).

Visit us at the [Stevanato Group tabletop](#) and join our [corporate presentation](#) during the conference session!

Discover how we exploit our range of [services](#), [products](#), and [technologies](#) to offer integrated solutions for the pharma and healthcare industry.



Speech:

Thursday, September 21st - 01:30 pm to 3:00 pm (SAST)

Andrea Zambon – Corporate Business Development

SESSION:

["Leveraging Innovative Platforms for Novel Vaccines"](#)



[Book a meeting with us](#)



Thank You!