

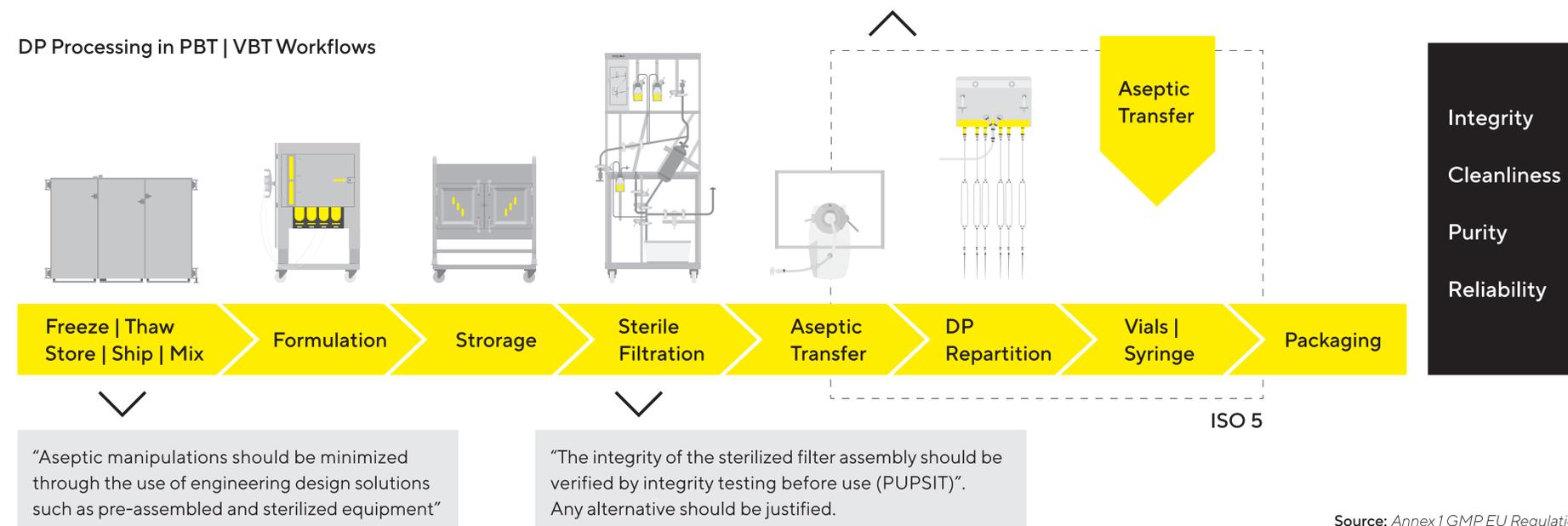
Faster and Safer With Single-Use Technologies in Final Fill and Finish



Contamination Control Strategy (CCS)
Is The Cornerstone of the Entire Annex 1
for Drug Product Processing

“The transfer of materials, equipment and components into the grade A or B areas should be carried out via unidirectional process [...] Where sterilisation upon transfer of the items is not possible, a procedure which achieves the same objective of not introducing contamination should be validated (e.g., using rapid transfer system for isolator...)”

DP Processing in PBT | VBT Workflows



Source: Annex 1 GMP EU Regulation

Formulation

Flexsafe® Pro Mixer

Flexsafe® Pro Mixer technology combines speed and efficiency to deliver high-performance mixing during powder dissolution, along with a levitating impeller to preserve the drug during low shear blending applications. It includes:

- Drive unit for automated control of mixing speed and time, mixing recipes, and remote control
- Palletank® for Mixing: Integrated weighing and heat exchange jacket functions and remote I/O box
- Mixing bag with in-line monitoring and control of pH, temperature, and conductivity
- Pre-assembled SU pH sensors and conductivity sensor

Component Transfer

Rapid Transfer Port

Biosafe® 110 includes:

- Alpha port (RTP) with 110 mm diameter (installed onto the wall of the isolator)
- Single-use beta bags for material transfer (fluid, components, and more)

The beta bag connects to the alpha port with magnetic docking, avoiding rotation and the risk of particulate generation.

Fluid Transfer

Biosafe® RAFT

- Transfer up to three lines (3/8" or 1/2")
- Use the Biosafe® mechanism
- Only available in ETO
- Implements easily in UPS | DSP or an isolator in final filling (combined with the Octoplus FF®)

SART System™ Technology

- Smart connecting system for safe liquid transfer across a wall between two areas of different classifications
- SART System™ with Gammasart ATD™, a SART port with an external disposable connector device that you can sterilize by autoclave or gamma-irradiation

Liquid Repartition

Octoplus FF® Designed Specifically For Final Filling

- Individual filling lines on a flat bag bottom
- Optimized 8 L wallet-shape bag designed for filling applications (99.5% recovery product)
- Large design space and components adapted to multiple filling line designs (e.g., tubings and needles)
- Different packaging configurations with or without Biosafe® for transferring to the filling line