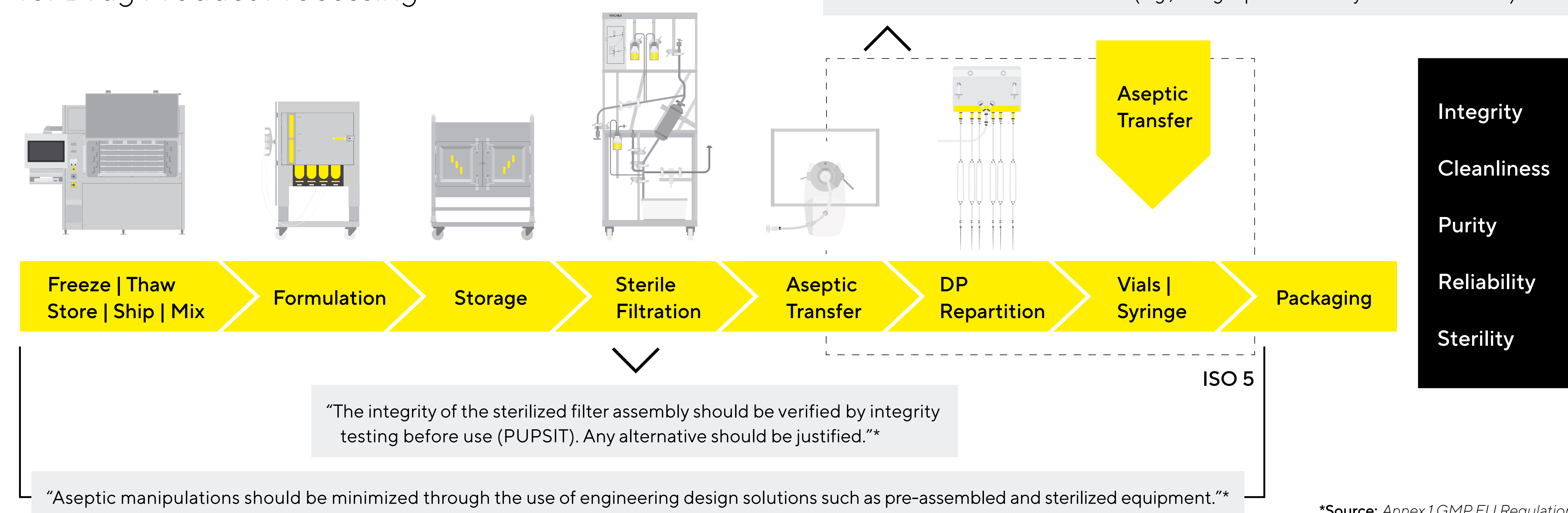


# Master. Fill. Finish.

## Faster and Safer Single-Use Technologies From Thaw to Final Fill.



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



### 1. Drug Substance Receipt & Thaw

Celsius® FFT | FFTp with Safecore™ Technology are single-use, sterile and ready to use containers with an innovative bag-in-plate design for exceptional protection during the entire cold chain of bulk drug substances. Different container sizes (from 2 to 75 L) to be managed in stand alone or palletized mode make the technology fully flexible and scalable from lab to commercial scale.

- Freezing containers require no tools to assemble
- Plates are transparent to allow visual confirmation of thawing completion and product quality check for aggregation
- Each unit can be supplier integrity tested (SIT) with helium technology (2 µm sensitivity) for the bag and direct lines
- Configurable with various tubing and connector | disconnect technologies
- Integrated line management system for secured tubing, pinch-clamp, and connector storage

### 2. Drug Product Formulation

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 is fully scalable from benchtop (from 5 L) to commercial product (up to 1,000 L). The same mixing technology is available up to 3,000 L.

- Drive unit for control of mixing speed and time, mixing recipes, and remote control
- Palletank® for Mixing: Integrated weighing and heat exchange jacket functions
- Flexsafe® mixing bag with pre-assembled single-use pH and conductivity sensors
- Pro Mixer Connection Unit for monitoring critical process parameters such as weighing, temperature, pH, conductivity, and controlling mixing speed

### 3. PUPSIT & Sterile Filtration

Sartorius’ pre-configured single-use filter transfer sets for final filling reduce design phase wait times by up to 80%. Standardized product design and consistent operating procedures streamline handling and reduce the risk of operator error, regardless of filter type and size. The qualified, sterile filter transfer set for final filling complies with PUPSIT requirements outlined in the EU GMP Annex 1.

- Pre-design for fast availability
- High standardization promotes usability and risk mitigation
- PUPSIT optimized design meeting regulatory expectations
- Stainless-steel holder simplifies installation and optimizes assembly placement to minimize product loss
- Automated PUPSIT system available to further reduce errors that could happen during manual processing

### 4. Aseptic Transfer

Biosafe® 110 – 200 mm includes:

- Alpha port (RTP) with internal or external opening (for glove-less intervention) installed onto the wall of the isolator
- Single-use beta bags for material transfer (fluid, components, tools) and removal (petri plate, waste, in-process control samples)
- One single-use connection to prevent any risk of cross-contamination
- The beta bag connects to the alpha port with magnetic docking, avoiding rotation and the risk of particulate generation

SART System™ Technology:

- Smart connecting system for safe liquid transfer across a wall between two areas of different classifications
- Small footprint and external disposable connector device that can be sterilized by autoclave or gamma-irradiation

### 5. Single-Use Filling

The OctoPlus FF® is a single-use set for the repartition of the drug product into the final containers (vials, syringes, cartridges, etc.). It eliminates CIP | SIP validation and operation costs in the ISO 5 area, while contributing to improve the operator security and the drug product quality.

- Individual filling lines on a flat bag bottom
- Optimized 8 L wallet-shape bag designed for filling applications (99.5% product recovery)
- 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