The anatomy of Aseptic Transfer:

where sterility becomes fragile

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In bio-pharma, where the drug product cannot withstand terminal sterilization, **the sterility of components depends entirely on controlling the most fragile steps of the journey.**

The landscape evolved beyond the standard 121°C sterilization process:

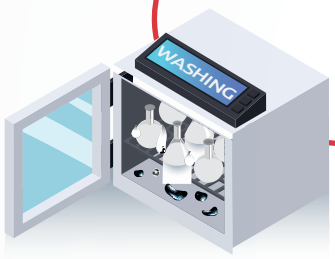
- More modalities (biologics, ATMP, high-value / low-volume)
- More formats (RTU nested, syringe, cartridge)
- More pressure (speed-to-clinic + supply resiliency)

Let's explore the **6 process steps** where sterility must be actively protected:

01. Starting point

Components arrive at the facility dirty from the manufacturer. The worst-case bioburden requires a rigorous sterilization cycle.

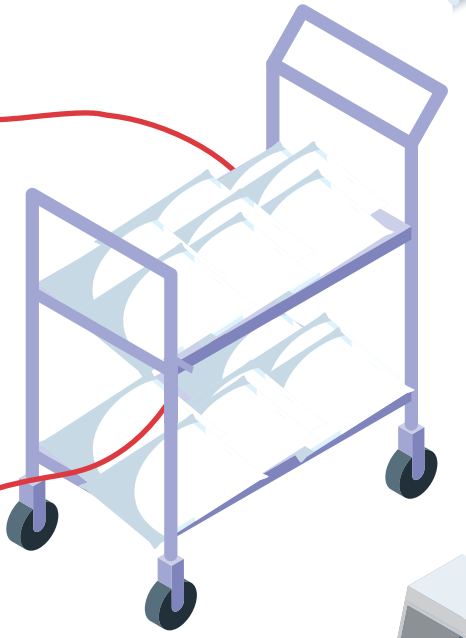
- *Used / assembled part*
- *Worst-case bioburden*
- *CCS starting point*



02. Washing

A critical control point for the removal of particles, endotoxins and residues.

- *Bioburden*
- *Endotoxins particles*



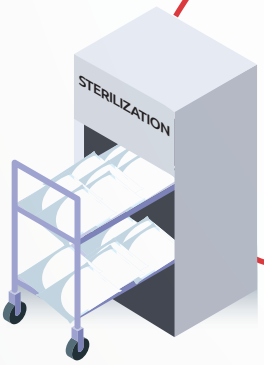
03. Packaging

Components are prepared for the autoclave. The choice between Tyvek® bags or Canisters is a strategic, risk-based decision.

- *Tyvek®*
- *Canister*
- *Risk-based selection*

Packaging strategy: governing non-absorbable process risks

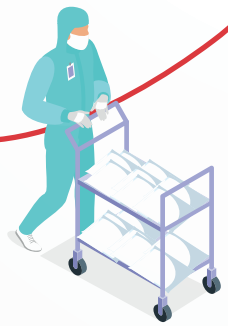
Method	Pros	Cons
Tyvek bags	• *Flexibility* • *Adaptability for small and irregular components* • *Limited infrastructure required*	• *Human contamination risks* • *Challenging seal integrity and condensating removal*
Canister	• *Automation ready* • *Minimized contamination risks* • *Robust closed system*	• *Non-forgiving to residual air and condensate* • *Requires explicit control of phase transitions*



04. Sterilization

Saturated steam must penetrate the packaging, displace air and eliminate all pathogens over.

- *Air–steam displacement*
- *Condensate formation and removal*
- *Packaging and filter integrity*



05. Transfer

The movement from the autoclave to the Grade A Isolator via a Rapid Transfer Port (RTP) must preserve the sterile barrier.

- *Potential exposure*

06. Isolator

Sterile parts enter the filling line with minimal human intervention. The aseptic transfer is completed.

- *Open interface*
- *Grade A boundary*
- *Closed CCS*

Fedegari's approach: taking ownership of the most fragile process transitions

By designing cycles around air removal, condensate behavior, and steam penetration, we make implicit risks explicit and controllable, turning regulatory compliance into a repeatable and defendable process outcome.