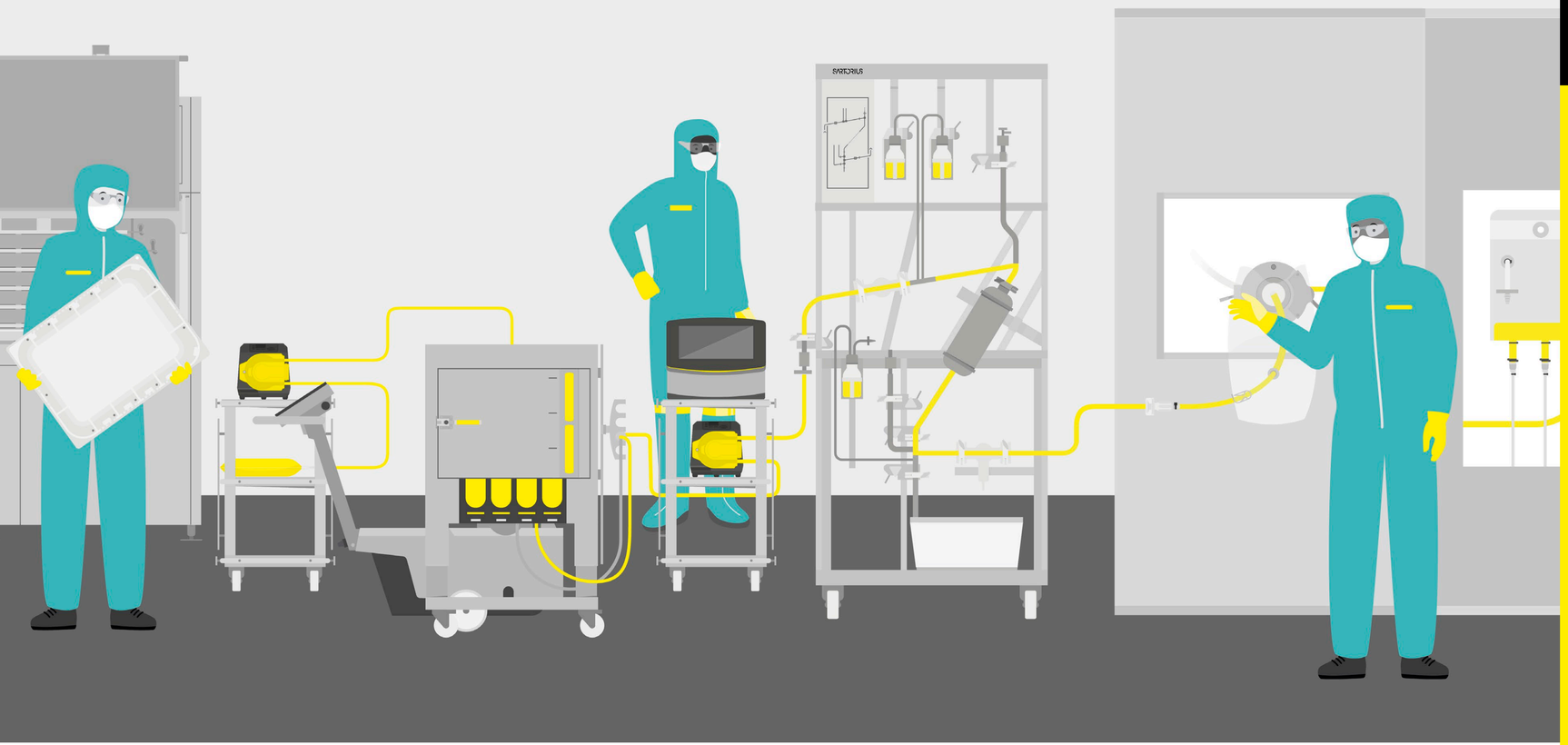


Simplifying Progress

Future-Proof Your Fill & Finish

Explore a Portfolio Designed for Flexibility,
Quality and Safety From Thaw to Final Fill

Click Here to Start

SARTORIUS

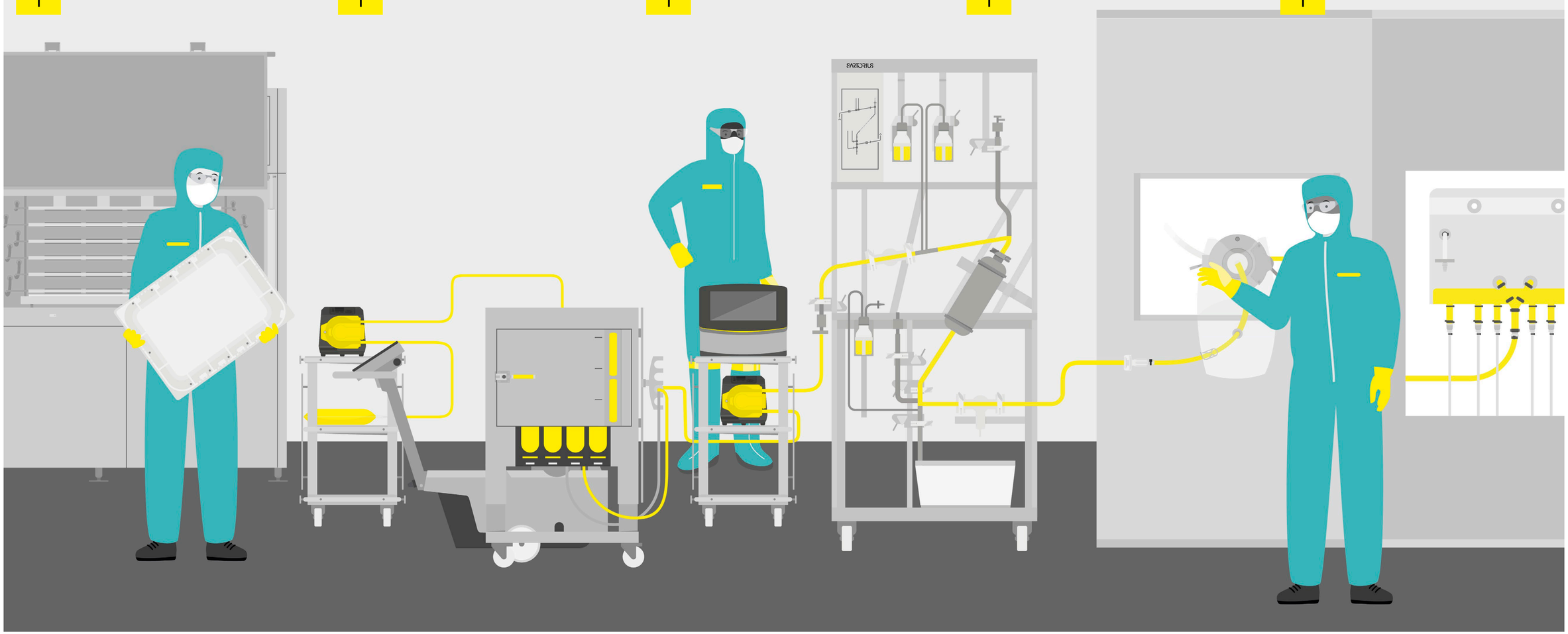
Drug Substance Receipt and Thaw

Drug Product Formulation

PUPSIT* and Sterile Filtration

Aseptic Transfer

Single-Use Filling



*Pre-Use Post-Sterilization Integrity Test

Goals
- Meet regulatory compliance
- Provide scientific evidence of product quality
- Ensure patient safety

Challenges
- Sterility in aseptic processing
- Navigating complex and evolving requirements from regulators worldwide
- Validation timelines

Solutions
- Risk-based validation strategy
- Global regulatory and quality expertise
- +30 years of experience in complex and global validation projects

Single-Use and Validation in One Place

Confidence® Validation Services are designed to support biopharma companies in meeting the highest regulatory and quality standards while accelerating time to market. We offer comprehensive support across the entire validation lifecycle—from validation protocol development and execution to final documentation and audit readiness.

Our services cover sterile filter validation, including Bacterial Challenge Testing, Product Specific Integrity Testing, Chemical Compatibility Testing, Adsorption Testing, Extractables & Leachables Testing, Validation of PoULT of Transfer Sets, and to support your contamination control strategy we provide Particle Release Testing for Filters and Particle Validation Standards to be used during Visual Inspection Training Programs.

What sets us apart is our risk-based validation approach, which helps streamline efforts by focusing on the most critical parameters—ensuring compliance without unnecessary delays. We combine global regulatory expertise with local support, helping our partners navigate regional requirements and agency expectations with confidence. In addition, our in-house laboratories enable faster turnaround times and greater flexibility in test method development and execution, ensuring both speed and adaptability in even the most complex validation scenarios.

Confidence®
Validation Services

"As regulatory expectations tighten worldwide, robust Fill & Finish validation is no longer optional—it's essential. It ensures product sterility, patient safety, and compliance across every batch, safeguarding both public health and your market access."

Nicole Liu, Confidence® Validation Services

Supporting Success Beyond the Portfolio

When it comes to final formulation and fill, success depends on more than having the right tools. It requires the right support, at the right time, from people who understand your process challenges firsthand. From validation and qualification to ongoing maintenance, our services are designed to support your team across the entire lifecycle of your fill and finish line.

Whether you need help validating performance, resolving issues on-site, or meeting sustainability goals, we bring the technical know-how and responsiveness you need to stay ahead, without slowing down.

"In final formulation and fill, it's never just about the equipment. It's about having someone by your side who's seen it before, solved it before, and can guide you through—with the data, the documentation, and the experience to back it up."

Paolo Sacca, Field Account Project Manager

Qualification
IQ | OQ of equipment
Maintenance
Calibration and preventive maintenance of equipment

Sustainability

Field Support
- Global and local on-the-field support
- Experienced teams of subject matters experts

Access Fill & Finish Resources

Your final step is our first priority. Read more about how Sartorius addresses the challenges of fill and finish, every step along the way.

Drug Substance Receipt and Thaw

White Paper
Robust by Design: Addressing New Challenges in Bulk Drug Substance Management

Webinar
Securing Sensitive Drug Substances in Freeze and Thaw

Drug Product Formulation

Webinar
How to Improve Mixing with Computational Fluid Dynamics

Application Note
Low Shear Single-Use Mixing and Blending

PUPSIT and Sterile Filtration

Webinar
Common Challenges in Designing Final Filtration

Blog
The Complete Guide to Pre-Use, Post-Sterilization Integrity Testing (PUPSIT)

Audiocast
Unfiltered: The Great PFAS Debate

Application Note
Sartopore Evo®

Aseptic Transfer

Webinar
Studio Science — Simplifying Final Filling: Single-Use Transfer and Filling Solutions

Video
Aseptic Transfer Using Biosafe® Monolever Port Outside Opening

Related Product Videos

Single-Use Filling

Video
One Fully Integrated Solution for Drug Product Repartition

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565 Johnson Avenue
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Toll-Free +1 800 368 7178

For further information, visit
sartorius.com

Last updated: 03 | 2026

Drug Substance Receipt and Thaw

Goals
- Drug product quality
- Yield
- Safe operation

Challenges
- Safe handling
- Risk of hazardous product
- Product loss

Solutions
- Fully scalable cold chain management
- Controlled thawing equipment
- Total containment configurations available

Explore Drug Substance Receipt and Thaw

Sartorius Solutions in Focus

Celsius® FFT and FFTp

Celsius ® FFT | FFTp with Safecore™ Technology are single-use, sterile and ready to use containers with an innovative bag-in-plate design (cassette) for exceptional protection during frozen storage and shipping of bulk drug substances.

- 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 is supplier integrity tested (SIT) with helium technology (2 µm sensitivity) for the bag and direct lines
- Configurable with various connector | disconnector technologies
- Integrated line management system for secured tubing, pinch-clamp, and connector stowage

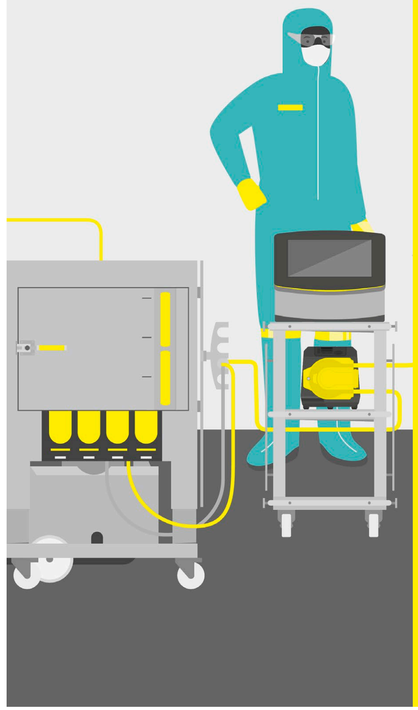
Related Products
- **Freezing Containers:**
  Celsius® FFT | FFTp with Safecore™ Technology
- **Shippers:**
  Celsius® FFT Bulk Shipper
  Celsius® FFT | FFTp Box Shipper

Connected Services
- \+ Validation services
- \+ Additional support

"Aseptic manipulations should be minimized through the use of engineering design solutions such as pre-assembled and sterilized equipment."

EudraLex Vol. 4 | Annex 1 (EU GMP Regulation), 2.2

Drug Product Formulation



Goals
- Homogenity
- Product quality
- Yield

Challenges
- Shear sensitivity
- High viscosity
- Toxic payloads

Solutions
- Advanced mixing technology with levitating impeller
- Closed-loop formulation systems
- Scalable buffer prep platforms
- Ease of use and ergonomics design

Explore Drug Product Formulation

Sartorius Solutions in Focus

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 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.

It includes:
- 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

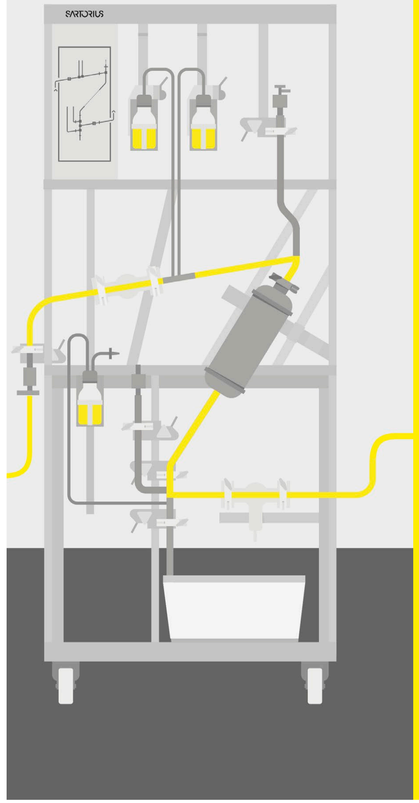
Related Products
- **2D Bag:** Flexsafe® 2D Mixing and Storage Bag
- **Integrity Tester:** Supplier Integrity Test (Helium Technology)
- **Leak Tester:** Sartocheck® for Point-of-Use Leak Test

Connected Services
- \+ Validation services
- \+ Additional support

"The use of closed systems can reduce the risk of microbial, particle and chemical contamination from the adjacent environment."

EudraLex Vol. 4 | Annex 1 (EU GMP Regulation), 4.3

PUPSIT* and Sterile Filtration



Goals
- Product quality and yield
- Sterility assurance
- Regulatory compliance (Annex 1)

Challenges
- Product loss
- Excipient and protein adsorption
- Operator inefficiency and errors
- Risk of contamination and leaks
- PUPSIT without breaking sterility
- Long design phase and delivery times for single-use filter assemblies

Solutions
- Low adsorptive sterilizing-grade filter
- PUPSIT-ready, standardized filter assemblies for final sterile filtration
- Automated filter integrity testing

Explore PUPSIT and Sterile Filtration

Sartorius Solutions in Focus

Filter Transfer Sets for Final Filling

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
- Regulatory compliant and PUPSIT optimized
- 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

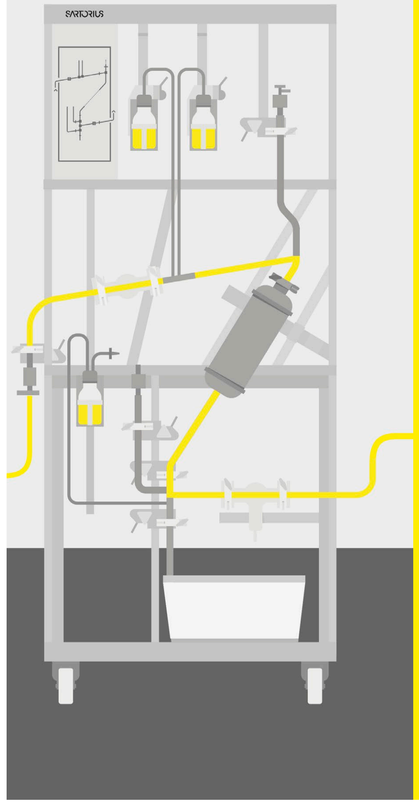
Related Products
- **Integrity Tester:** Sartocheck® 5 Plus
- **Final Filtration:** Sartopore Evo®
- **PUPSIT System:** Manual and Automated PUPSIT Skids

Connected Services
- \+ Validation services
- \+ Additional support

> *"The integrity of the sterilised filter assembly should be verified by integrity testing before use (PUPSIT) […]"*
>
> EudraLex Vol. 4 | Annex 1 (EU GMP Regulation), 8.87

*Pre-Use Post-Sterilization Integrity Test

PUPSIT* and Sterile Filtration



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Solutions
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Explore PUPSIT and Sterile Filtration

Sartorius Solutions in Focus

Sartopore Evo®

Sartopore Evo® offers advanced final filtration solutions with its innovative surface-coated PES membrane, ensuring high throughput and minimal adsorption. Designed for diverse biopharmaceutical applications, they provide reliable performance across various scales.

Primary features:
- Minimized adsorption of proteins and excipients, like PS20 and PS80, ensure increased yield and stable drug formulation
- High filter capacity and flow rates for efficient process operations
- No intentional use of PFAS compounds, ensuring security of supply as well as usability in manufacturing

Related Products
- **Integrity Tester:** Sartocheck® 5 Plus
- **Final Filtration:** Sartopore Evo®
- **PUPSIT System:** Manual and Automated PUPSIT Skids

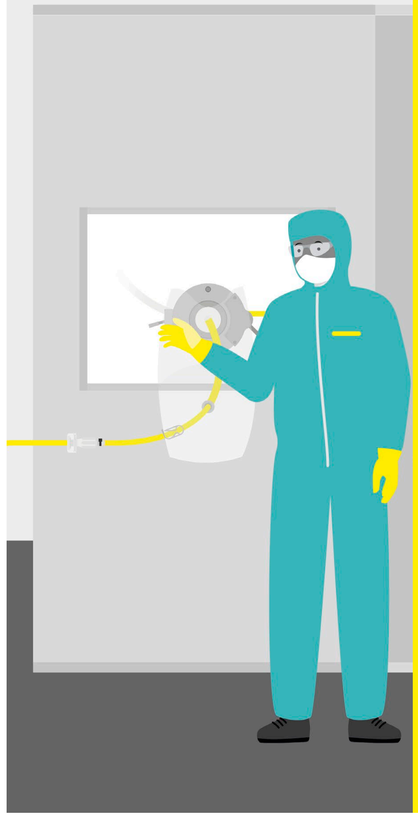
Connected Services
- \+ Validation services
- \+ Additional support

"The integrity of the sterilised filter assembly should be verified by integrity testing before use (PUPSIT) [...]"

EudraLex Vol. 4 | Annex 1 (EU GMP Regulation), 8.87

*Pre-Use Post-Sterilization Integrity Test

Aseptic Transfer



Goals
- Safe liquid and component transfer
- Sterility assurance

Challenges
- Preventing product loss
- Avoiding contamination (particulates, microbial, leachables)
- Gloveless transfer
- Risk for hazardous product

Solutions
- Contamination control strategy
- Flexible single-use devices
- External openings for gloveless transfer
- Total containment after beta-port closure

Explore Aseptic Transfer

Sartorius Solutions in Focus

Biosafe® Rapid Transfer Port (RTP) and Bags

Biosafe® 110 – 200 mm includes:
- Alpha port (RTP) with internal or external opening (for gloveless 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

Biosafe® Rapid Aseptic Fluid Transfer (RAFT)

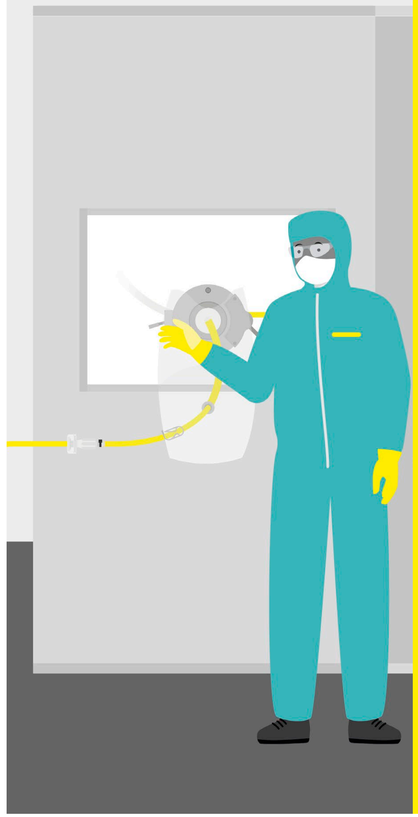
- Easily integrates into an isolator when combined with the Octoplus FF® or Flexsafe 2D Advanced FF® filling bag

Related Products
- **Filling Bag:** Octoplus FF®
- **2D Filling Bag:** Flexsafe® 2D Advanced FF®
- **Sterile Connector:** Opta® SFT
- **Final Filtration:** Sartopore Evo®
- **Air Monitoring System:** MD8 Airscan®

Connected Services
- \+ Validation services
- \+ Additional support

> *"The transfer of materials, equipment and components into the grade A or B areas should be carried out via undirectional 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."*
>
> EudraLex Vol. 4 | Annex 1 (EU GMP Regulation), 4.11

Aseptic Transfer



Goals
- Safe liquid and component transfer
- Sterility assurance

Challenges
- Preventing product loss
- Avoiding contamination (particulates, microbial, leachables)
- Isolator footprint

Solutions
- Contamination control strategy
- Flexible single-use devices
- Smallest isolator footprint

Explore Aseptic Transfer

Sartorius Solutions in Focus

SART System™ Rapid Transfer Port

- Smart connecting system for safe single liquid transfer across a wall between two clean rooms of different classification
- Error-proof: The port is equipped with mechanical interlock systems that prevent an accidental opening without the Gammasart ATD™ connector in place and accidental release of the outer part of the connector

SART System™ with Gammasart ATD™

- SART port with small footprint and external disposable connector device that can be sterilized by autoclave or gamma-irradiation
- The disposable Gammasart ATD™ connector may be opened and re-used up to three times. Multiple transfers of different volumes can be processed without the need of re-sterilization.

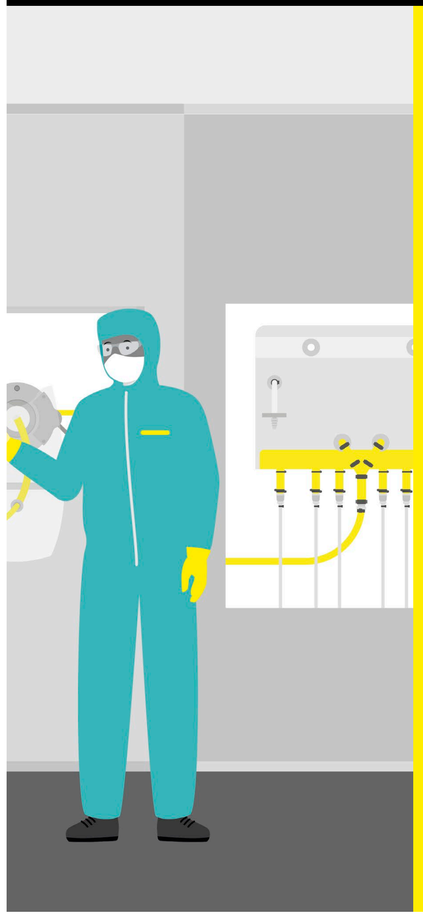
Related Products
- **Filling Bag:** Octoplus FF®
- **2D Filling Bag:** Flexsafe® 2D Advanced FF®
- **Sterile Connector:** Opta® SFT
- **Final Filtration:** Sartopore Evo®
- **Air Monitoring System:** MD8 Airscan®

Connected Services
- \+ Validation services
- \+ Additional support

"The transfer of materials, equipment and components into the grade A or B areas should be carried out via undirectional 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."

EudraLex Vol. 4 | Annex 1 (EU GMP Regulation), 4.11

Single-Use Filling



Goals
- Dose accuracy
- Product recovery
- Accelerate time to market

Challenges
- Preventing product loss
- Ensuring flexibility across filling lines
- Minimizing contamination risk to product and environment
- Changeover time between batches

Solutions
- Pre-sterilized single-use filling sets
- Removing need for CIP | SIP validation
- Maximize product recovery by design
- Shorten installation time

Explore Single-Use Filling

Sartorius Solutions in Focus

Octoplus FF® Designed Specifically for Final 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.

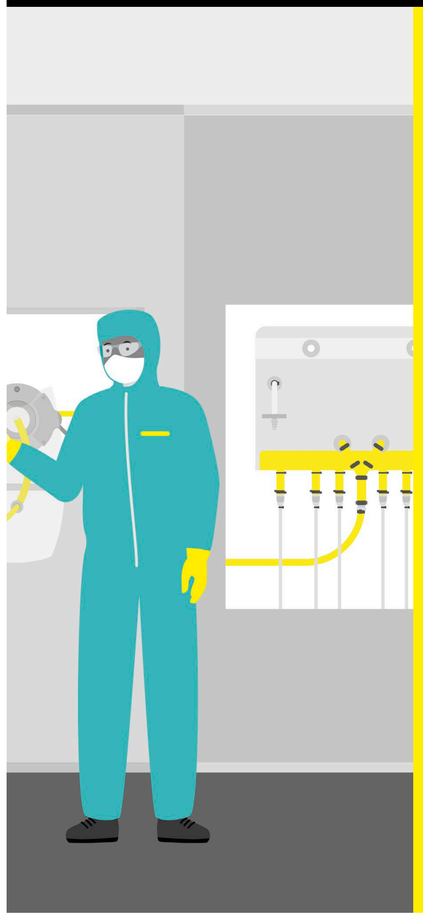
- Individual filling lines on a flat bag bottom
- Optimized 8 L wallet-shape bag designed for filling applications (99.5% product recovery)
- Large design space and components adapted to multiple filling line designs (e.g., tubings and needles)
- Different packaging configurations with or without Biosafe®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

Related Products
- **Transfer Port System:** Biosafe® RTP and Beta-Bag (Rapid Transfer Port)
- **Transfer Port System:** SART System™(Smart Liquid Transfer Port)
- **Sterile Connector:** Opta® SFT
- **Final Filtration:** Sartopore Evo®
- **Air Monitoring System:** MD8 Airscan®

Connected Services
- \+ Validation services
- \+ Additional support

> *"Aseptic manipulations should be minimized through the use of engineering design solutions such as pre-assembled and sterilized equipment."*
>
> EudraLex Vol. 4 | Annex 1 (EU GMP Regulation), 8.15

Single-Use Filling



Goals
- Dose accuracy
- Product recovery
- Accelerate time to market

Challenges
- Preventing product loss
- Ensuring flexibility across filling lines
- Minimizing contamination risk to product and environment
- Changeover time between batches

Solutions
- Pre-sterilized single-use filling sets
- Removing need for CIP | SIP validation
- Maximize product recovery by design
- Shorten installation time

Explore Single-Use Filling

Sartorius Solutions in Focus

Flexsafe® 2D Advanced FF® Designed Specifically for Final Filling

Flexsafe® 2D Advanced FF is custom filling sets for various final filling applications. 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.

- Various smaller bag sizes from 1 L to 5 L to fit small batch volume for personalized medicines
- Large design space and components adapted to filling line designs (tubings, needles)
- Premium bag from 1 L to 5 L with high assurance of quality supply
- Well-characterized film and materials
- Different packaging configurations inside or outside the isolator, with or without Biosafe® for transferring to the filling line

Related Products
- **Transfer Port System:** Biosafe® RTP and Beta-Bag (Rapid Transfer Port)
- **Transfer Port System:** SART System™(Smart Liquid Transfer Port)
- **Sterile Connector:** Opta® SFT
- **Final Filtration:** Sartopore Evo®
- **Air Monitoring System:** MD8 Airscan®

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- \+ Validation services
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