

Simplifying Progress



Protect What Matters Most in ADC Manufacturing.
Molecule. Process. Operator.

[Click here to start](#)

SARTORIUS

Introduction

Antibody–drug conjugates (ADCs) are an advanced class of targeted cancer therapeutics that combine the specificity of monoclonal antibodies with the potency of cytotoxic drugs, enabling selective delivery of chemotherapy directly to tumor cells. Increasing clinical success and technological advances position ADCs as strong candidates for the next gold standard in cancer treatment.¹

ADCs are among the most potent and complex therapies in development today. The same properties that make ADCs effective—high potency, complex chemistry, and narrow operating windows—also make them challenging to manufacture reliably and safely at scale.

ADC manufacturing is best understood as a risk-managed workflow, where manufacturers must safeguard molecular integrity, process consistency, and operator safety at every step. When damage is introduced early, manufacturers can't correct it downstream. Process variability compounds during scale up, and operator exposure to cytotoxic payloads poses serious safety and compliance risks.

This interactive e-book walks through the ADC manufacturing workflow, highlighting how Sartorius solutions help manufacturers manage risk, stabilize performance, and enable safer, scalable ADC production—from thaw through final fill.

ADC manufacturing consists of a series of tightly linked process steps, each influencing the quality, safety, and scalability of the final therapeutic.

Each step is designed to help manufacturers protect what matters most.



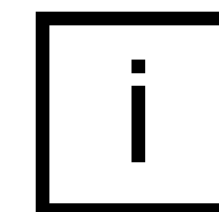
Protect the molecule by preserving structural integrity and controlling critical quality attributes.



Protect the process by enabling reproducible, scalable operations using chemically compatible materials.



Protect the operator by reducing exposure through closed and contained workflows.



Flip to the next page for an overview of the workflow, and select any step to explore its objective and challenges, along with examples of how Sartorius solutions can support the process.

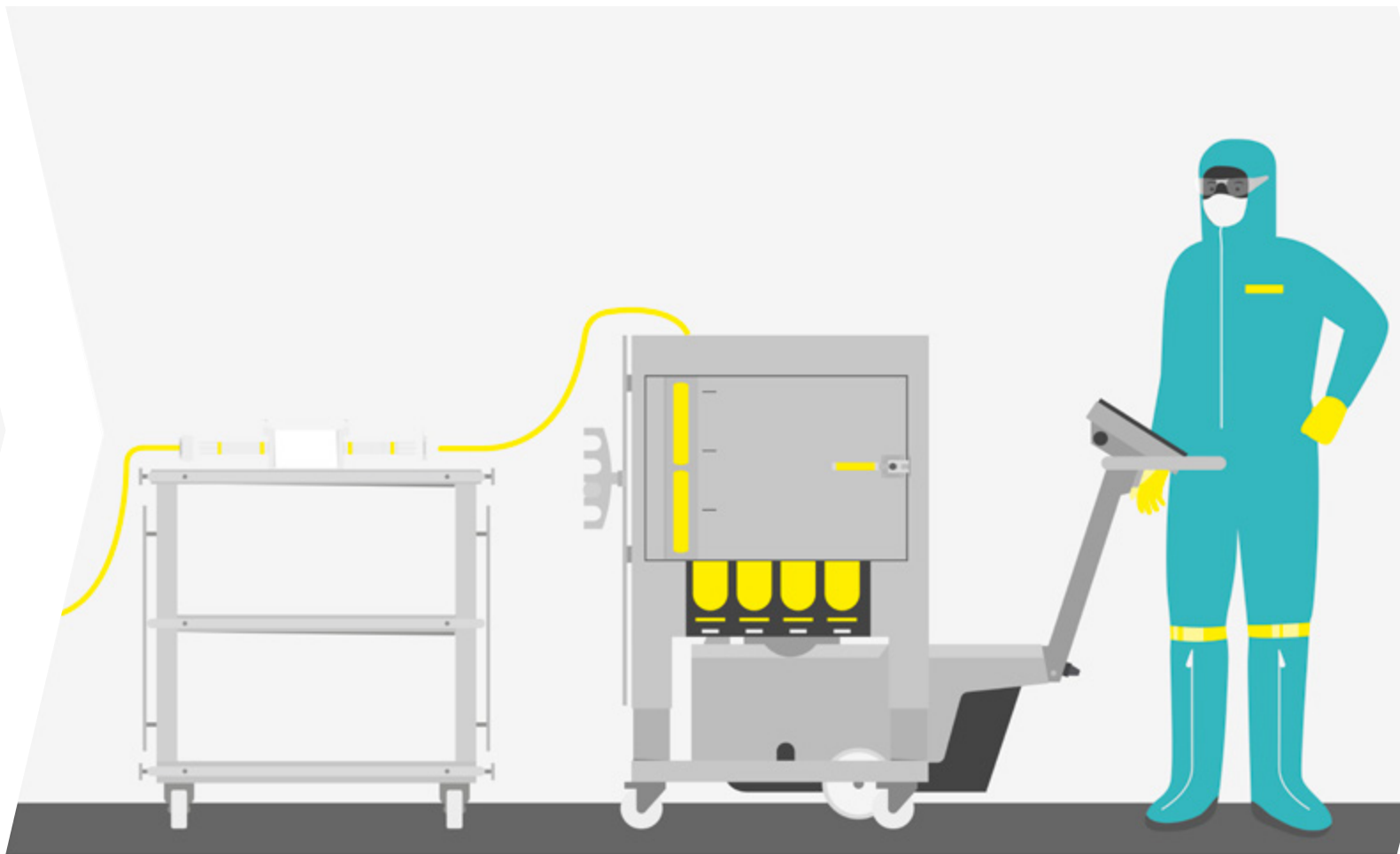
ADC workflow overview



1

mAb thaw

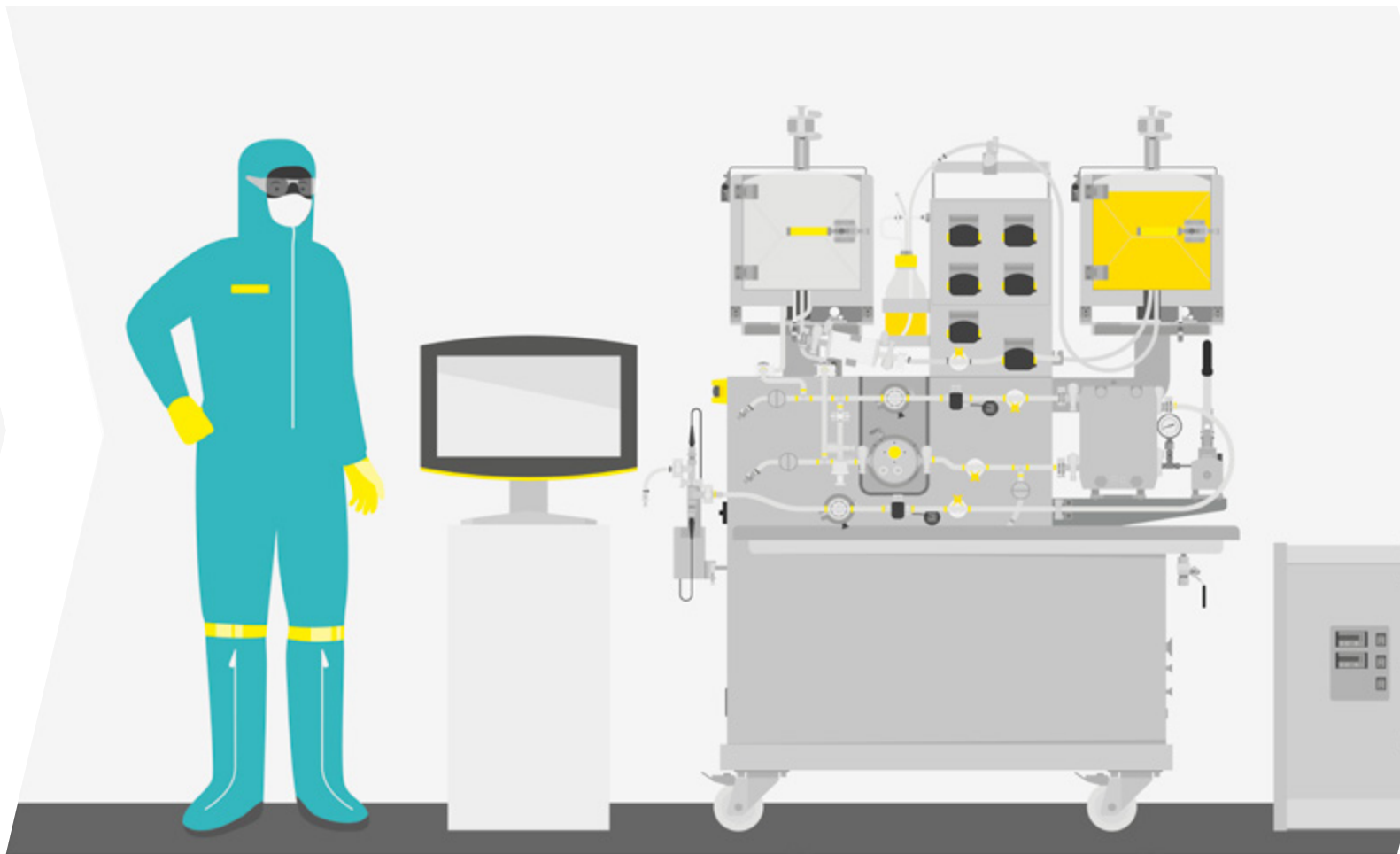
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2

mAb filtration

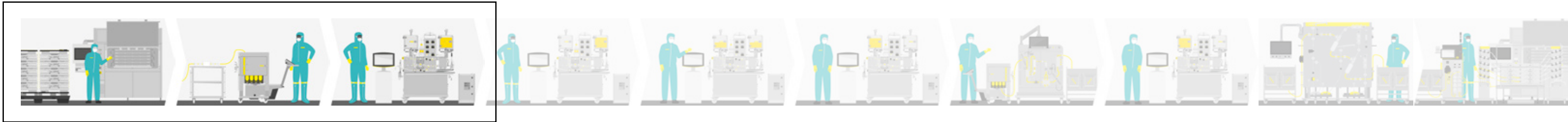
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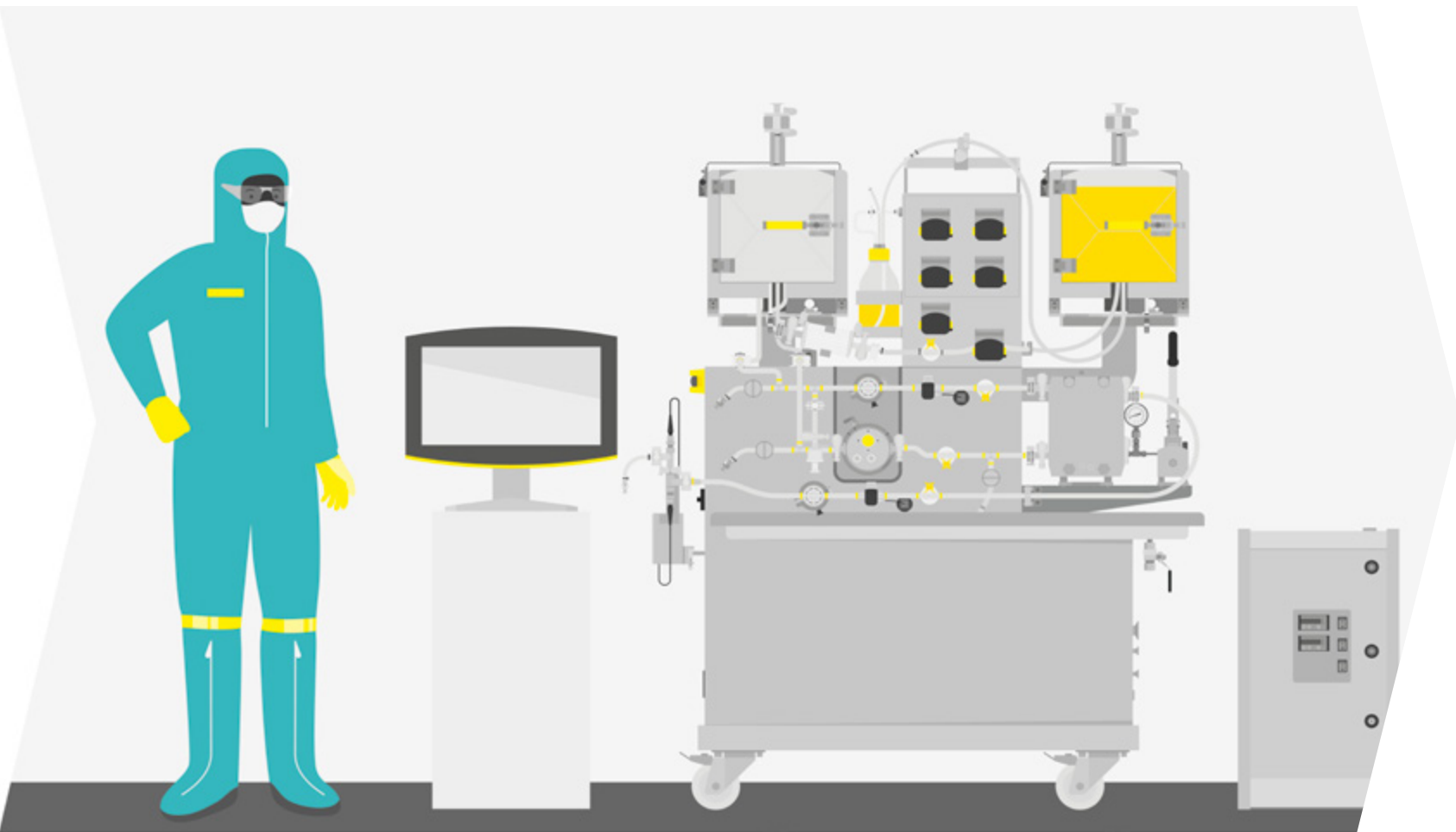
3

mAb conditioning

[Learn more](#)



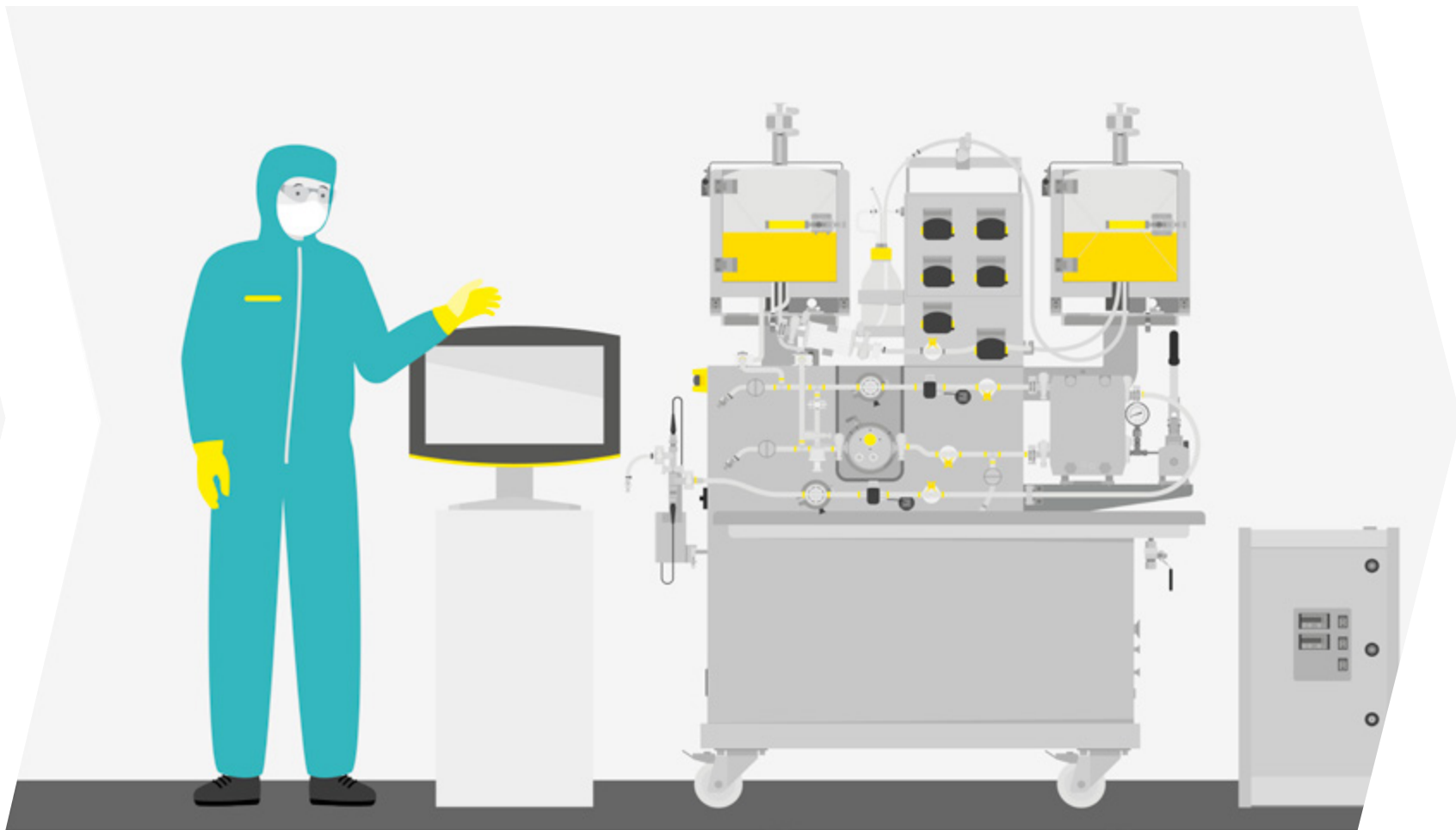
ADC workflow overview



4

Conjugation

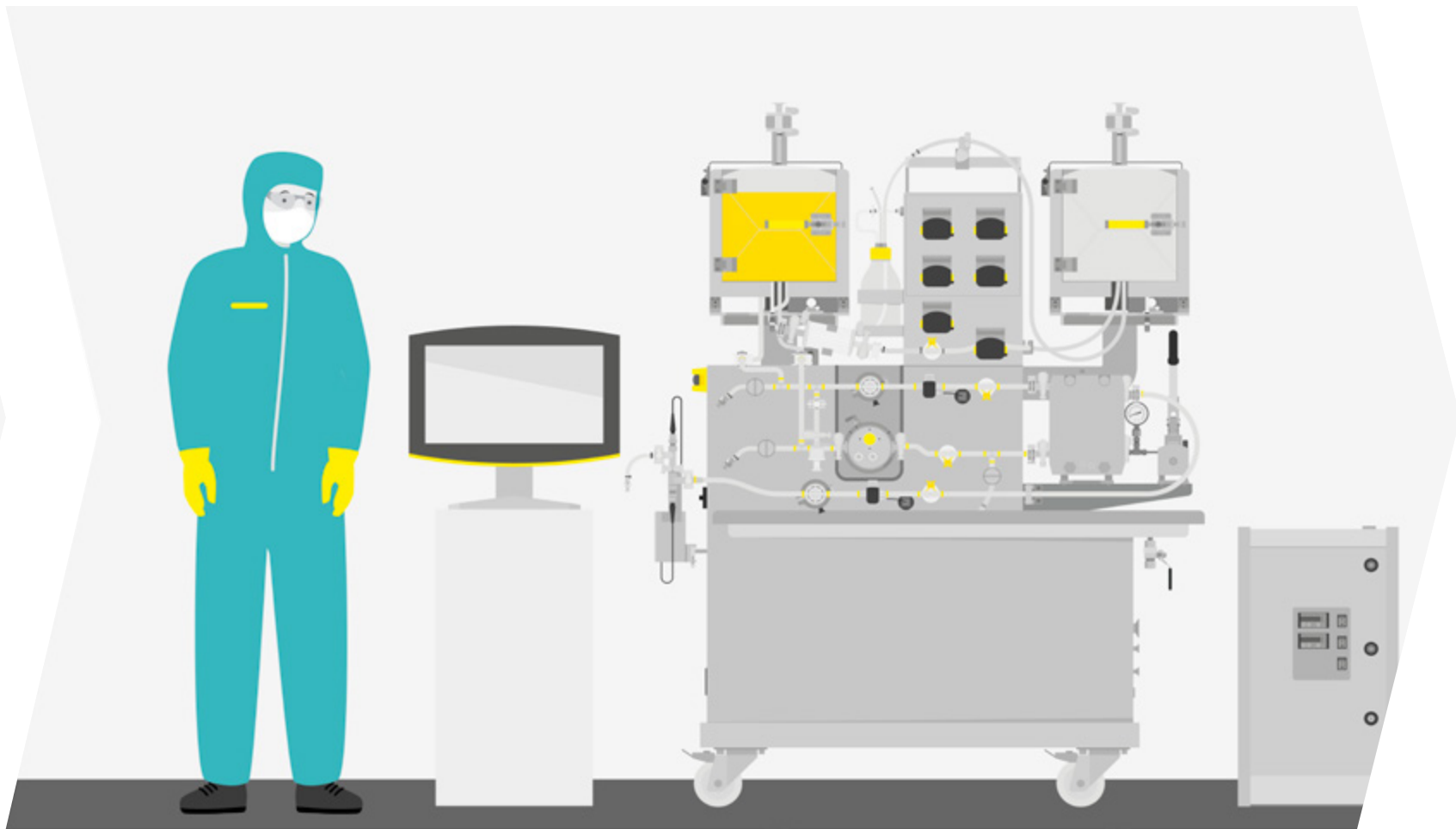
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5

Aggregate removal

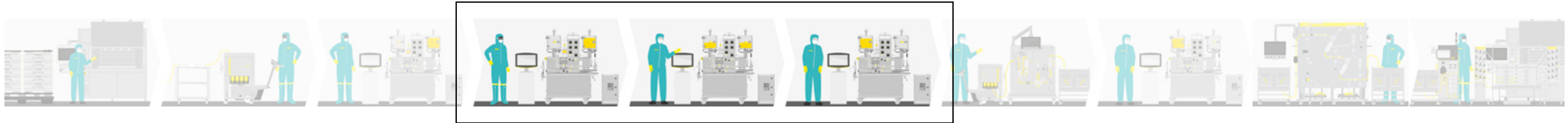
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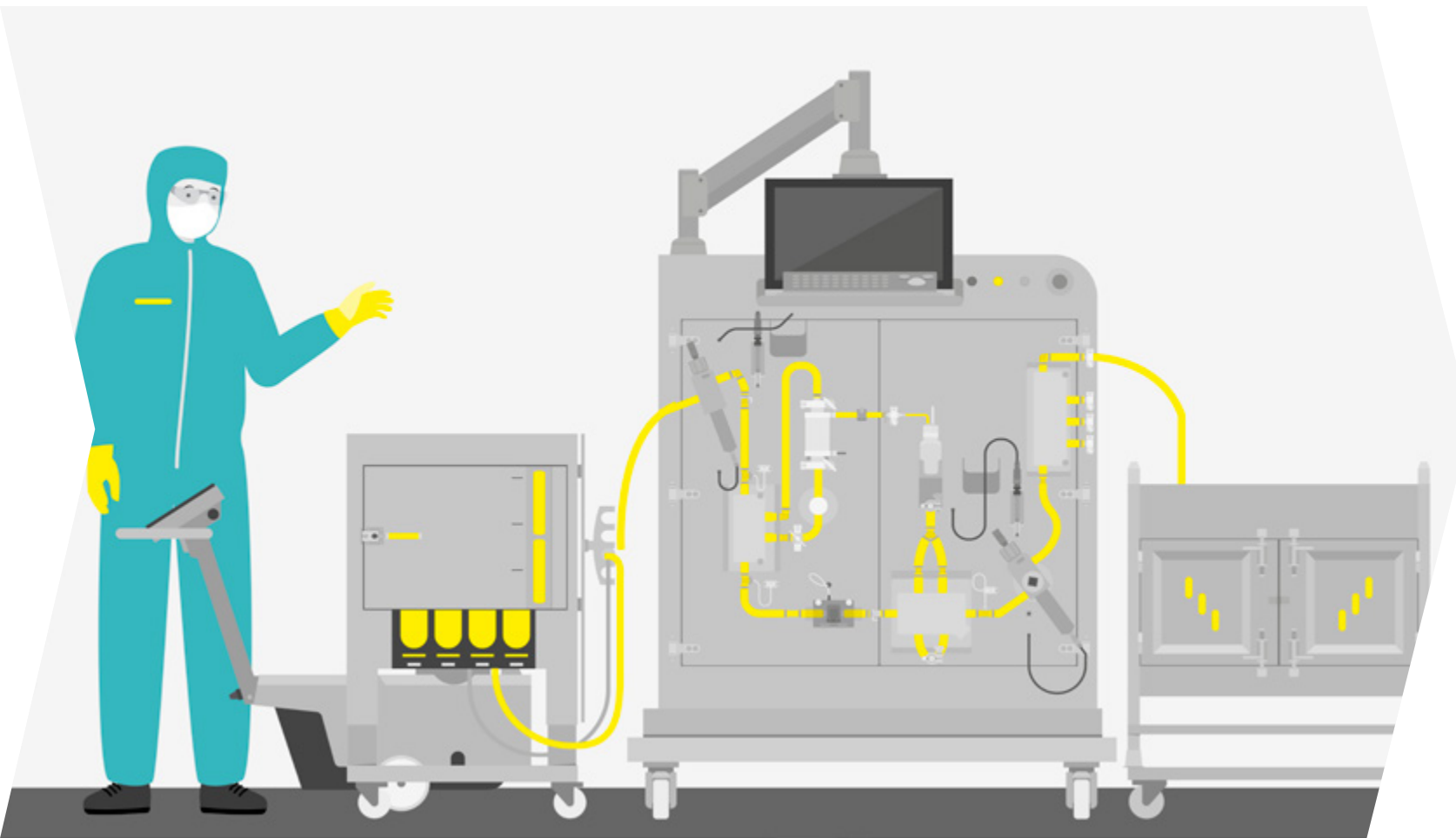
6

Residual conjugate removal

[Learn more](#)



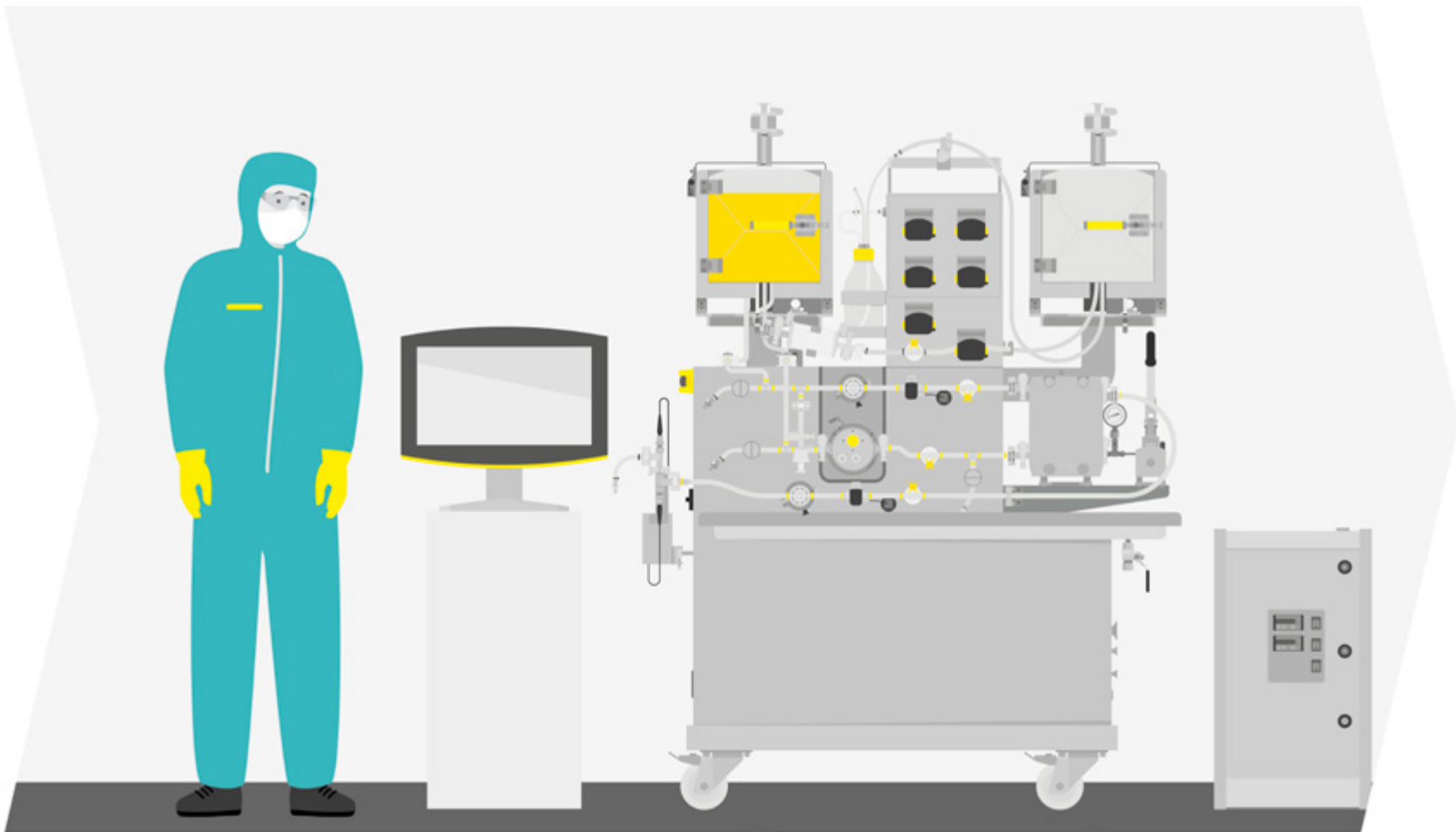
ADC workflow overview



7

DAR refinement

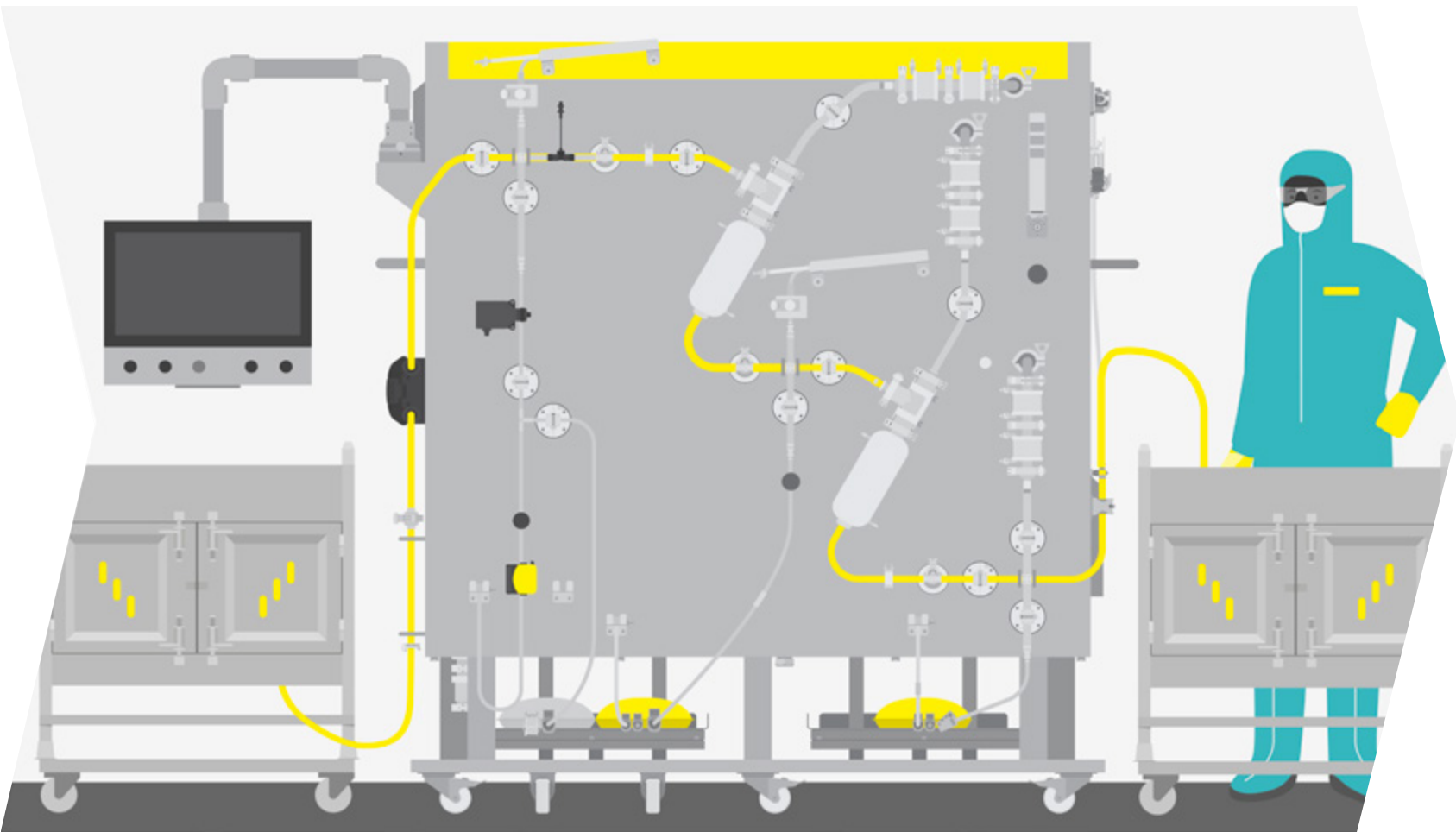
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8

ADC concentration & formulation

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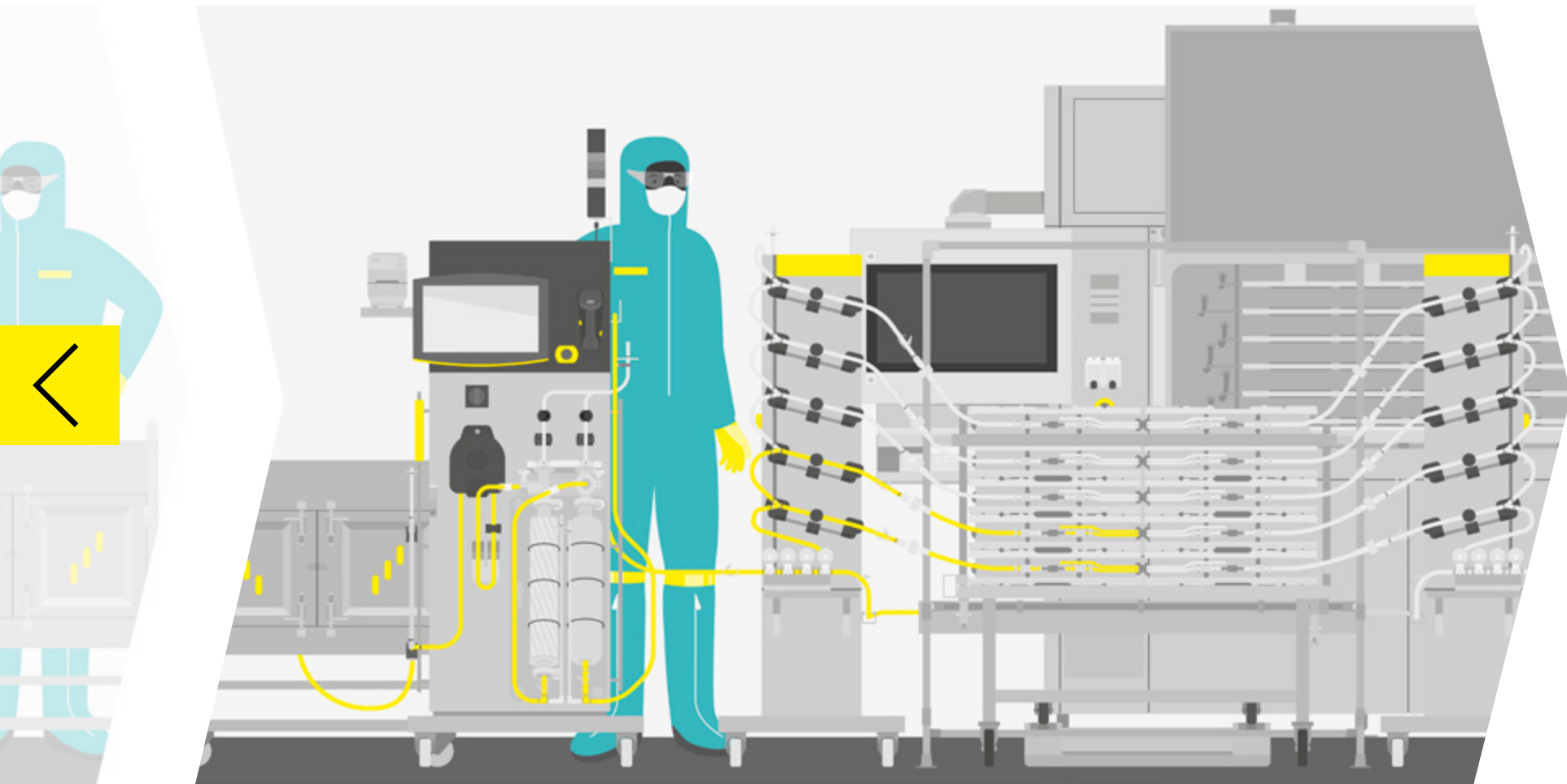
9

Sterile filtration

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ADC workflow overview



10

Fill, freeze, and ship or store

Learn more



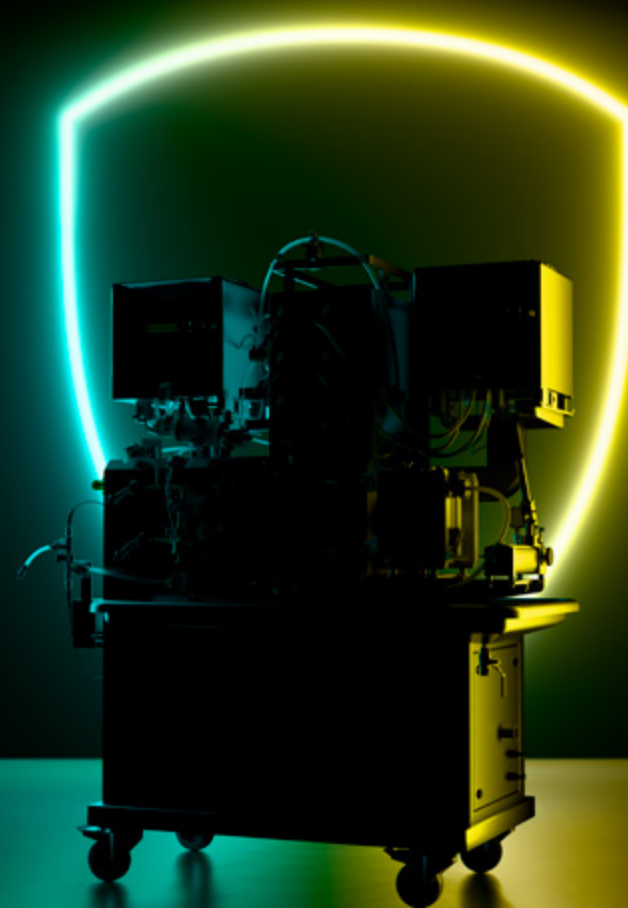
Protect the molecule. Protect the process. Protect the operator.

ADC manufacturing only succeeds when manufacturers can effectively control risk across the entire workflow, from the first thaw through final storage. The complexity and potency of ADCs leave little margin for error — molecular damage is irreversible, process variability compounds quickly, and operator exposure carries serious safety and compliance consequences.

Protecting the molecule means preventing aggregation, structural damage, and uncontrolled DAR through low shear handling, controlled transitions, and solvent compatible materials.



Protecting the process means eliminating variability through closed, standardized, and automated workflows that scale predictably.



Protecting the operator means engineering exposure risk out of the process with contained transfers and minimal manual handling.



Together, these protections form the foundation for reliable, compliant, and scalable ADC manufacturing.

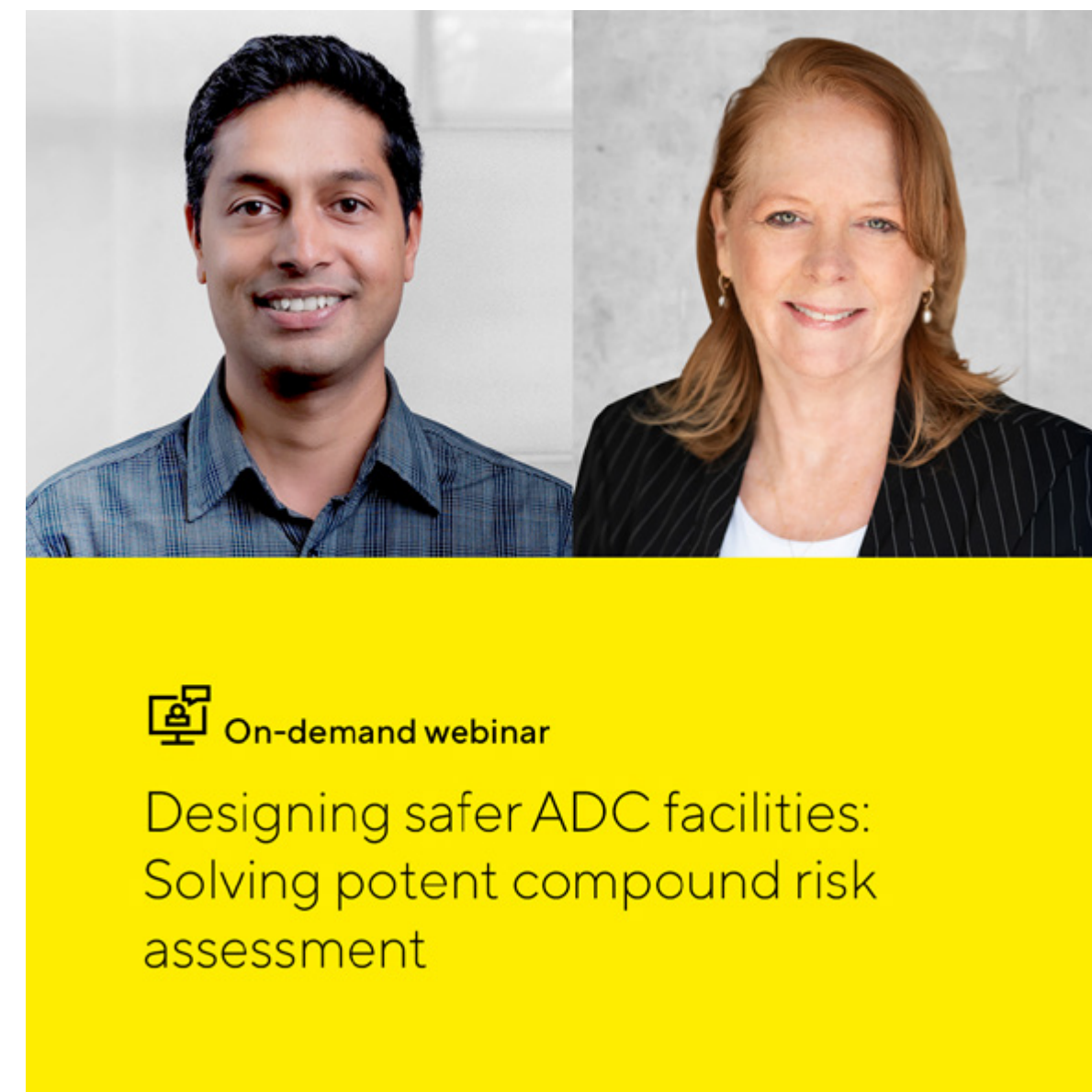
Continue exploring ADC solutions

Contact a specialist to discuss your specific ADC challenges and solutions.



Contact a specialist

Watch our webinar about designing safer ADC facilities.



Watch the webinar

Watch our expert panel's discussion on critical considerations in ADC manufacturing.



Watch the expert panel's discussion

Read our custom report about comprehensive solutions for optimizing ADC production.



Read the custom report



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Toll-Free +1 800 368 7178

ADC workflow overview



mAb thaw

Process objective

Bring the frozen monoclonal antibody (mAb) to ambient temperature while preserving stability and biological activity. Controlled thaw protects molecular integrity and ensures consistent downstream conjugation performance.

Key risks & challenges

- Uncontrolled freeze-thaw gradients
- Aggregation
- Irreversible loss of activity

Focus product

Celsius® FFTp

Celsius® FFTp provides controlled, uniform freeze-thaw of bulk drug substance using a robust bag in shell design optimized for horizontal plate freezers. It helps protect mAb structural integrity and stability during freezing, storage, and transport while integrating with existing cold chain infrastructure.

Key points

- Designed for fast, reproducible freeze-thaw with uniform heat transfer
- Robust single-use container protects high-value bulk drug substance
- Compatible with existing plate freezers and cold chain workflows

Related products

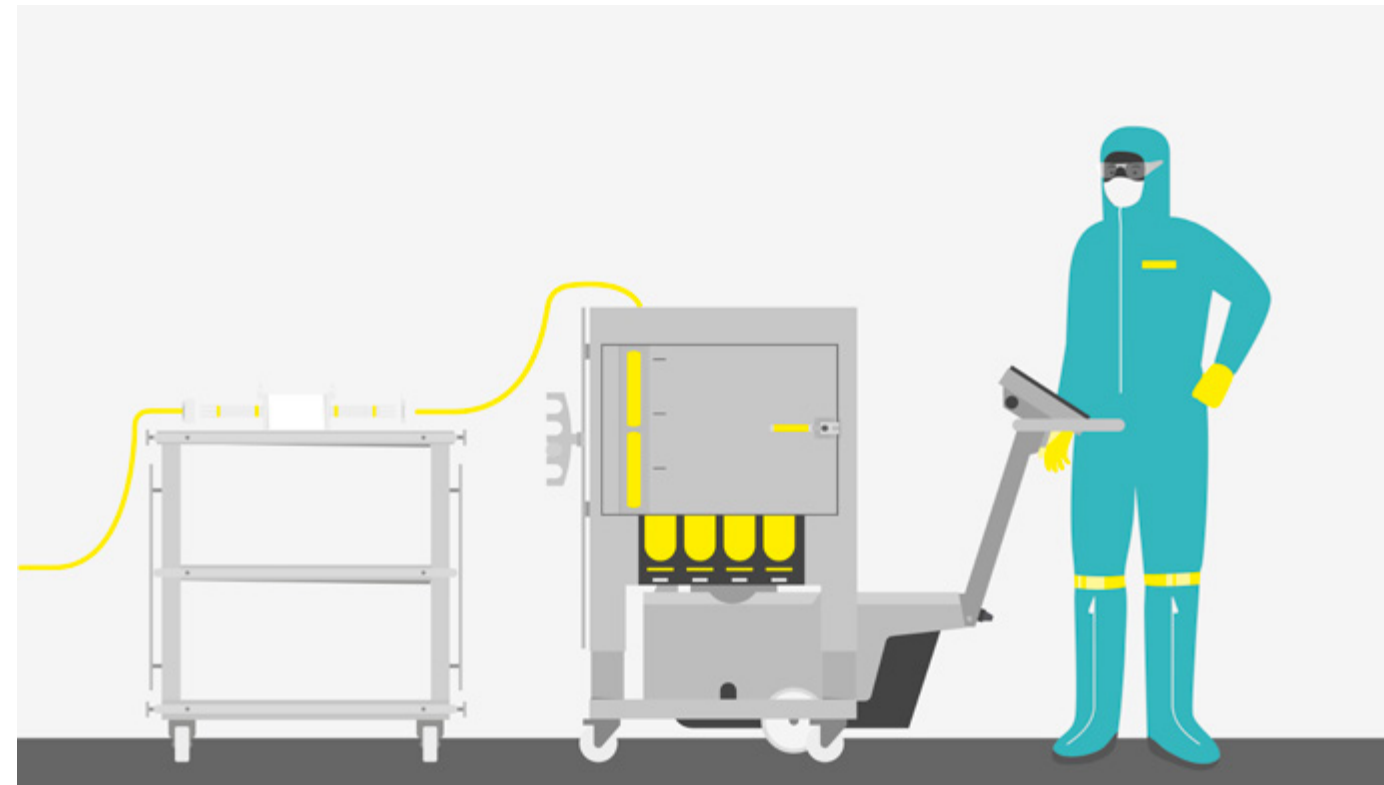
- Celsius® S3
- Celsius® Pak
- Flexsafe® Bags
- BioWelder® TC
- BioSealer® TC

1

mAb thaw

[Learn more](#)

ADC workflow overview



mAb filtration

Process objective

Remove particulates while maintaining mAb biological activity prior to ADC processing. Low binding sterilizing filtration protects molecule quality and process reliability.

Key risks & challenges

- Protein binding or loss
- Filter integrity failure
- Sterility risk

Focus product

Sartopore® 2 XLG

Sartopore® 2 XLG is a sterilizing-grade filter with a dual layer membrane that delivers high throughput and low fouling. It supports efficient filtration of ADC intermediates while protecting yield and enabling predictable scale-up from development to production.

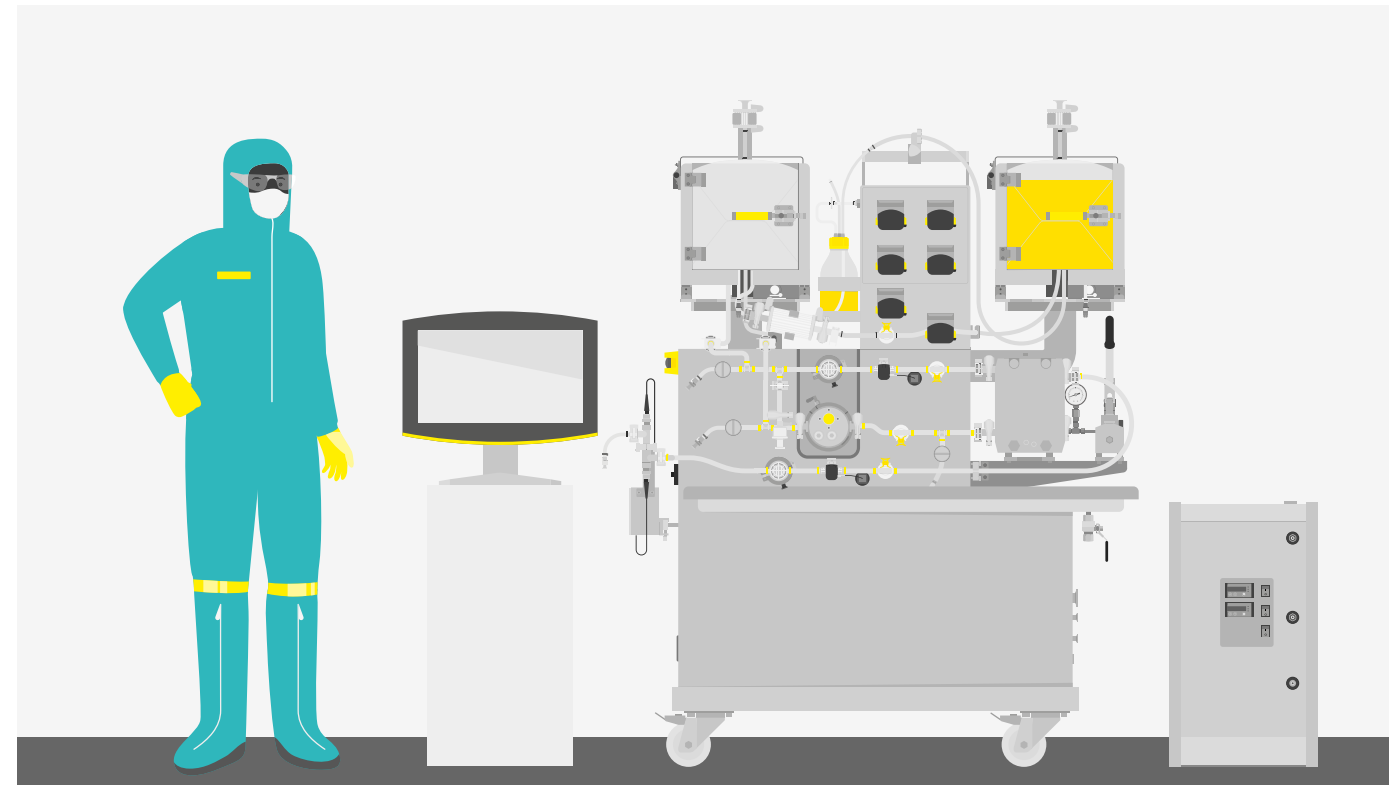
Key points

- Dual layer membrane improves capacity and reduces filter consumption
- Broad chemical compatibility across ADC process conditions
- Scalable formats support linear transfer from R&D to manufacturing

Related products

- SartoScale® 25
- Sartocheck® 5
- Flexsafe® Bags
- BioWelder® TC
- BioSealer® TC

ADC workflow overview



mAb conditioning

Process objective

Adjust pH and buffer composition to stabilize the mAb for efficient conjugation. Controlled ultrafiltration/diafiltration (UF | DF) protects molecular stability and enables reproducible conjugation conditions.

Key risks & challenges

- Inconsistent buffer exchange
- Shear stress
- Scale up variability

Focus product

Sartoflow® Expert SU

Sartoflow® Expert SU is a fully automated single-use, intensified tangential flow filtration (TFF) system that integrates mixing, sterile filtration, and UF | DF in one closed loop. It streamlines ADC processing at development and pilot scale by reducing transfers, improving reproducibility, and protecting both product and operator.

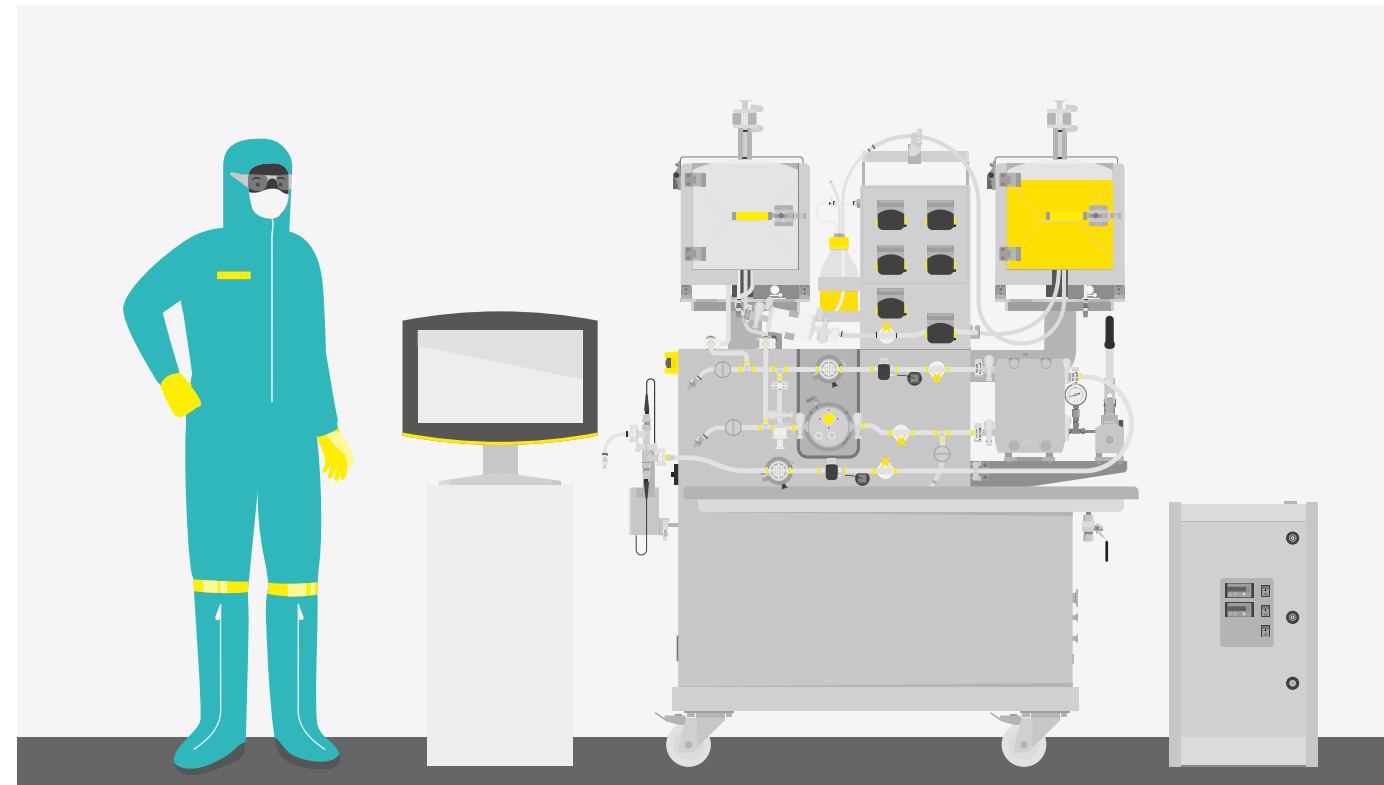
Key points

- Combines multiple unit operations in one closed system
- Reduces manual transfers and bioburden risk
- Designed specifically to support ADC and bioconjugate workflows

Related products

- Ambr® Crossflow
- Sartoflow® Smart
- Sartoflow® 1200 SU
- Sartoflow® 5000 SU
- Sartocon® Self-Contained Units
- Hydrosart® Cassettes
- Flexsafe® Pro Mixer

ADC workflow overview



Conjugation

Process objective

Chemically link cytotoxic payload to the mAb with precise control and containment. Closed, low shear mixing protects molecule quality, process control, and operator safety.

Key risks & challenges

- DAR variability
- Solvent compatibility
- Exposure risk
- Protein aggregation

Focus product

Flexsafe® Pro Mixer

Flexsafe® Pro Mixer delivers low shear, controlled single-use mixing across ADC manufacturing steps. Its scalable design supports consistent mixing performance while protecting shear-sensitive molecules and enabling closed, reproducible operation from development through commercial scale.

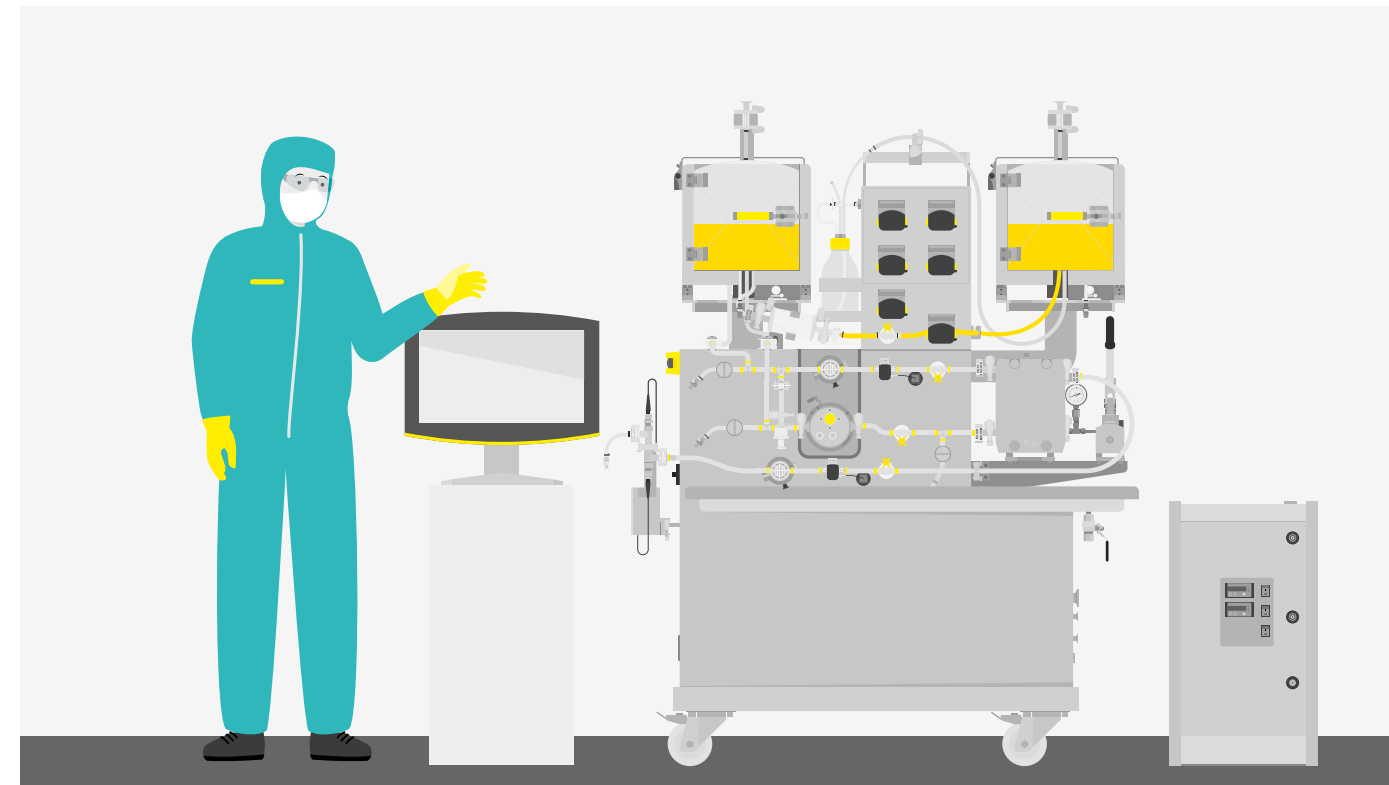
Key points

- Low shear mixing protects sensitive ADC intermediates
- Scalable design supports predictable performance across volumes
- Closed, single-use operation reduces handling and contamination risk

Related products

- Sartoflow® Expert SU
- Sartoflow® 5000 SU

ADC workflow overview



Aggregate removal

Process objective

Remove high molecular weight species generated during conjugation. Solvent-tolerant filtration protects ADC quality while supporting safe handling.

Key risks & challenges

- Chemical incompatibility
- Product loss
- Exposure risk

Focus product

Sartolon® filters

Sartolon® sterile filters use a hydrophilic nylon membrane with broad chemical compatibility, making them well suited for solvent rich ADC streams. The design supports high throughput and reliable aggregate removal while maintaining sterilizing-grade performance.

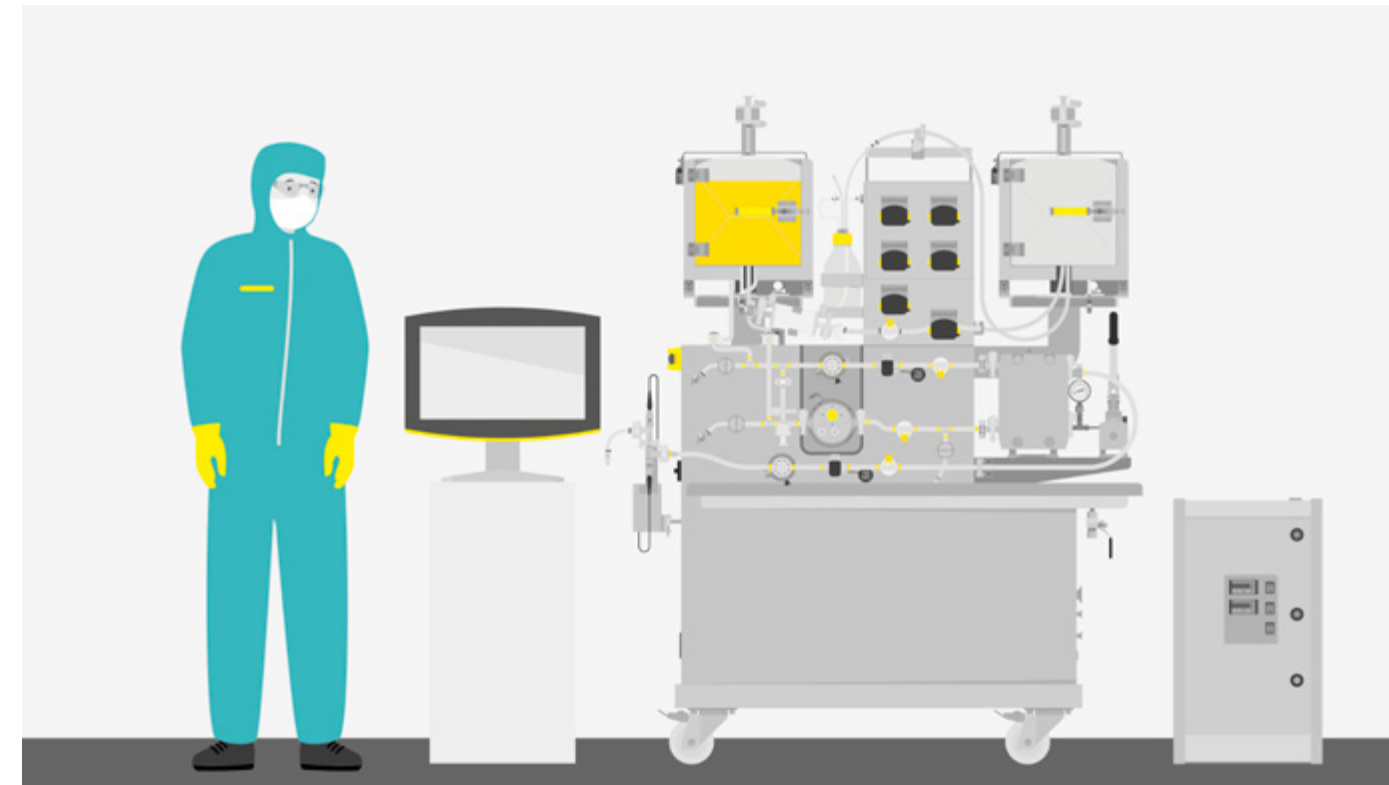
Key points

- Excellent chemical compatibility for aggressive solvents
- High throughput supports efficient aggregate removal
- Validated sterilizing-grade performance for ADC processes

Related products

- Sartoflow® Expert SU
- Sartopore Evo®
- Sartofluor®
- Flexsafe® Pro Mixer
- Flexsafe® Bags
- BioWelder® TC
- BioSealer® TC

ADC workflow overview



Residual conjugate removal

Process objective

Remove free drug linker molecules to enhance safety, especially for the patient. Gentle, scalable separation protects molecular quality and DAR consistency.

Key risks & challenges

- Incomplete removal
- Scale-up variability
- Exposure risk

Focus product

Sartocore® SCU

Sartocore® SCU enables efficient removal of residual conjugates while safeguarding operators through a closed, contained single-use design. It minimizes exposure to potent compounds, supports safe handling, and ensures consistent separation performance across ADC downstream operations.

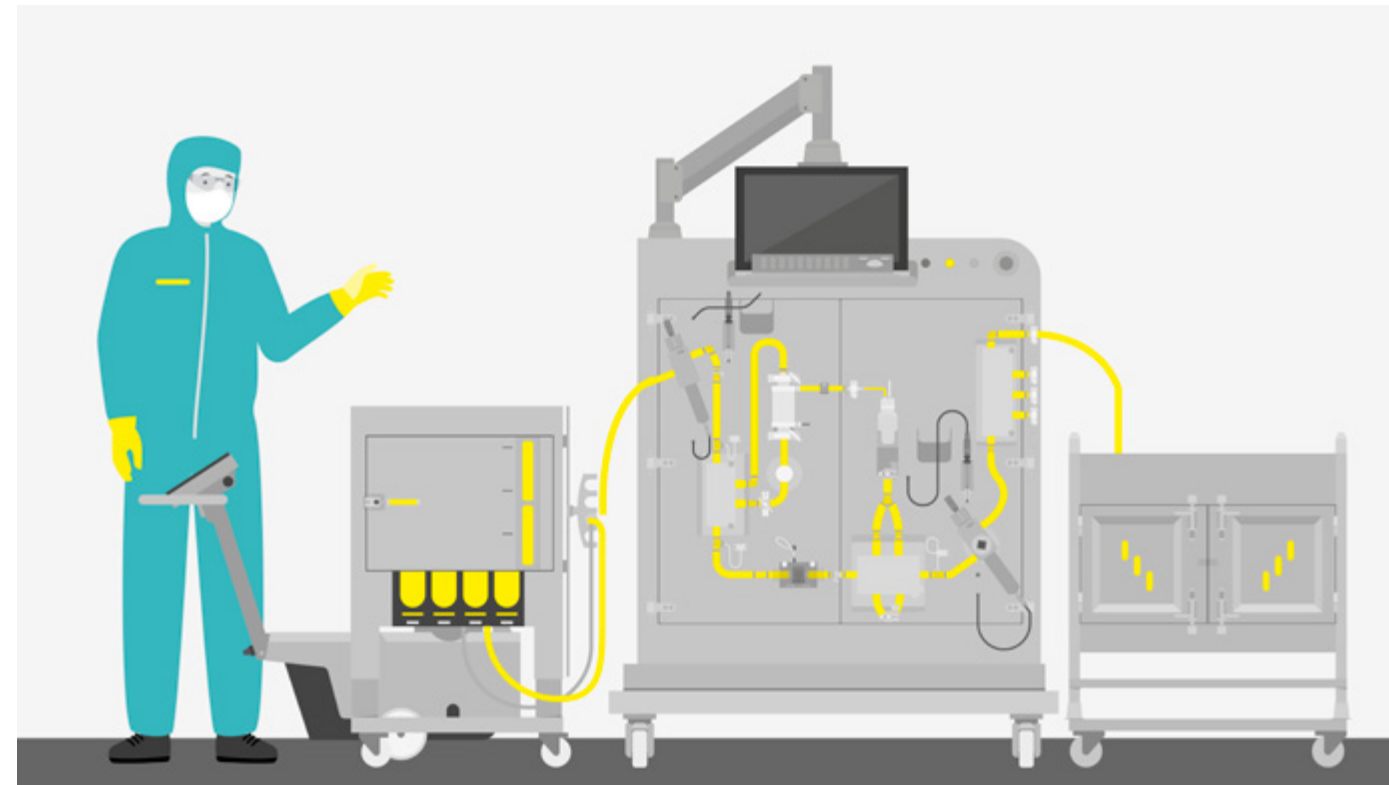
Key points

- Closed, single-use system minimizes operator exposure
- Efficient separation enables reliable removal of residual conjugates
- Scalable, ready-to-use format simplifies safe transfer from development to manufacturing

Related products

- Ambr® Crossflow
- Sartoflow® Expert SU
- Sartoflow® 5000 SU
- Hydrosart® Cassettes
- Flexsafe® Bags

ADC workflow overview



DAR refinement

Process objective

Fine-tune DAR to reach targets, and optimize efficacy and safety. Closed chromatography enables precise, repeatable DAR control.

Key risks & challenges

- Media selection
- Process consistency
- Operator exposure

Focus product

Resolute® Flowdrive SU

Resolute® Flowdrive SU is a single-use chromatography system designed for precise, reproducible ADC purification and DAR refinement. Automated operation and flexible flow kits support consistent separation performance while reducing manual handling and exposure risk.

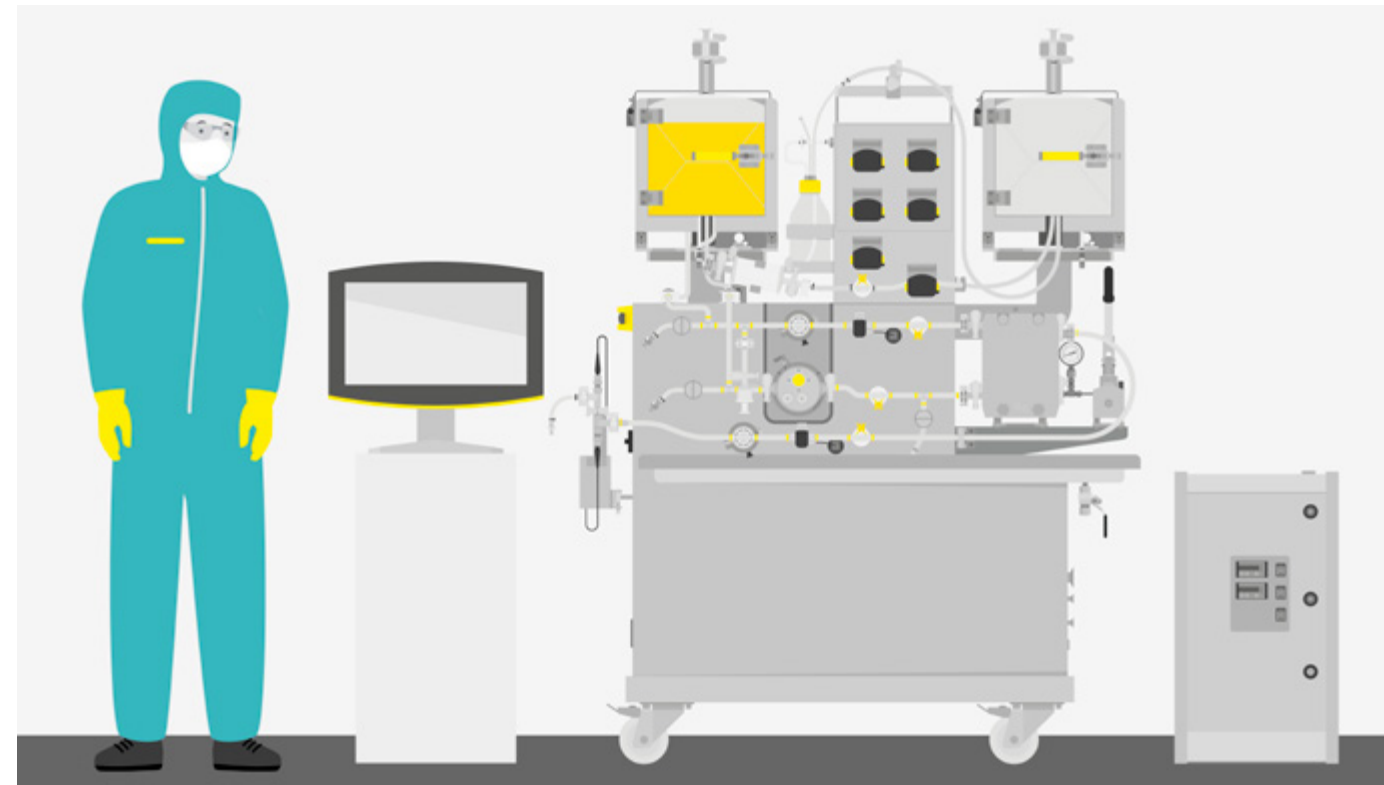
Key points

- Supports high-resolution ADC separations and DAR control
- Single-use design minimizes cleaning and changeover time
- Automation improves reproducibility and operator safety

Related products

- Sartobind® S
- Sartobind® Phenyl
- Flexsafe® Pro Mixer
- Flexsafe® Bags

ADC workflow overview



ADC concentration and formulation

Process objective

Concentrate ADC and adjust buffer and excipients to reach target formulation. Controlled, closed processing protects stability and reproducibility.

Key risks & challenges

- Shear-induced aggregation
- Formulation variability
- Exposure risk

Focus product

Sartoflow® 5000 SU

Sartoflow® 5000 SU is a commercial-scale single-use TFF system for ADC concentration and formulation. Fully automated UF | DF enables consistent, scalable processing while supporting closed operation and high product recovery at production volumes.

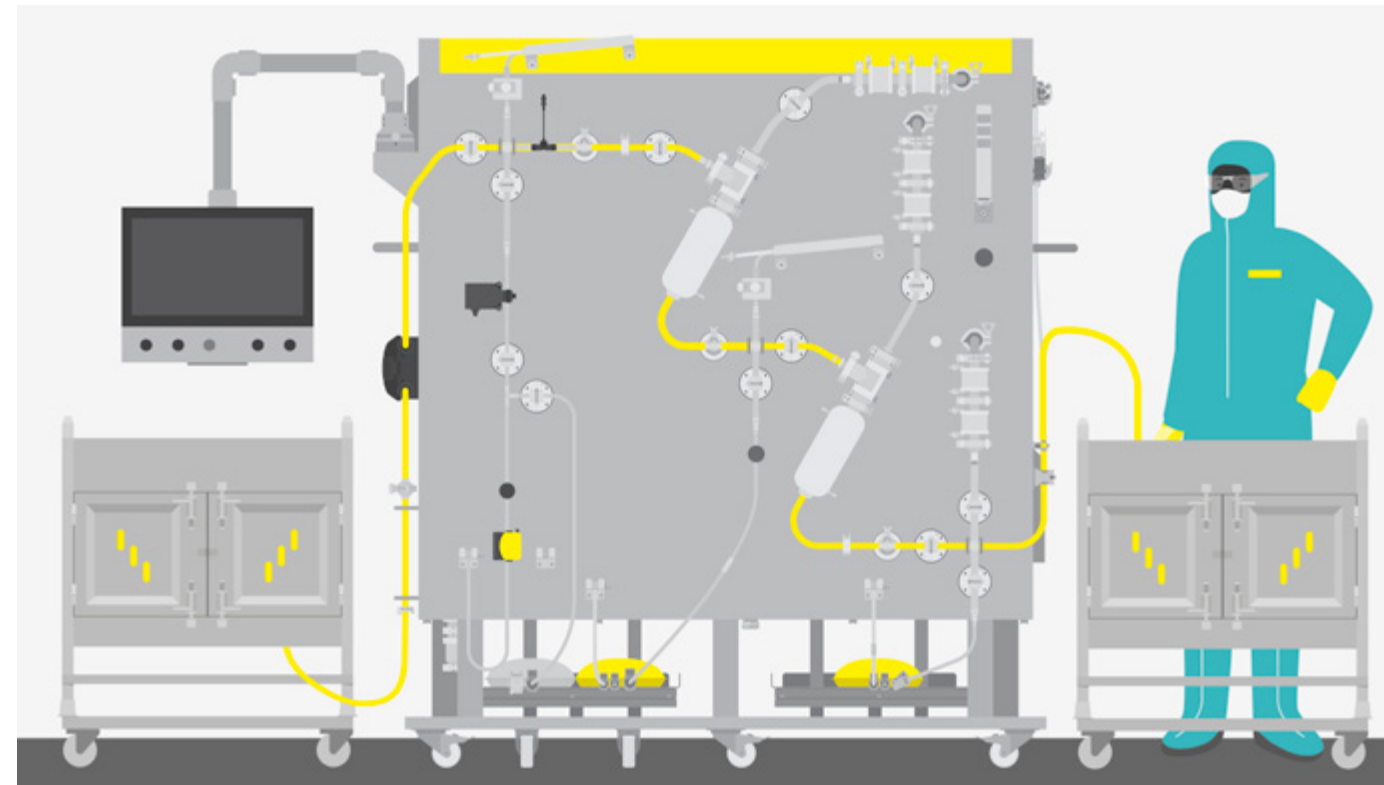
Key points

- Designed for commercial scale single use TFF
- Automation supports consistent UF | DF performance
- Closed flow paths help protect product and operators

Related products

- Sartoflow® Expert SU
- Sartoflow® 1200 SU
- Sartocon® Self-Contained Units
- Hydrosart® Cassettes
- Flexsafe® Pro Mixer
- Flexsafe® Bags

ADC workflow overview



Sterile filtration

Process objective

Remove microorganisms to ensure sterility and regulatory compliance. Integrity-verified filtration protects sterility and yield.

Key risks & challenges

- Filter fouling
- Yield loss
- Integrity failure
- Exposure risk

Focus product

Sartopore® Evo

Sartopore® Evo is ideal for sterile filtration of final bulk ADCs by minimizing product loss, providing high throughput, and assuring reliable integrity for consistent batch release.

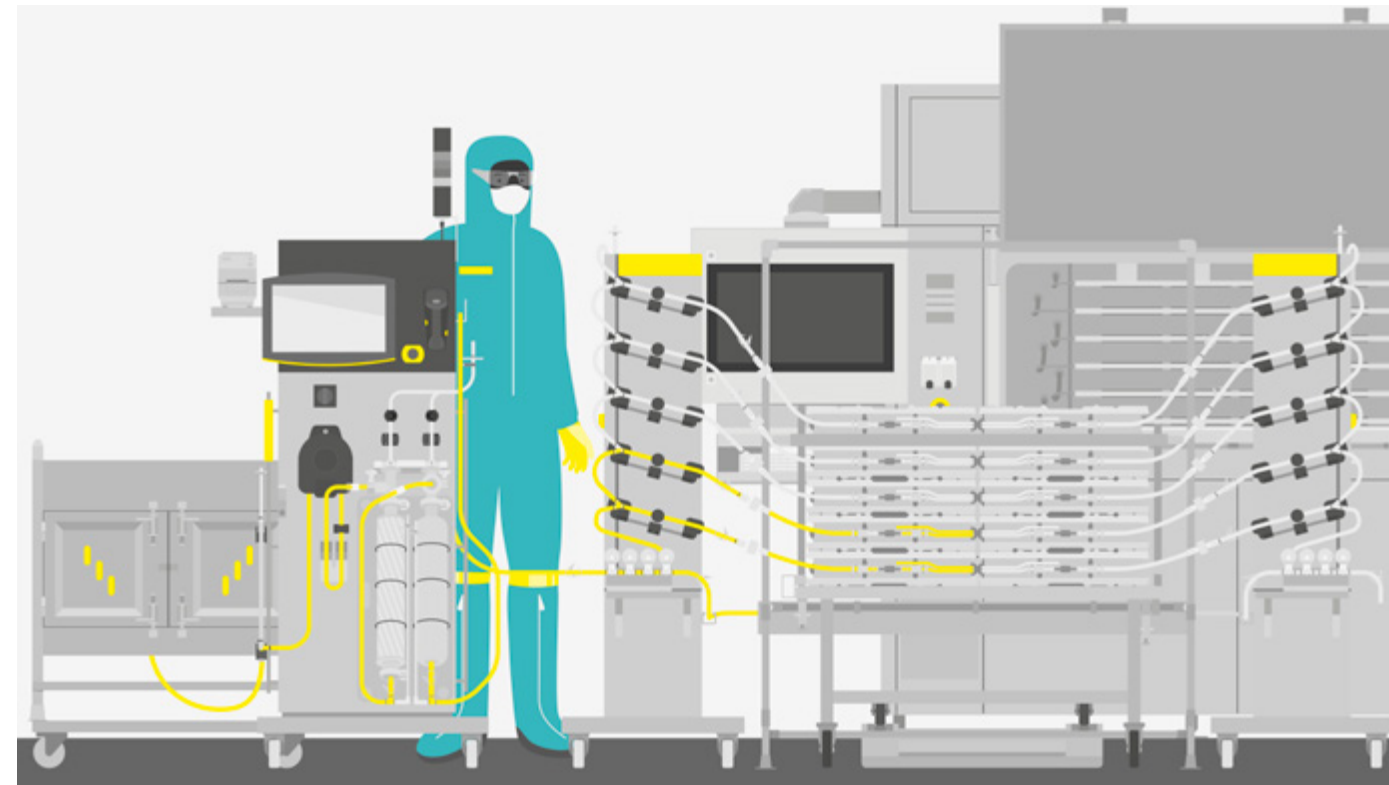
Key points

- Ultra-low adsorption protects final product yield
- High throughput reduces fouling risk
- Reliable wetting and membrane performance support integrity assurance

Related products

- Sartopore® 2 XLG
- Sartocheck® 5
- SartoScale® 25
- Flexsafe® Bags
- BioWelder® TC
- BioSealer® TC

ADC workflow overview



Fill and freeze, and ship and store

Process objective

Dispense, freeze, and store or ship ADC intermediates in controlled conditions. Closed filling and controlled freezing protect molecular stability through storage and transport.

Key risks & challenges

- Non-uniform freezing
- Container failure
- Cold chain excursions

Focus product

AliquoT® system

Our AliquoT® system provides automated filling designed for accurately transferring bulk drug substance into Celsius® containers. It supports consistent filling, high product recovery, and closed operation – helping protect ADC quality while simplifying cold chain preparation.

Key points

- Accurate, repeatable filling into Celsius® containers
- High product recovery minimizes valuable ADC loss
- Closed, automated operation reduces contamination risk

Related products

- Celsius® FFTp
- Celsius® S3
- Flexsafe® Bags
- BioWelder® TC
- BioSealer® TC