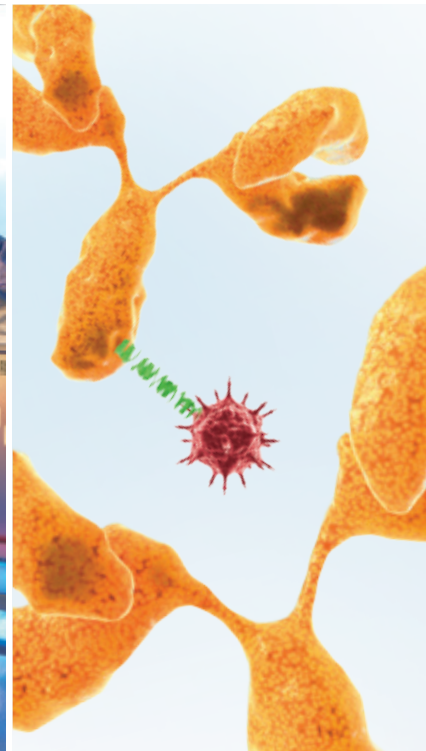




sartorius stedim  
biotech

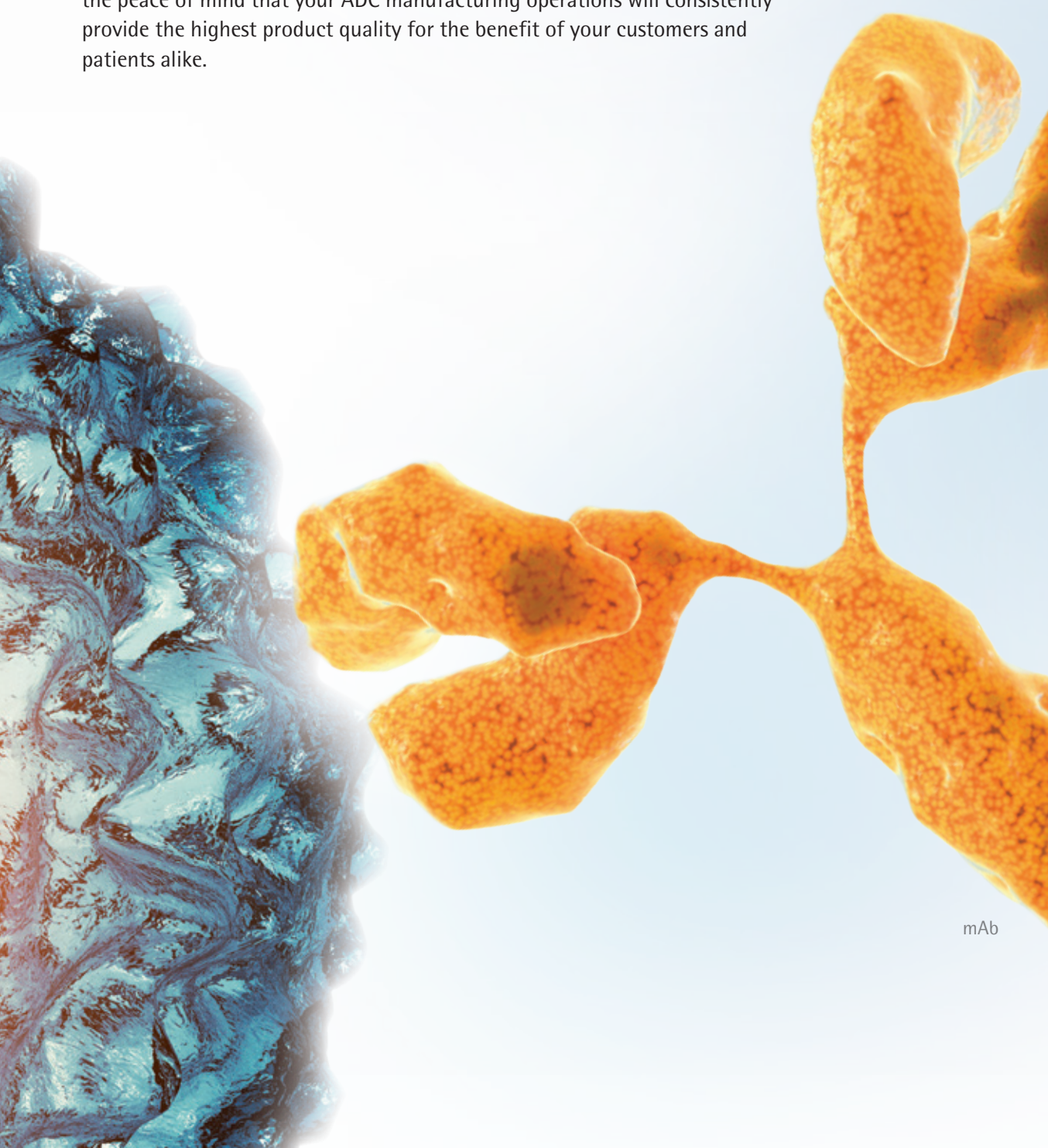
## Single-use Systems and Consumables: The Perfect Match for ADC Manufacturing



turning science into solutions

# Ready-to-use Systems for ADC Manufacturing

ADC (Antibody-drug conjugates) manufacturing and operator safety go hand in hand. Ready-to-use, pre-flushed and fully contained systems for prior- and post-use will make your life easier, giving you greater safety, reliability and flexibility. Single-use equipment eliminates the drawbacks and risks of conventional stainless steel systems that require large amounts of water and agents for intensive cleaning, and involve the risks of cross-contamination and residual cytotoxin even after cleaning. Single-use systems will give you the peace of mind that your ADC manufacturing operations will consistently provide the highest product quality for the benefit of your customers and patients alike.

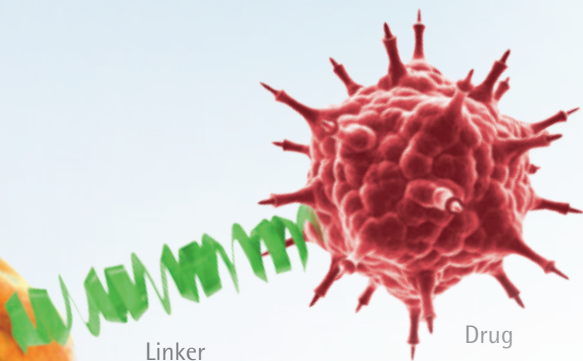


## Increased Operator and Product Safety

- Reduced cleaning
- Compatibility tests
- One film for all

## High Cost Efficiency

- Lower CAPEX
- Shared equipment for multi-product manufacturing
- Less biowaste to handle



## Reduced Time-to-Market

- Fast delivery of equipment
- Scalability – from lab scale to commercial manufacturing

## Your Process

# Homogenization of Thawed mAbs

After you have thawed mAbs in a controlled process, you need to ensure they are transferred aseptically. Sartorius Stedim Biotech fully contained single-use equipment is designed to help you meet the highest product and operator safety levels for transfer.

A homogeneous solution is essential for reproducible processes. Single-use systems based on levitation mixing technology enable you to conveniently optimize the safety of your ADC products.

### Lab Scale

## Our Solution

Flexboy®



### Clinical Phase

Palletank  
(200 L)



### Commercial Manufacturing

Palletank  
(2,000 L)



# Modification of mAbs

Whether you need to reduce disulfide bonds or modify lysine residues in your mAbs to prepare them for conjugation, Sartorius Stedim Biotech single-use technologies are the perfect solution. The reason: You can readily use these robust technologies during the different phases ranging from development to commercial manufacturing to increase your operator and product safety right from the start. They can accomplish all these steps.

# Conjugation and Quenching

Get the best of both worlds with Sartorius Stedim Biotech: Conjugate your cytotoxin to your antibody and quench the reaction afterwards. In addition, control your DAR (Drug-to-antibody ratio) by precise dosing of your drug linker solution.

Take advantage of maximum process control by mixing, heating and cooling, sampling and dosing your additions to obtain the perfect ADC.

MYCAP™



Biostat® B with UniVessel® SU



Jacketed Palletank (50 L)



FlexAct® for Conjugation and Quenching



Multifunctional System

Jacketed Palletank (3,000 L)



FlexAct® for Conjugation and Quenching – Dual Mode



Multifunctional System

# Concentration and Diafiltration

Reduce volumes and increase concentrations, while minimizing your contamination risk and operational costs with one-bag operation – no product transfer between conjugation and concentration. Our performance: Sartocon Ultrafilter ensure the removal of toxic components and solvents at low flux and short process time, avoiding aggregation and product loss.

Safety comes first: Protect your product and operator by using self-contained, preflushed and presterilized Sartocon Self Contained Unit (SCU) ultrafilters for prior- and post-use process integrity.

## SARTOFLOW® Alpha plus SU



# Formulation

Bring your ADC in shape: Adjust the conductivity and pH, and add excipients with the highest accuracy.

Control your process parameters continuously and store your intermediate product under carefully controlled conditions, while reducing your manufacturing footprint with shared Sartorius Stedim Biotech equipment ready to move when you are.

## UniVessel® SU



## FlexAct® for Ultra-| Diafiltration



## Palletank for LevMixer®<sup>1</sup> (50 L)

<sup>1</sup> LevMixer® is a trademark of Pall Corporation and this product uses Pall patented LevMixer® technology. All information on patents can be found at [Pall.com/patents](http://Pall.com/patents).



## FlexAct® for Ultra-| Diafiltration – Dual Mode



## Palletank for LevMixer®<sup>1</sup> (1,000 L)

<sup>1</sup> LevMixer® is a trademark of Pall Corporation and this product uses Pall patented LevMixer® technology. All information on patents can be found at [Pall.com/patents](http://Pall.com/patents).



## Sterile Filtration

Ensure product safety by using sterile connectors and contained technologies to reduce contamination risks right from the beginning. On top of these Sartorius Stedim Biotech products, benefit from our proven solutions for bioburden reduction. So that your ADCs will successfully meet all current safety standards.

## Freezing

Intermediate or long-term storage? It's your choice! Freeze your ADCs in a fully controlled process to ensure conservation of all their properties. Prepare them for shipment to one of your Fill and Finish sites or partners worldwide and ship these products around the globe in a safe and fast way by using our Freeze and Thaw technologies.

Sartopore Platinum®



Celsius® FFT  
(4 L)



Sartopore® Platinum  
MidiCaps®



Celsius® Pak  
(16.6 L)



Sartopore® Platinum  
T-Style MaxiCaps®



Celsius® FT100



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