

Monoclonal antibodies

mAb process playbook

Single-use technology recommendations for
mAb production up to 2,000 L



Reduce tech transfer lead times while improving processing flexibility

More than ever, biomanufacturers are seeking support to quickly and efficiently produce a wide variety of therapies to meet the growing population's needs. Striving to enable and complement our customers' goals, we've leveraged our multi-divisional, end-to-end workflow strategies to provide a highly flexible, standard, single-use offering: the mAb Process Playbook. While production facility layouts may vary across internal and external networks, these products are designed to address all unit operations regardless of infrastructure, enabling more consistency and simpler tech transfers. Our global CDMO manufacturing capacity ultimately helps reduce labor costs and supports the challenging task of getting lifesaving medicines to patients without delay. The library of standard and multi-functional products in the mAb Process Playbook will help to optimize your network supply chain by using the minimal number of unique manifolds to address diverse unit operations requirements.

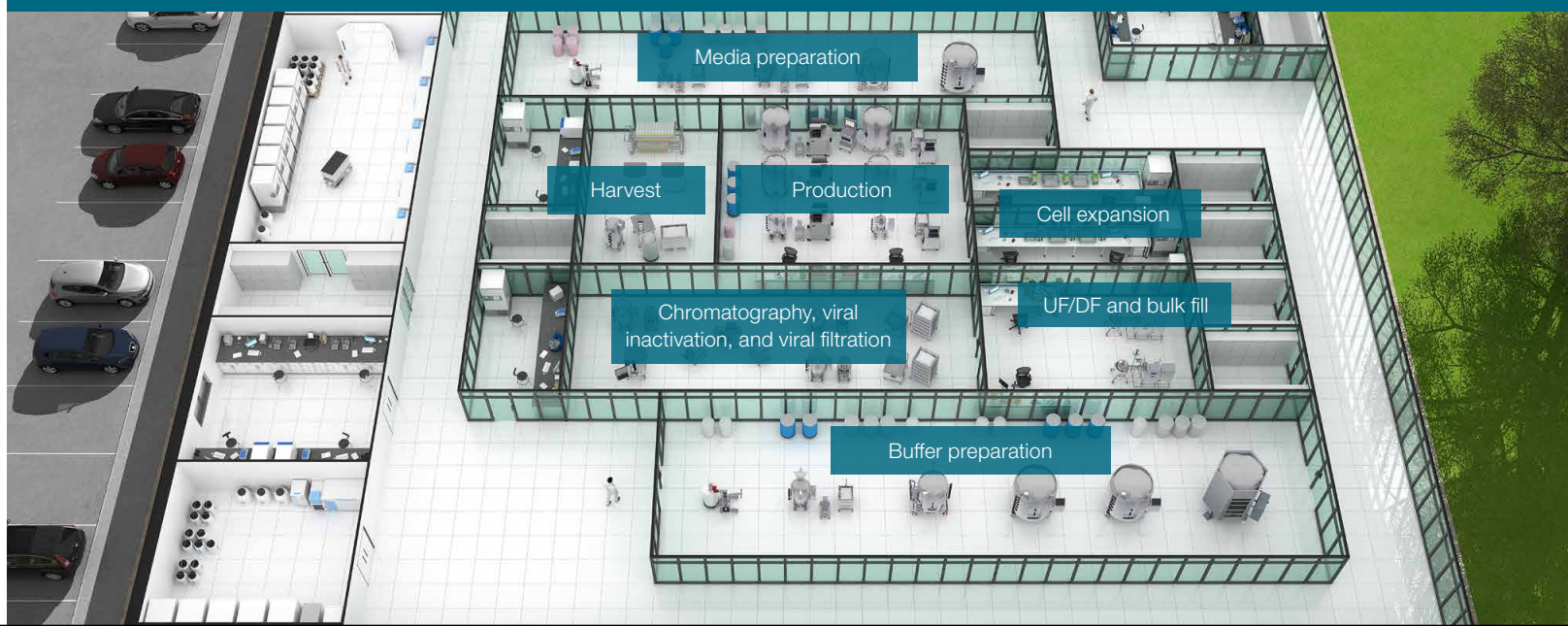
This library is designed to help reduce the labor involved in process engineering for your specific application. It also aligns with the latest industry understanding and best practices of closed processing for your specific modality from industry thought leaders like BioPhorum, PDA, ISPE, and ASME, while leveraging the history of innovation built by our single-use equipment.

Pre-engineered for different processing modalities and scales, this innovative, end-to-end manufacturing strategy builds upon industry-accepted, single-use manifolds, components, and bioprocessing containers. The versatile, standard offering can drastically reduce the time-consuming upfront activity of process design and limit unnecessary associated component management while not restricting process capability. Instead of spending time sorting out process engineering flows, focus on getting to market faster by increasing batch production and lowering costs by leveraging this playbook.

With more biomanufacturers adopting single-use technologies (SUT), we remain focused on rapid delivery of high-quality products. Our standardized SUT workflow solution is backed by an industry-leading network of harmonized global SUT manufacturing sites with production redundancy. A robust supply chain of reliable, off-the-shelf components means you can rest assured during operation.

Our mAb Process Playbook helps to simplify your workflows and, in turn, produce therapies for patients more efficiently. Let's reimagine what a true supplier–manufacturer partnership looks like and what an innovative, optimized bioprocessing platform is capable of.

Explore each unit operation to learn more about our recommended single-use products »



Media preparation

Media preparation

Buffer preparation

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From campaign to campaign, media preparation can radically change to produce the necessary volume and aliquots to support the cell expansion and production bioreactor processes. The mAb Process Playbook is specifically designed to tackle this challenge by allowing seamless adjustment between operational scales while helping to ensure you're never without the appropriate scale bioprocess containers (BPCs) and single-use mixers.

By mixing and matching the functionally closed and briefly exposed manifold options, you can easily transition across scales, flow rates, sterile boundary requirements, and aliquot quantities. Your media preparation suite can operate efficiently with a minimal number of pre-assembled, single-use products.

Q: Having a library of standard manifolds to choose from is ideal for media preparation, but how can you help alleviate the stress of raw material shortages during this high demand for single-use consumables?

A: Thermo Fisher Scientific has established a multi-tiered strategy to improve the resiliency of our supply chain that utilizes standardization, global capacity expansion, and quality harmonization processes to help ensure you will receive consistent access to high-quality products.

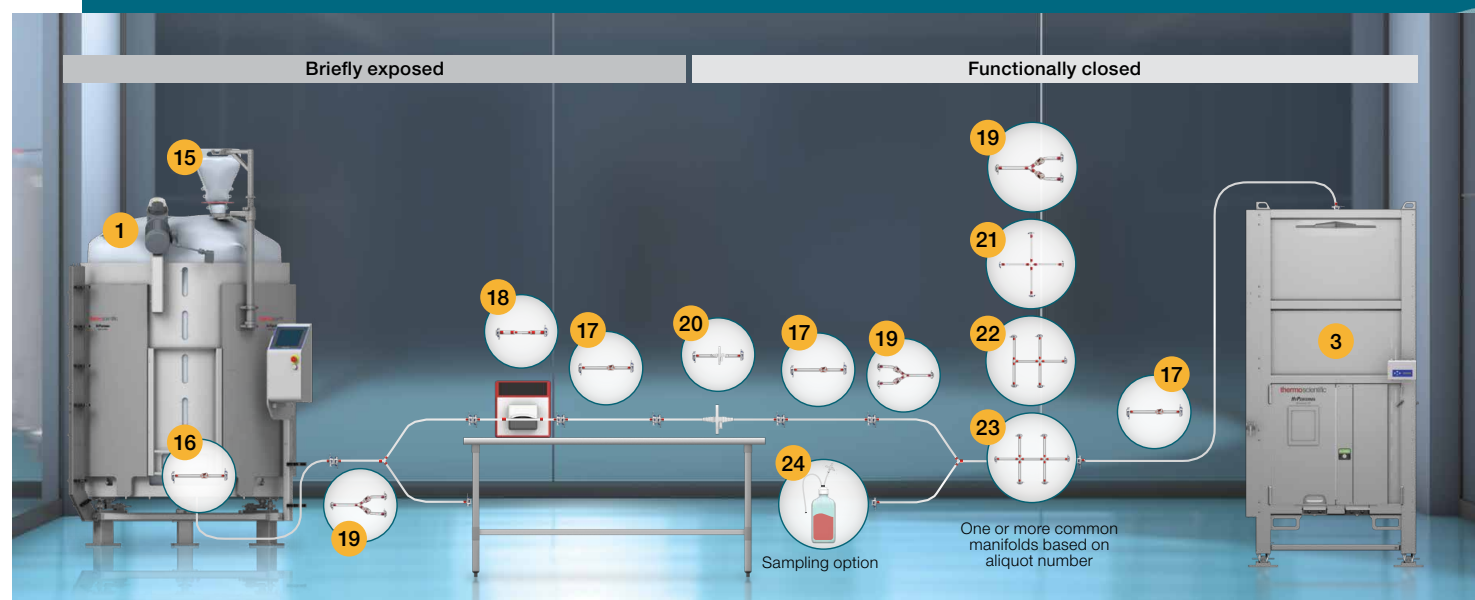
Learn more about our single-use manufacturing network »

Consider these media preparation-related products:

- **Gibco™ mammalian cell culture media**
- **Thermo Scientific™ Nalgene™ production media bottles**
- **Thermo Scientific™ PowderTainer™ II BPC**

Looking for a partner in media formulation and manufacturing?

For large-scale clinical or commercial biomanufacturing applications, rely on **world-class, validated Gibco™ cGMP Media Custom Services.**



Flow diagram key: Reference these numbers in the product selection guide tool.

- | | | |
|---|--|---|
| 1. Thermo Scientific™ HyPerforma™ Single-Use Mixer (S.U.M.) with BPC | 17. Thermo Scientific™ Standard Fluid Transfer Assembly: Jumper | 21. Thermo Scientific™ Standard Fluid Transfer Assembly: 4-way manifold |
| 3. Thermo Scientific™ HyPerforma™ Smartainer™ 3.0 Storage System with BPC | 18. Thermo Scientific™ Standard Fluid Transfer Assembly: Pump tubing | 22. Thermo Scientific™ Standard Fluid Transfer Assembly: 5-way manifold |
| 15. PowderTainer II BPC | 19. Thermo Scientific™ Standard Fluid Transfer Assembly: Y manifold | 23. Thermo Scientific™ Standard Fluid Transfer Assembly: 6-way manifold |
| 16. Thermo Scientific™ Standard Fluid Transfer Assembly: Adapter | 20. Thermo Scientific™ Standard Fluid Transfer Assembly: Filter manifold | 24. Thermo Scientific™ Standard Single-Use Bottle Assembly systems |

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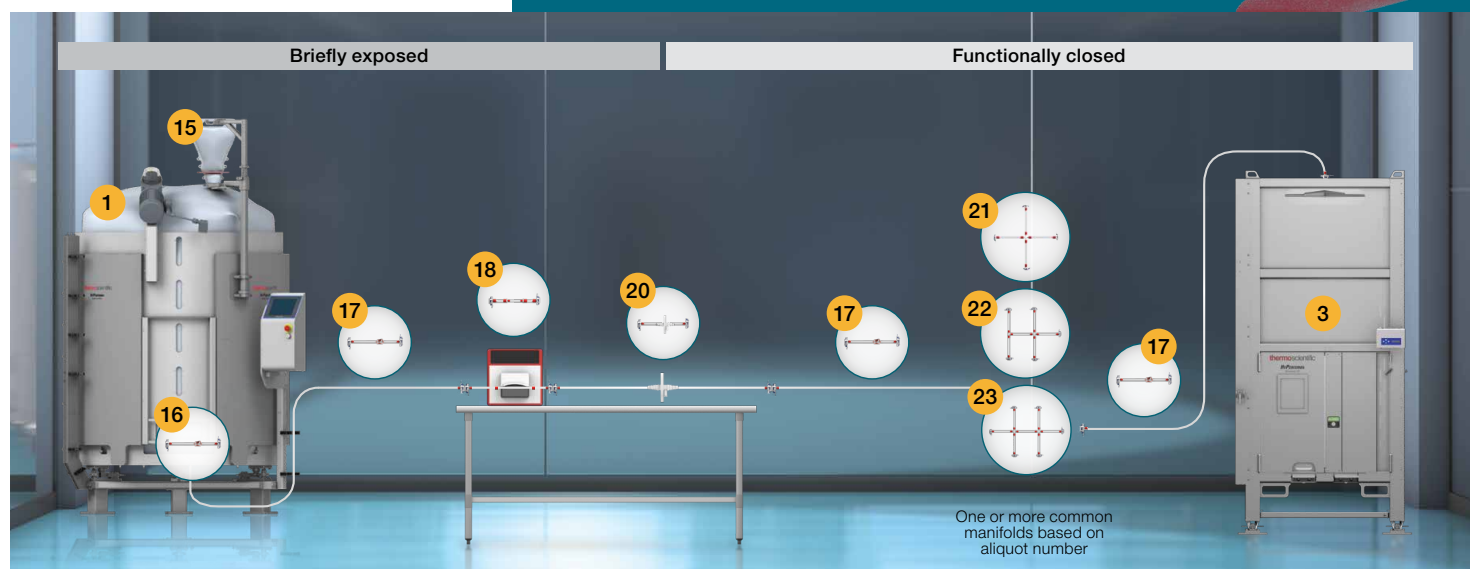
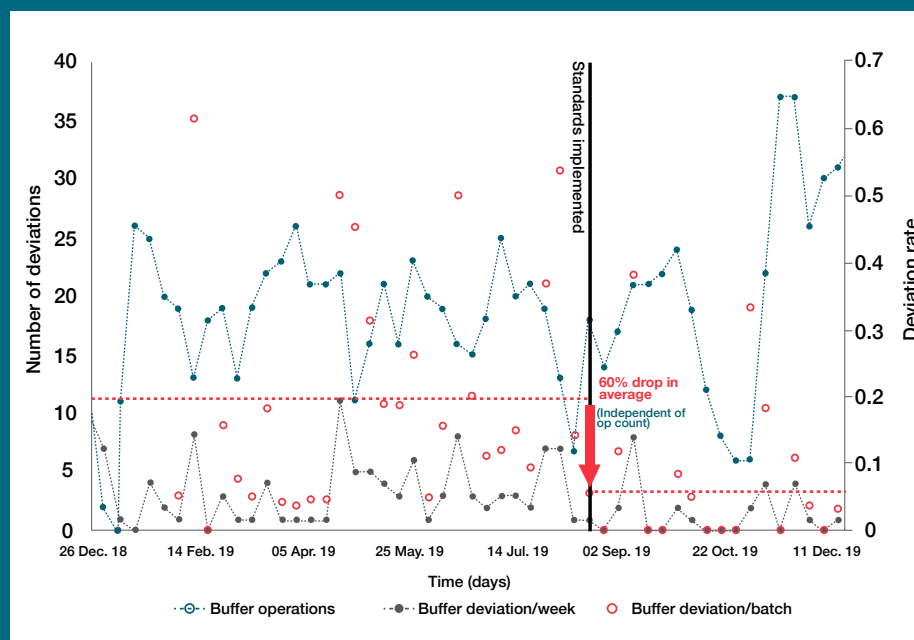


The buffer preparation consumable catalog allows for peace of mind, whether you're optimizing production of high volumes, a high or low chromatography buffer, or a small-volume final formulation buffer. A defined filtration strategy and closed processing system is a process necessity. The mAb Process Playbook offers manufactured products with complementarity of connectors, tubing types, and tubing inner diameters (1/8–1 in.) designed to ensure that your high-flow and high-volume application feels the same as the low-volume and low-flow buffer preparation.

Customers experience increases in success rate using this consistent design approach across scales. After implementing this catalog and methodology, customers observed up to 60% decrease in buffer preparation deviations and, subsequently, saved their organizations time and money, in addition to re-focusing on production instead of complexity management.

Case study

Using these standard recommendations in a 12-month study program, the customer was able to see a \$520K cost reduction in total deviation expenses after standards were implemented in their media and buffer preparation operations.



Flow diagram key: Reference these numbers in the product selection guide tool.

- | | | |
|---|---|--|
| 1. HyPerforma S.U.M. with BPC | 17. Standard Fluid Transfer Assembly: Jumper | 22. Standard Fluid Transfer Assembly: 5-way manifold |
| 3. HyPerforma Smartainer 3.0 Storage System | 18. Standard Fluid Transfer Assembly: Pump tubing | 23. Standard Fluid Transfer Assembly: 6-way manifold |
| 15. PowderTainer II BPC | 20. Standard Fluid Transfer Assembly: Filter manifold | |
| 16. Standard Fluid Transfer Assembly: Adapter | 21. Standard Fluid Transfer Assembly: 4-way manifold | |

Upstream bioprocessing

Explore the mAb process

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Cell expansion

During the cell expansion stage of monoclonal antibody manufacturing, the process starts with vial thawing where a single vial containing approximately 1 mL of frozen cells is thawed in a pre-warmed water. The thawed vial is then transferred into a biological safety cabinet (BSC). Inside the controlled, classified air, an open process takes place where the vial is transferred to a Thermo Scientific™ Nalgene™ Erlenmeyer shake flask. The inoculated shake flask is then transferred to a shaking incubator that has controls for temperature, CO₂, and humidity control, and is monitored through an alarm system. The culture expands and is transitioned to a larger-volume holding container.

To provide a seamless interface with the transfer assemblies in this mAb Process Playbook, the **Thermo Scientific™ HyPerforma™ Rocker Bioreactor** is available with standard Thermo Scientific™ Aegis™ 5-14 film BPCs. This will help to ensure a closed transfer from your flask to rocker cell expansion step at 10, 20, and 50 L sizes.

Rigid containment is also a solution that can be utilized within the cell expansion step: **Thermo Scientific™ Nalgene™ production bottles, Thermo Scientific™ Nunc™ Cell Factory™ systems, and Thermo Scientific™ Nunc™ Roller Bottles.**

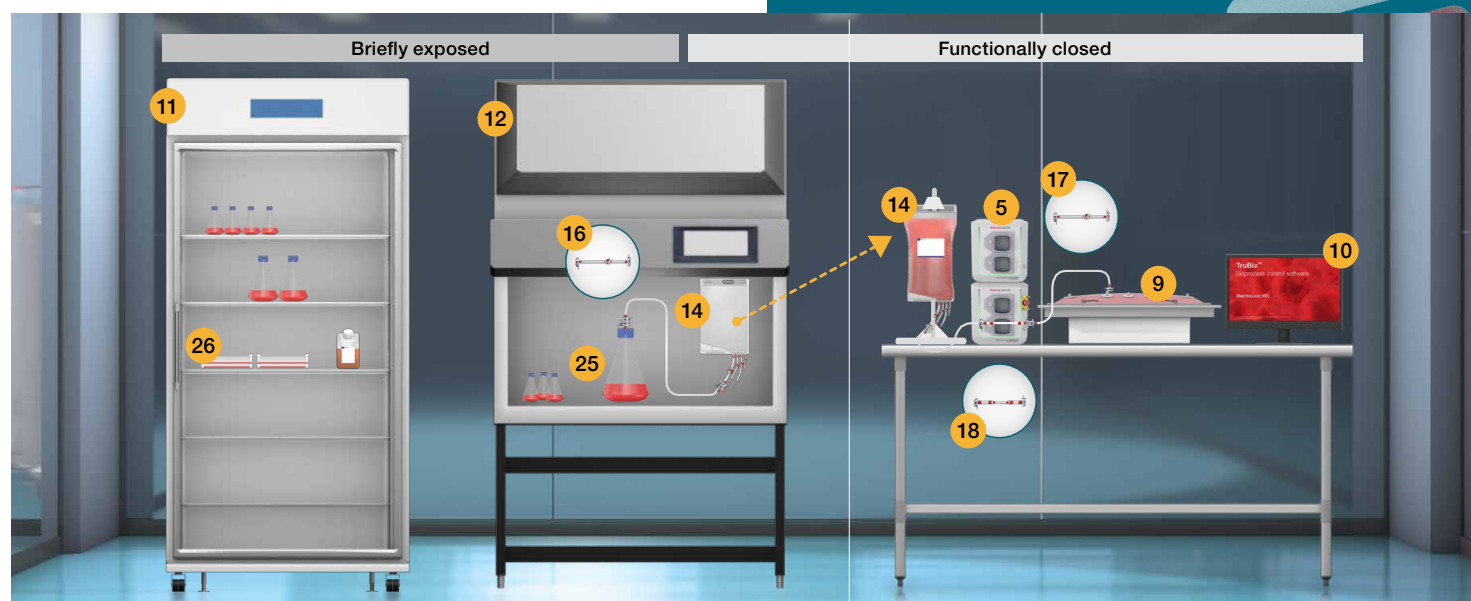
Application note



Read this application note to learn how the performance of CHO-S cells grown in N-1 reactor conditions in both Renolit™ 9101 and Aegis5-14 films show equivalent growth and demonstrate fitness for use.

Consider these cell expansion-related products:

- Erlenmeyer shake flasks
- Thermo Scientific™ biological safety cabinets
- Thermo Scientific™ CO₂ incubators
- Mammalian cell culture lines



Flow diagram key: Reference these numbers in the product selection guide tool.

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|---|--|---|
| 5. Thermo Scientific™ HyPerforma™ GXCore™ Bioprocess Controller | 12. Thermo Scientific™ HeraSafe™ Biological Safety Cabinet | 18. Standard Fluid Transfer Assembly: Pump tubing |
| 9. HyPerforma Rocker Bioreactor with BPC | 14. Thermo Scientific™ Labtainer™ Pro BPCs | 25. Thermo Scientific™ Nalgene™ PC Fernbach Culture Flask |
| 10. Thermo Scientific™ TruBio™ Automation Software | 16. Standard Fluid Transfer Assembly: Adapter | 26. Nunc Standard Closed Cell Factory Systems and Nunc Roller Bottles |
| 11. CO ₂ incubator | 17. Standard Fluid Transfer Assembly: Jumper | |

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Production

We offer innovative mAb production solutions with Thermo Scientific™ BioProcess Containers (BPCs) for bioreactor scales, from rocker-style, to seed train, up to production-scale single-use bioreactors constructed of Aegis5-14 film.

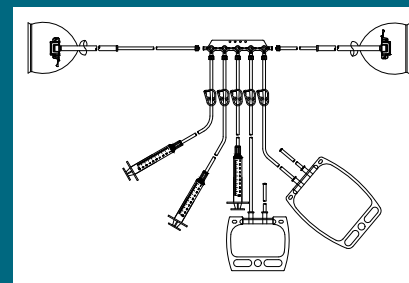
These BPCs and fluid transfer assemblies were specifically selected to facilitate the most efficient transfer rates and ease of transfer for the operator, speeding up transfer and harvesting processes. Connectors have been chosen based on real-time feedback from end users, common failure opportunities, and ergonomics, as well as function.

A primary goal of this step in the mAb manufacturing process is to generate an adequate number of cells for the inoculation of the production bioreactor. It's recommended that the operator conduct sampling to verify cell count, and at times a metabolite analysis needs to be performed aseptically using sampling manifolds in order to maintain the sterile boundary. Ideal products to support this processing step are found below.

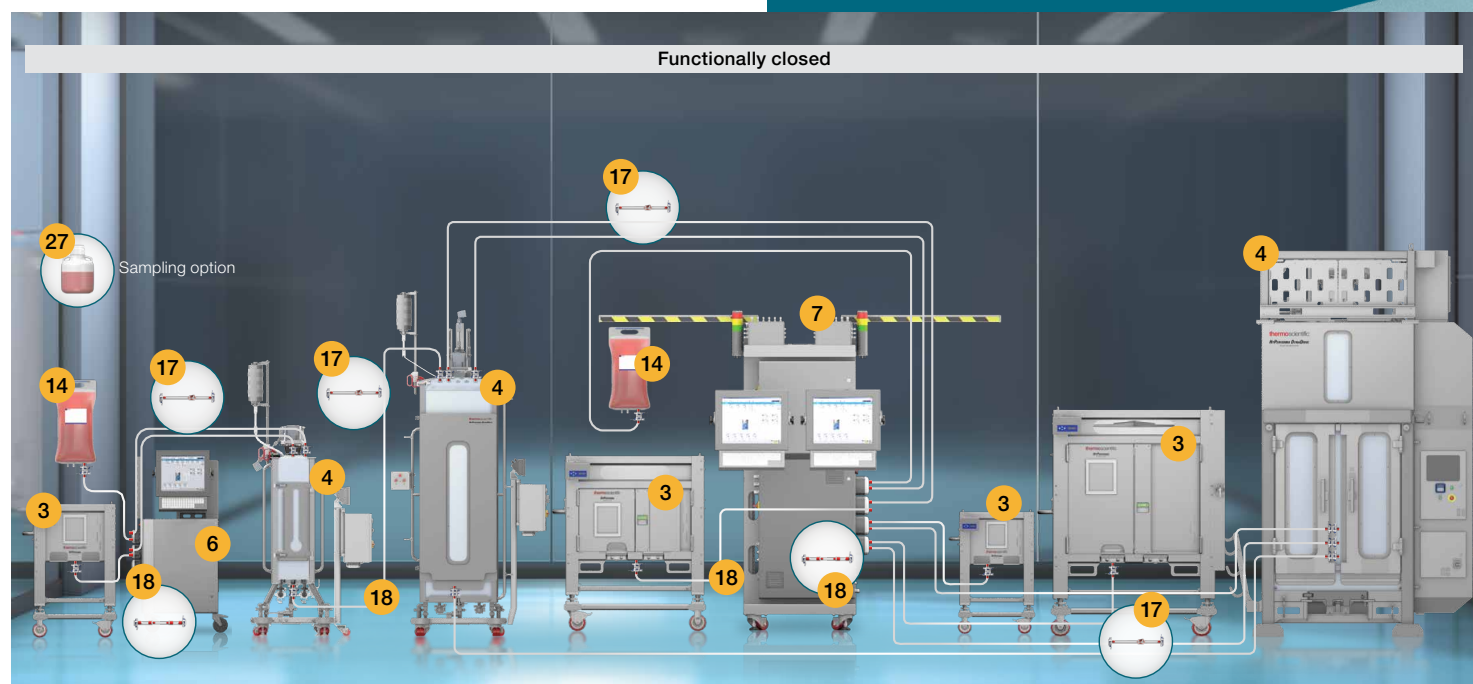
Consider these production-related products:

- Thermo Scientific™ HyPerforma™ DynaDrive™ Single-Use Bioreactor (S.U.B.)
- Thermo Scientific™ HyPerforma™ Rocker Bioreactor
- Single-use sensors
- Metabolomics Data Analysis

An ideal solution for sampling



Ask your sales representative about our sampling manifold solutions.



Flow diagram key: Reference these numbers in the product selection guide tool.

- | | | |
|---|--|---|
| 3. HyPerforma Smartainer 3.0 Storage System with BPCs | 7. Thermo Scientific™ HyPerforma™ G3Pro Bioprocess Controller with TruBio software | 18. Standard Fluid Transfer Assembly: Pump tubing |
| 4. HyPerforma DynaDrive S.U.B. | 14. Labtainer Pro BPCs | 27. Nalgene production carboys |
| 6. Thermo Scientific™ HyPerforma™ G3Lite Bioprocess Controller with TruBio software | 17. Standard Fluid Transfer Assembly: Jumper | |

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Harvest

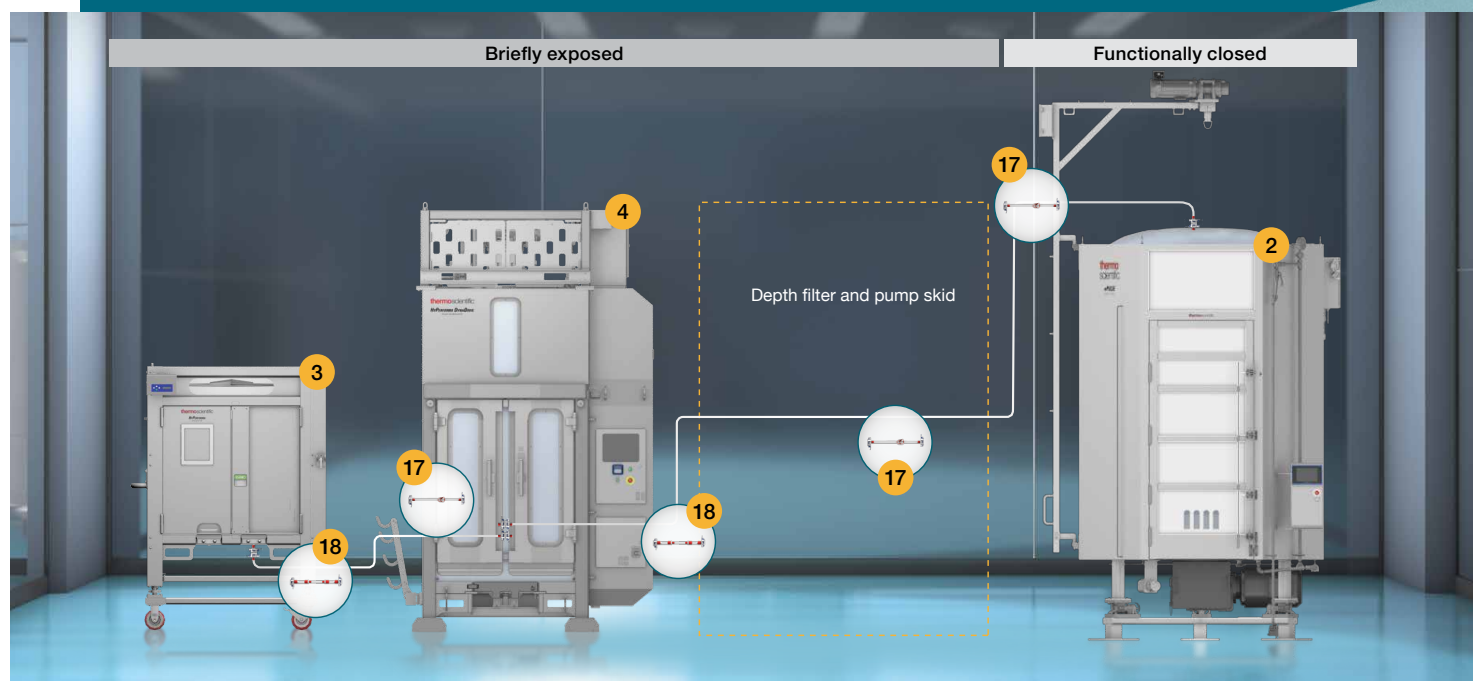
During the harvest step in the process of mAb manufacturing, the molecule of interest is recovered from the large cellular debris, and further purification and filtration steps follow. The outcome of the harvest step is an intermediate process with a high protein yield with minimal impurities, ready for further downstream processing steps. Efficient, process-specific products will aid in maintaining a bioburden-free environment while removing cells and large cellular debris, and meeting desired high titer levels. This mAb Process Playbook is designed specifically to identify the necessary standard products to reach your manufacturing goals through each step of monoclonal antibody manufacturing.

Q: How are the mAb Process Playbook products specifically beneficial for the harvest step of mAb manufacturing?

A: The standard fluid transfer assemblies in this playbook have been developed by applying years of industry knowledge and supplier experience to create BPCs and fluid transfer assemblies that are designed to interface with any harvest equipment you currently have in your operations. These standard products help to provide flexibility and supply chain optimization across all unit operations.

Consider these harvest-related products:

- Custom and bulk analytical reagents
- Thermo Scientific™ imPULSE™ Single-Use Mixers (S.U.M.s)
- Thermo Scientific™ HyPerforma Smartainer 3.0 Storage System
- Thermo Scientific™ HyPerforma™ Single-Use Mixers (S.U.M.s)
- Thermo Scientific™ Harvestainer™ Microcarrier Separation System (for smaller volume operations, 3–12 L)



Flow diagram key: Reference these numbers in the product selection guide tool.

- | | |
|---|---|
| 2. imPULSE S.U.M. with BPC | 17. Standard Fluid Transfer Assembly: Jumper |
| 3. HyPerforma Smartainer 3.0 Storage System with BPCs | 18. Standard Fluid Transfer Assembly: Pump tubing |
| 4. HyPerforma DynaDrive S.U.B. | |

Downstream bioprocessing

Pre-viral

Purification via chromatography or filtration covers a wide spectrum of unit operations specifically chosen to most effectively and efficiently separate a target product from a variety of process- and product-related impurities, adventitious agents, and residual chemical components from the cell culture and harvest processes. Accounting for different requirements regarding system closure in pre-viral (viral-positive) and post-viral (viral-negative) areas, the standard components can form the basis of any downstream manufacturing strategy. Potential workflow options adhere to current industry best-practices and standard engineering principles while meeting the needs of your processes. Our designs easily accommodate a wide range of processing strategies typically observed with purification of 2,000 L bioreactors with mAb titers of 1–10 g/L.

Chromatography

Thermo Fisher has long-standing experience delivering high-quality resins to support the purification of mAbs, and we are excited to build on this tradition of excellence with our mAb Process Playbook. Our design goal is to deliver the most value for all tubing and associated single-use materials supporting any chromatography process from any vendor.

The Thermo Scientific™ HyPeak™ Single-Use Chromatography System with Thermo Scientific™ TruChrom™ automation software, an innovative system that expands upon our ability to deliver flexibility to our customers from pilot to production scale using state-of-the-art engineering. The integrated fluid transfer assemblies are complete with sensors and robust connections to minimize risk and enable functionally closed-system operation.

Learn more »

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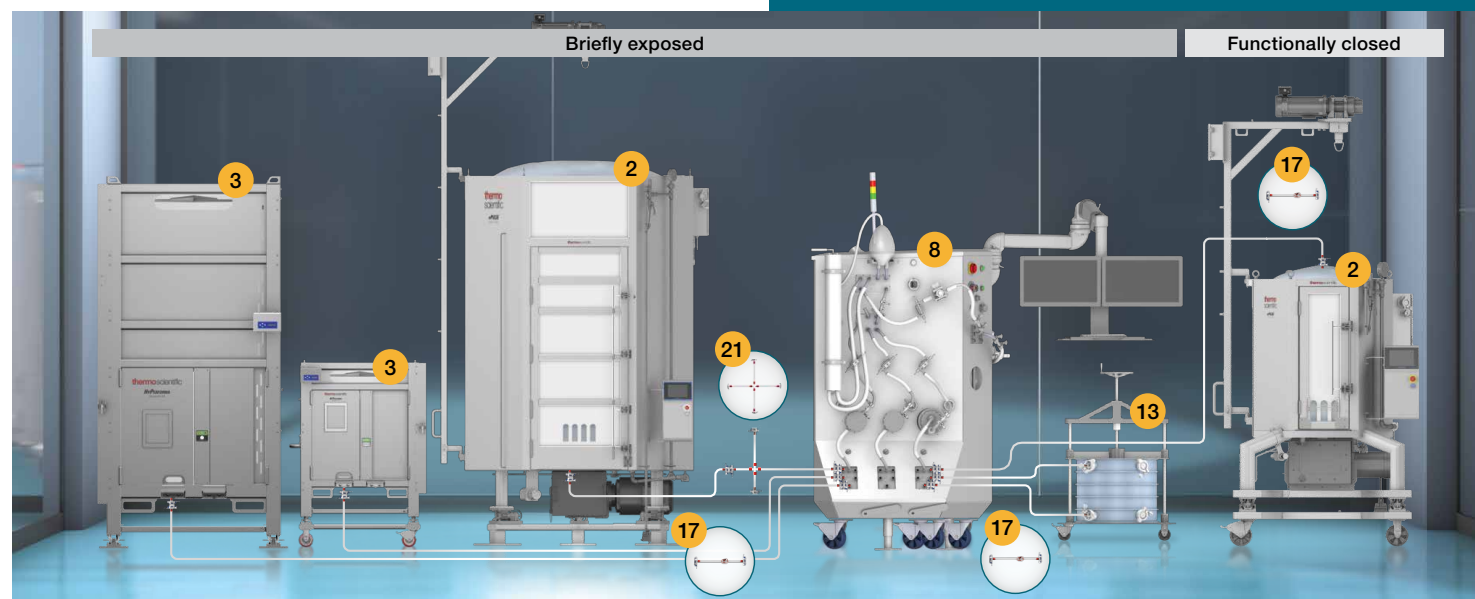
Bulk fill

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Consider these purification-related products:

- Thermo Scientific™ POROS™ affinity HIC and IEX resins
- Thermo Scientific™ CaptureSelect™ antibody toolbox resins
- Analytical products for chromatography



Flow diagram key: Reference these numbers in the product selection guide tool.

- | | | |
|---|--|--|
| 2. imPULSE S.U.M. with BPC | 8. HyPeak Chromatography System with TruChrom software | 17. Standard Fluid Transfer Assembly: Jumper |
| 3. HyPerforma Smartainer 3.0 Storage System with BPCs | 13. Prepacked column with Thermo Scientific™ bioprocess resins | 21. Standard Fluid Transfer Assembly: 4-way manifold |

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Pre-viral

Viral inactivation, general manipulations, and adjustments

Viral inactivation, a critical step in downstream processing, is supported by a combination of standard manifolds, transfer assemblies, sample assemblies, BPCs, and hardware regardless of volume. Our primary goal is to provide support for connecting the containment of your viral clearance steps in a modular format that is robust and easy to implement.

Whether designing a one- or two-tank strategy, let our team of professionals assist you in making sure you are getting the most value out of your single-use operations.

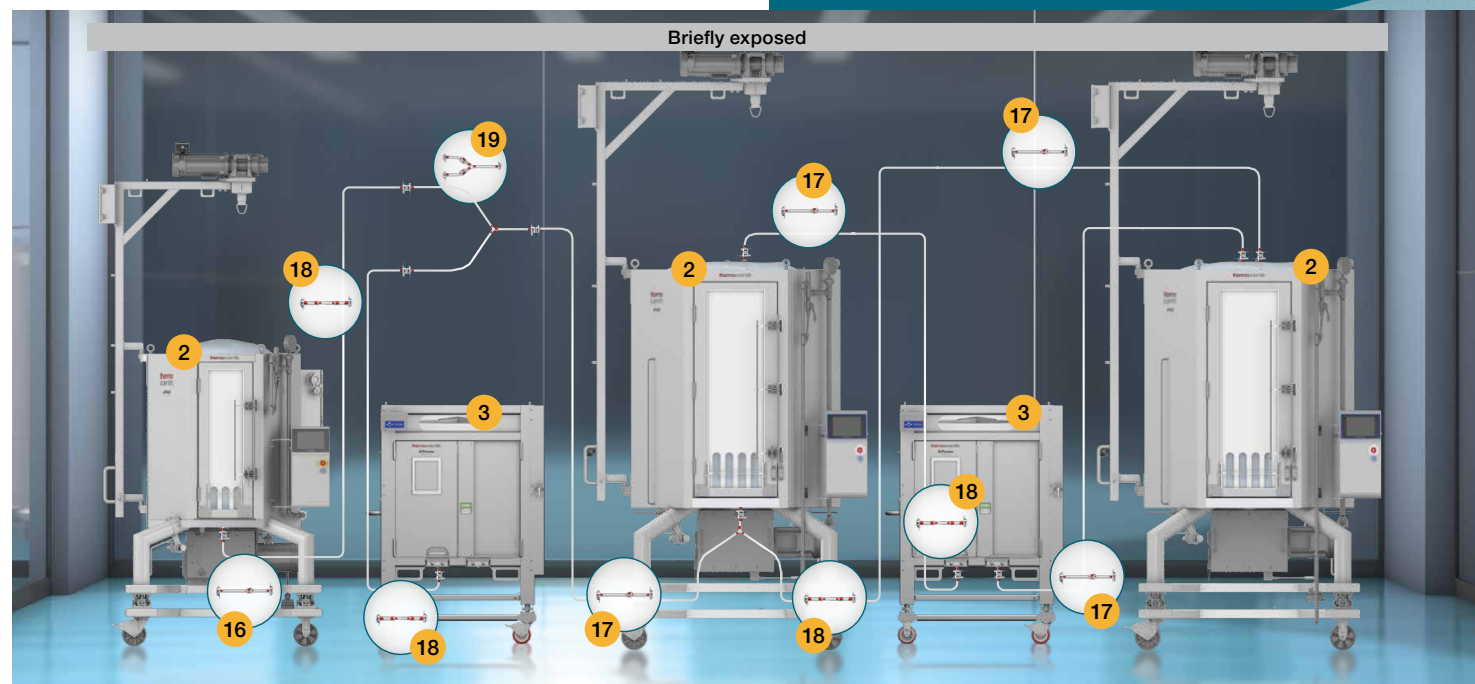
Consider these viral inactivation–
related products:

Production chemicals and sourcing services



Read this brochure

to learn how to uncover hidden costs that may be impacting your ability to mitigate risk and optimize operational efficiencies within your supply chain.



Flow diagram key: Reference these numbers in the product selection guide tool.

- | | |
|--|---|
| 2. imPULSE S.U.M. with BPC | 17. Standard Fluid Transfer Assembly: Jumper |
| 3. HyPerforma Smartainer 3.0 Storage System with BPC | 18. Standard Fluid Transfer Assembly: Pump tubing |
| 16. Standard Fluid Transfer Assembly: Adapter | 19. Standard Fluid Transfer Assembly: Y manifold |

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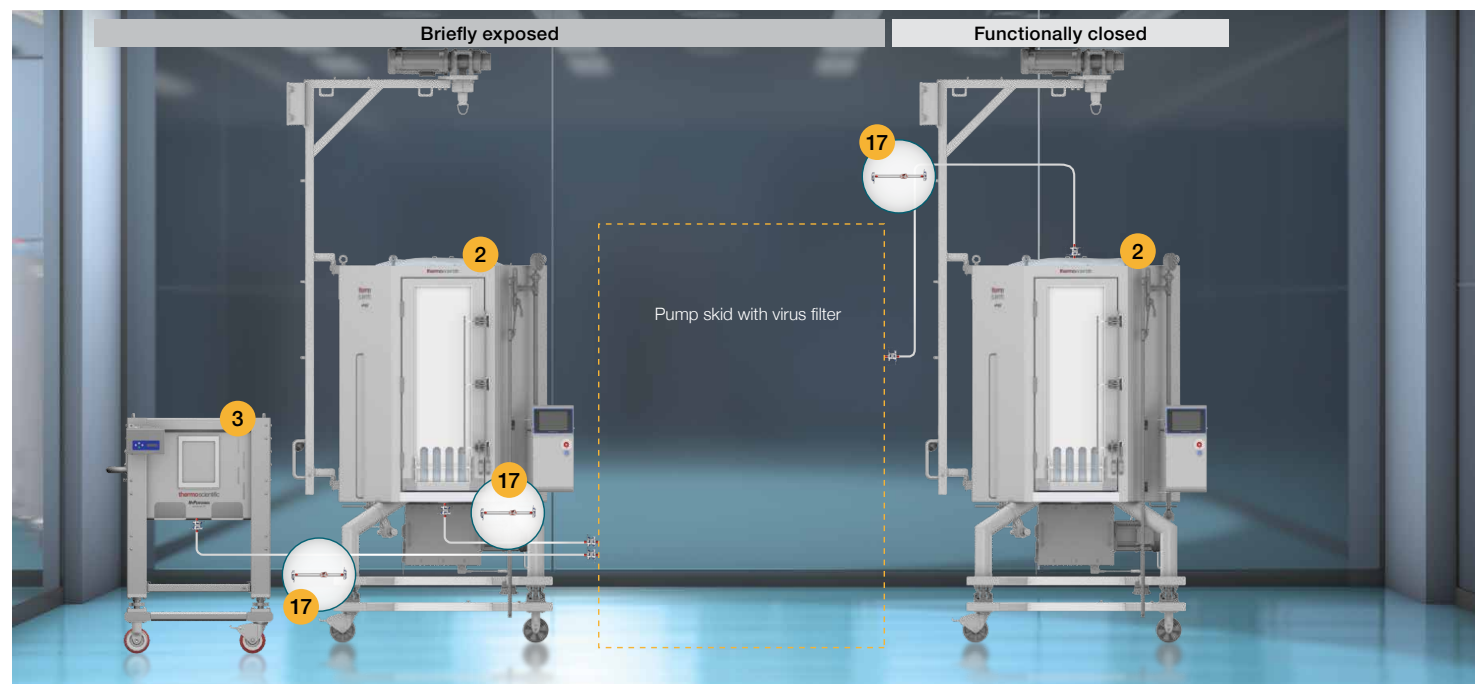


Viral filtration

Depending on the process, a variety of unit operations and intermediate adjustments may occur in the pre-viral areas including titrations, dilutions, depth or absolute filtration, and viral filtration prep. Thermo Fisher offers single-use BPCs with features to accommodate all of these applications. By leveraging decades of experience in designing process solutions across the industry, we're confident we can meet your process needs.

Purification BPC features

- Chambers manufactured with Aegis5-14 film—a five-layer film produced in a cGMP facility
- Suitable for freezing down to -80°C (-112°F) and storage applications, after purification steps have been completed
- The BPC chamber and tubing design minimizes chances of carrying over a portion of untreated pool into the next unit operation; additionally, the design minimizes unwanted foaming and splashing
- BPC ports have been positioned at the base of the BPC chamber, a design element intended to minimize potentially poorly mixed areas within the BPC
- BPCs have been engineered so an additional inlet port can be added through any spare inlet—on the top or bottom of the BPC chamber
- Probe ports have been positioned flush on the face of the chamber to eliminate any poorly mixed areas within the BPC



Flow diagram key: Reference these numbers in the product selection guide tool.

2. imPULSE S.U.M. with BPC
3. HyPerforma Smartainer 3.0 Storage System with BPC
17. Standard Fluid Transfer Assembly: Jumper

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Post-viral

UF/DF

Whether interfacing with standard, customized, stainless steel, or single-use skids, this mAb Process Playbook offers the right complement of mixers, BPCs, transfer assemblies, and supporting single-use infrastructure to help ensure success for any ultrafiltration/diafiltration (UF/DF) setup.

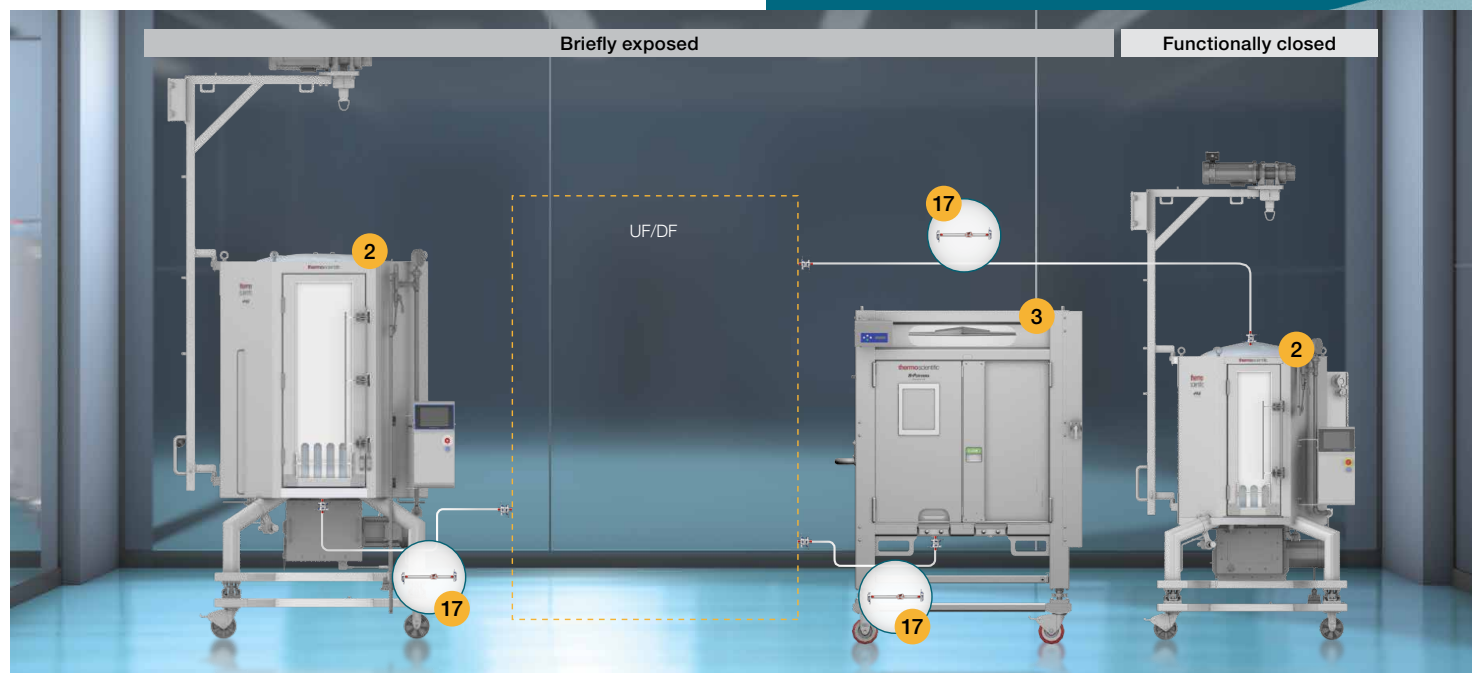
Ask your field application scientist (FAS) how you can use our extensive library of closed connector manifolds and ferruled connectors to support closed processing around this critical step or the appropriate hybrid interface to a stainless steel system.

Aegis5-14 film—the bioprocessing film of choice for mixing and buffer storage

Our BPCs are built to meet your single-use upstream and downstream bioprocessing needs. Our films are engineered to meet the most demanding requirements of your individual bioproduction processes.

Aegis5-14 film is a single-web, five-layer polyethylene (PE) film produced in a cGMP facility—the outer layer is a polyester elastomer coextruded with an EVOH barrier layer and a low-density polyethylene product contact layer with greatly reduced additive levels.

We have established redundant film manufacturing from multiple film extruders to strengthen the supply and quality of our BPCs.



Flow diagram key: Reference these numbers in the product selection guide tool.

2. imPULSE S.U.M. with BPC
3. HyPerforma Smartainer 3.0 Storage System with BPCs
17. Standard Fluid Transfer Assembly: Jumper

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Combining our fluid transfer assemblies and our BPCs constructed of Aegis5-14 film helps ensure that the last unit operation commonly used in the process is robust and capable for final drug substance product. The mAb Process Playbook itemizes a series of plug-and-play manifolds to allow for a combination of sizes, flowpaths, and variations. The manifold designs allow for a multi-product platform while utilizing a consistent platform strategy of minimal components.

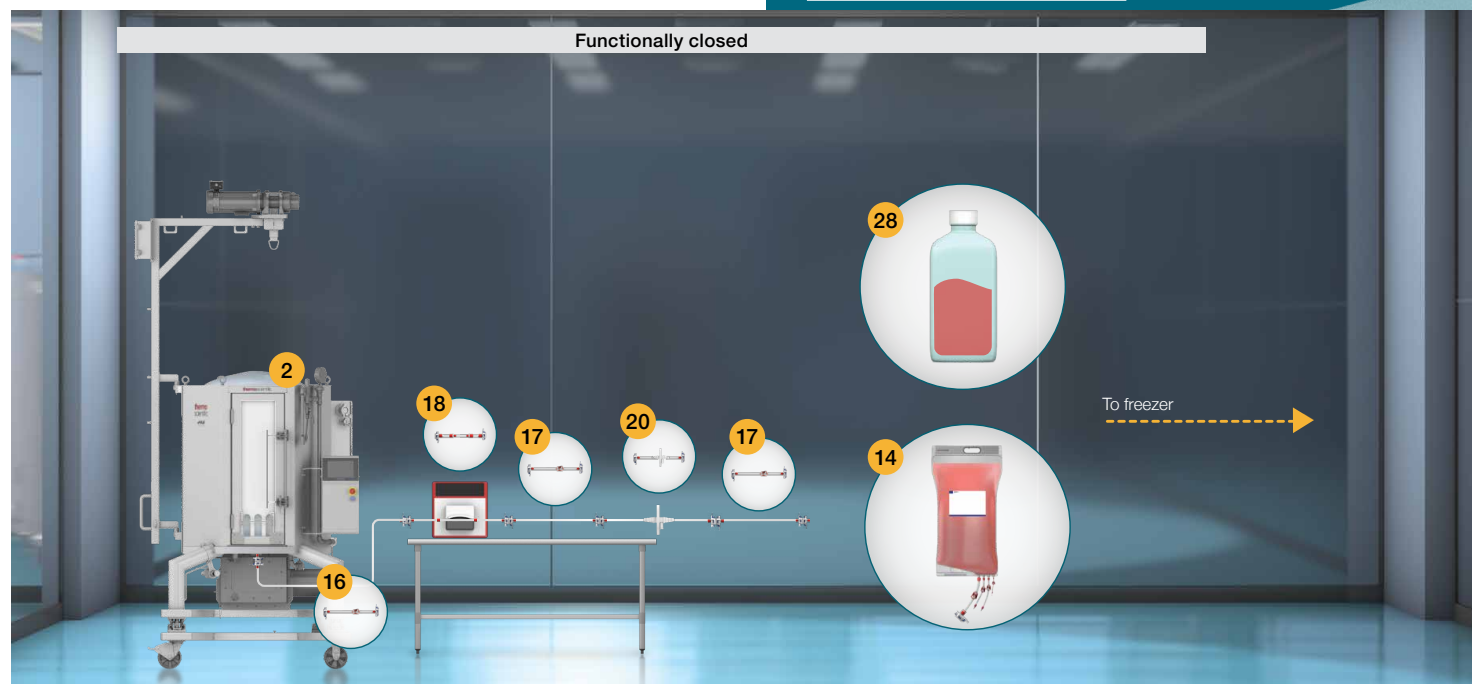
Our rigid containment portfolio is another ideal choice for bulk fill and storage. **Thermo Scientific™ Nalgene™ Polycarbonate (PC) Biotainer™ bottles and carboys and Nalgene™ HDPE Biotainer™ bottles and carboys** are ideal solutions for storage and transportation of frozen materials at as low as -100°C (-148°F). Our rigid containment solutions are available in multiple levels of cleanliness. For downstream processes specifically, the Thermo Scientific™ Nalgene™ Certified Platinum Clean HDPE Bottles and Carboys are highly recommended due to the very low level of sub-visible particulates and certification to below one-third of the allowable USP <788> particulate levels.

Labtainer Pro BPCs now with 360° of universal retention

The innovative design of the **Labtainer Pro BPC** provides improved flexibility and assurance without compromise. The Labtainer Pro BPC was developed in response to a variety of workflow needs to improve ease of use, high reliability, and assured quality. This industry leading product is now manufactured with the **Thermo Scientific™ BioTitan™ Retention Device**, for heightened performance and lower risk, replacing cable ties. The BioTitan device is designed to provide superior universal retention that minimizes the risk of leaks and failures at the connection point.



View the BioTitan
Retention Device
3D interactive tour



Flow diagram key: Reference these numbers in the product selection guide tool.

- | | |
|---|---|
| 2. imPULSE S.U.M. with BPC | 18. Standard Fluid Transfer Assembly: Pump tubing |
| 14. Labtainer Pro BPC | 20. Standard Fluid Transfer Assembly: Filter manifold |
| 16. Standard Fluid Transfer Assembly: Adapter | 28. Nalgene Platinum Certified Clean HDPE Biotainer Bottles and Carboys |
| 17. Standard Fluid Transfer Assembly: Jumper | |

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Below is a list of quick-reference links to learn more about the products featured in this playbook:

Bioprocessing equipment

- HyPerforma Single-Use Mixers
- imPULSE Single-Use Mixers
- HyPerforma Single-Use Bioreactors
- HyPerforma DynaDrive Single-Use Bioreactor
- HyPerforma Rocker Bioreactor
- HyPeak Single-Use Chromatography System
- HyPerforma bioprocess controllers
- HyPerforma Smartainer 3.0 stainless steel support systems

BPCs and standard fluid transfer assemblies

- Labtainer Pro BPCs
- Jumper tubing, aseptic
- Jumper tubing, non-aseptic
- Y manifolds
- 4-way manifolds
- 5-way manifolds
- 6-way manifolds
- Filter manifolds
- Adapters
- Pump tubing
- Exhaust vent filter assembly

Rigid Containment solutions

- Nunc Cell Factory systems
- Roller bottles
- Standard single-use bottle assemblies
- Production bottles
- Production carboys

Product selection guide tool

Use this standard product selection guide as an example to view recommended products that are used across multiple unit operations for a 2K mAb manufacturing process. These standard offerings will help optimize your supply chain. The color coding system provides a tiered recommendation structure across the entire workflow.

Single-use product selection guide
Solutions for monoclonal antibody (mAb) processes up to 2,000 L

Use this standard product selection guide to view recommended products that are used across multiple unit operations for a mAb manufacturing process up to 2,000 L. These standard offerings will help enable supply chain optimization for your process. The color coding system provides a tiered recommendation structure across the entire workflow. Products that do not have color indications are better suited for smaller scale processes, but are listed here to provide a full offering of recommendations.

Product Category	Unit Operation 1	Unit Operation 2	Unit Operation 3	Unit Operation 4	Unit Operation 5	Unit Operation 6	Unit Operation 7	Unit Operation 8	Unit Operation 9	Unit Operation 10	Unit Operation 11	Unit Operation 12	Unit Operation 13	Unit Operation 14	Unit Operation 15	Unit Operation 16	Unit Operation 17	Unit Operation 18	Unit Operation 19	Unit Operation 20	
Media Preparation																					
Buffer Preparation																					
Cell Expansion																					
Production																					
Harvest																					
Chromatography																					
Viral Inactivation																					
Viral Filtration																					
Ultrafiltration / Diafiltration (UF/DF)																					
Bulk Fill																					



The way forward in simplifying single-use designs

Optimize your process with support from a reliable and harmonized global network

A resilient supply chain for single-use technologies is critical to ensuring biopharmaceutical manufacturers are able to meet their key operational business goals. Unique customer needs require design flexibility. Many single-use suppliers offer a large variety of designs and components. This flexibility comes at a cost. Challenges associated with managing and relying upon a supply chain that includes multiple suppliers can include increased risk, lead times, and cost.

Our global single-use manufacturing network allows for more efficient capacity utilization through established manufacturing redundancies with the capability to transfer demand across the network to meet complex customer demand signals. A core strength in the application of open-architecture design principles to support customer-specific configurations is maintained and balanced with the option for standardized components and raw materials, pre-qualified and stocked for use across our network.

This mAb Process Playbook unlocks the value of single-use standardization by offering modular standard designs. Your organization will benefit from designs using standard components that are stocked and qualified for use across the our entire manufacturing network. We anticipate that this novel approach to single-use manufacturing will provide a more efficient and more sustainable single-use supply chain for our customers.

Learn more at thermofisher.com/sut
Ask our FAS team for specific recommendations associated with these strategies that ensure the most value for your operations.

thermo scientific

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