Allegro™ Connect

BULK FILL SYSTEM

Executing any process without the right degree of monitoring, control or reporting, runs the risk of process deviations. This could potentially lead to the adulteration of valuable drug products and intermediates, whilst wasting valuable operator time.

Allegro™ Connect systems provide robust, accurate and automated platforms that integrate with your manufacturing processes on every level, keeping unit operations within critical parameters to ensure that you spend less time collating data and more time optimizing your process.

Our range of Allegro Connect systems share a compact form factor, designed with operators in mind, and are configurable to meet your process requirements without the time-consuming pain of modification.

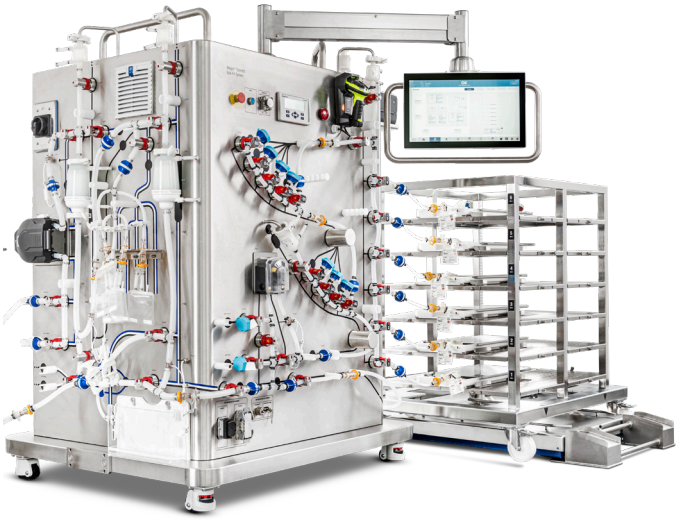


Fig 1. The Allegro Connect bulk fill system.

The Allegro Connect bulk fill system

The system is an automated filtration and filling system designed to accurately and aseptically aliquot bulk product into multiple biocontainers or bottles (Figure 1). Minimizing non-recoverable volume within the flow path is central to the design of the system. Automated techniques and novel design features have been incorporated to ensure that bulk fill step yields are consistent and optimal across a variety of bulk filling scenarios. Configurable to your needs, the system supports a wide range of liquid filter capsules and various filter combinations.

It can fill up to 320 containers with bulk drug substance, process buffer or cell culture media using preconfigured standard accessories. Designed to minimize process risk, the system dispenses product in a sterile single-use (SU) flow path, maintaining a closed process at all times. It automatically vents and wets liquid filters, along with performing filter integrity and manifold leak testing. Process risk is further minimized by a comprehensive validation package characterizing extractables as well as particulates, in accordance with current industry expectations.

Uncontrolled risk and preventable product loss at any stage in the manufacturing process is unwelcome. This is accentuated at this critical stage in the process and highlights the need for an efficient, robust and versatile solution to the bulk filling process.

The problem

With the cost of manufacturing under constant scrutiny, processes and technologies are consistently being reviewed to increase process productivity and the volume of drug substance produced per year (throughput). Current trends show an increasing number of multi-product facilities being built and/or being retrofitted together with significant investments in automated bioprocessing equipment.

The majority of bulk filling methods currently being used are manual and these potentially limit the production capacity (Figure 2). It is not uncommon to hear of these processes taking up to 30 hours, requiring up to four personnel at any one time. Current automated solutions, however, go some way to address this issue but have single-mindedly focusedon throughput of the facility at the expense of step yield and flexibility. A persistent challenge for bulk filling operations is process variability. This is not well addressed by the current generation of automated systems and is one of the main reasons for the relatively low adoption rates of automation in this operation when compared to other bioprocessing equipment.

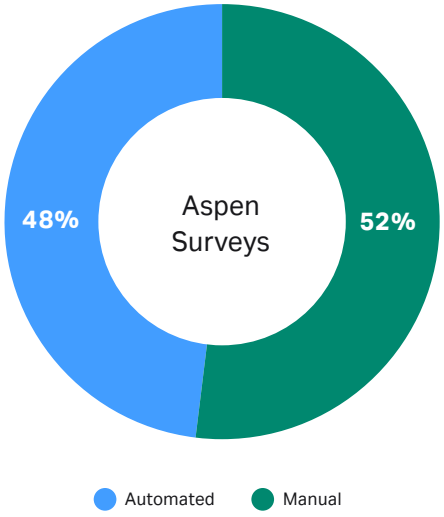


Fig 2. Aspen survey results.

The solution

The Allegro Connect bulk fill system is a highly configurable platform that can fill drug substance in both biocontainers and bottles (Table 1).

Here are some of the key features the system has to offer:

- Automatically fills up to 320 containers – biocontainers or bottles, from 1 to 20 L nominal volumes (Fig 3).
- Can support single, serial, or parallel liquid filtration arrangements using up to 2 × 508 mm (20 in.) filter capsules with automated venting, priming and aseptic sampling from the flow path via a sampling port upstream of the final liquid filter.
- Non-recoverable product volume within the system is < 2.5% of the feed volume.
- If homogeneity of the filtered product is a concern, the system can control an optional mixer, connected aseptically in the flow path after the final filter but before the dispensing station, where a secondary pump is used to dispense the filtered product into the bulk containers.
- It can achieve a filling accuracy of within ± 2%, using a single-floor weighing platform per workstation as opposed to one balance per container. This avoids excessive (re-)calibration activities when a multiple scales system is used for the filling process.

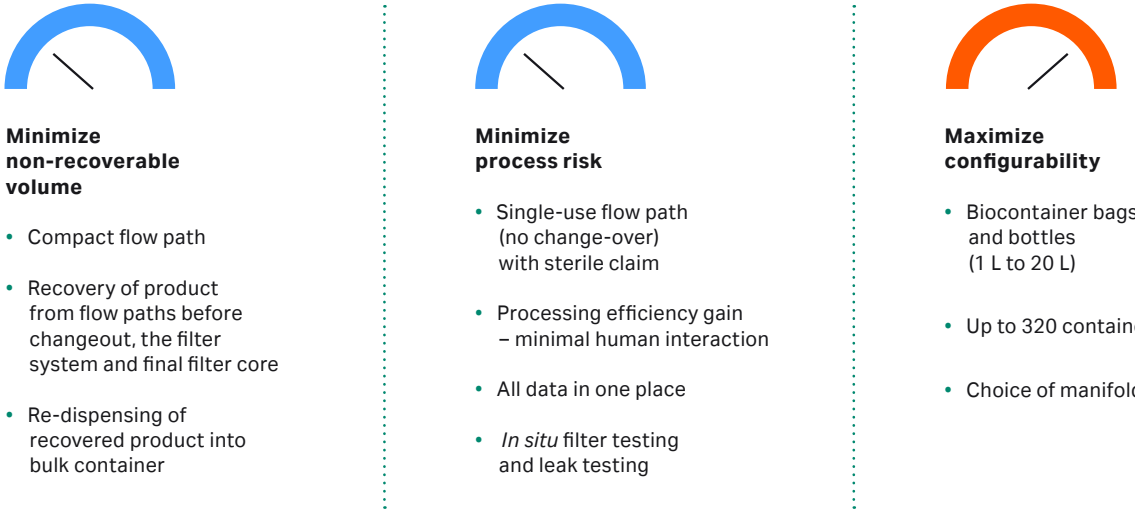


Fig 3. Key system benefits.

Table 1. Dispensing accuracies for containers.

Container nominal volume	Biocontainers	Bottles
1 L	± 2%	± 2%
2 L	± 2%	± 1%
5 L	± 1%	± 0.5%
10 L	± 0.5%	± 0.3%
20 L	± 0.5%	± 0.3%

- It has an integrated Palltronic® Flowstar LGR integrity test instrument to perform pre-use, post sterilization integrity testing (PUPSIT) and post-use integrity testing of liquid filter capsules. Leak testing of the single-use flow paths is also carried out, ensuring the main manifold is defect-free.
- It includes a label printer, allowing *in situ* tagging for all product and sample containers, enabling robust tracing with configurable labels automatically generated.
- It generates electronic batch records along with a summary compiling data including:
  - the single-use sensors within the flow path
  - single-use manifolds used for the batch (Table 2)
  - integrity and manifold leaking results (Table 3)
  - batch, lot information, and dispensed weight per container (Fig 4)
  - other critical process parameters, for example, differential pressure across filters (Fig 5)

Table 2. Batch record summary for single-use manifold.

Component	Product code	Lot number	Serial number	Expiry date
Filter	NP7UECVP1G	IF5156	00012	10-May-2023
Manifold	9496-1356Z	104226303	–	24-Mar-2023
Manifold	9496-1362T	104226077	–	08-May-2023
Manifold	9496-1402Z	104270531	–	10-May-2023
Manifold	7496-1579U	104250435	–	15-Apr-2023
Manifold	7496-1579U	104250435	–	15-Apr-2023
Manifold	9496-1519E	104250572	–	14-Apr-2023

Table 3. Batch record summary for single-use manifold.

Time	Executed test	Message	Unit	Result	Measured value
12-Aug-21 13:17:19	Forward flow test – F2 (to flush)	–	MBF01	Pass	6.5 mL/min
12-Aug-21 15:03:25	Forward flow test – F2 (to flush)	–	MBF01	Pass	5.9 mL/min
12-Aug-21 15:27:05	Leak test – up to primary	–	MBF01	Pass	0.2 mL/min

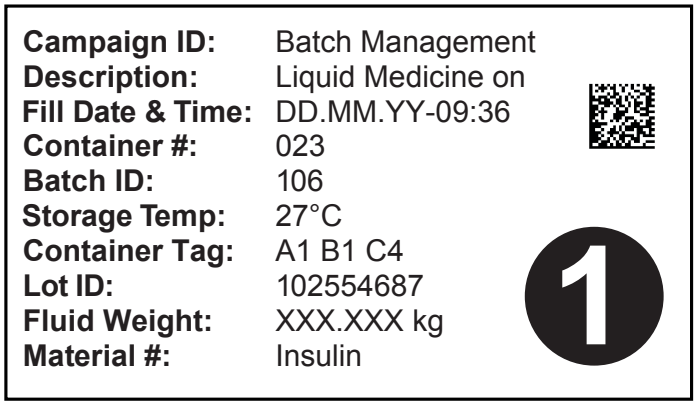


Fig 4. Example of label that is printed out for tagging all biocontainers and bottles.

- It controls the container filling flow rate between 0.15 and 8.5 L/min ensuring (1) the liquid filter capsules are primed correctly, (2) shear damage of the product is avoided, and, if applicable, (3) the processing time for filling the containers is minimized.
- A complete single-use flow path can be installed or uninstalled by a single operator in less than 60 minutes.
- Manual and automated control modes of operation are possible.

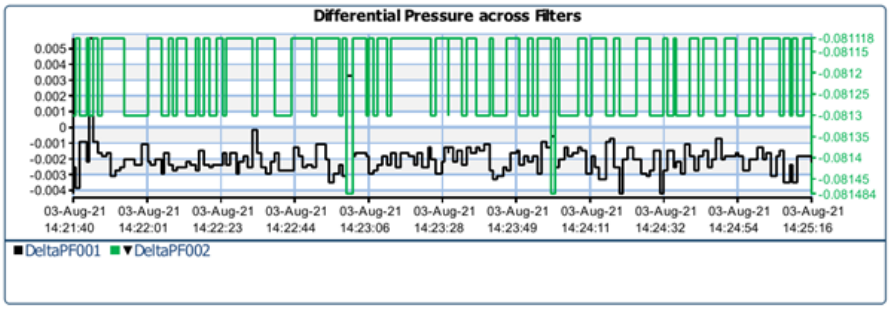


Fig 5. Example of the critical process parameter data available.

Processing efficiency gains
Up to 80% [1] time saving

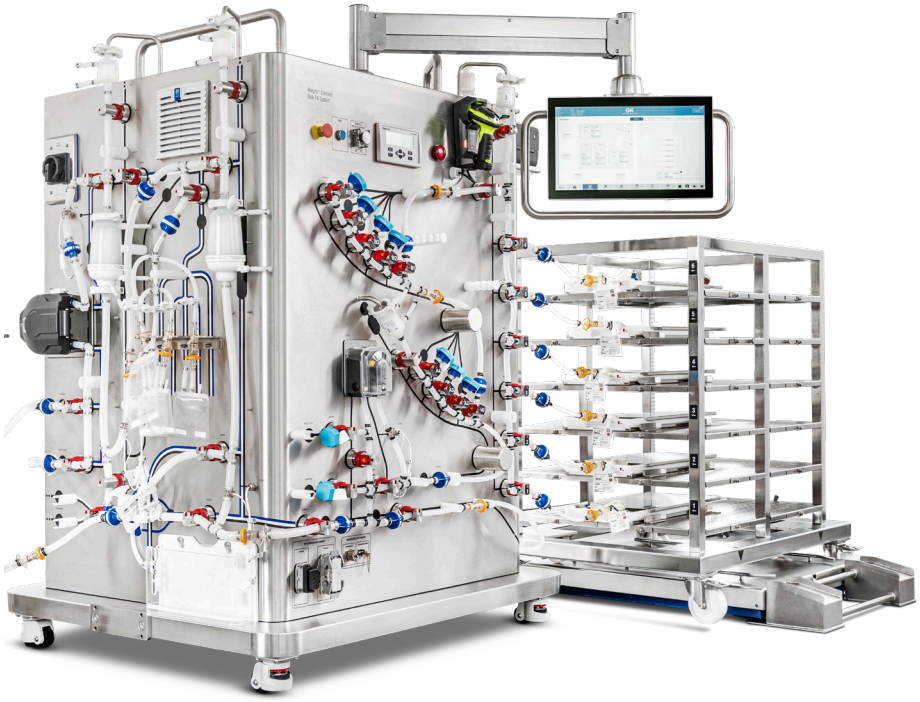
80%

High dispensing accuracies
Within ± 2% [2]

± 2%

Minimized product loss
< 2.5% of feed volume

< 2.5%



Compact footprint
1.3 × 2.6 m

Fig 6. High performance single-use filling.

[1] Value based on customer feedback.
[2] For data refer to application note Accurate aliquoting of bulk drug substance over a range of product viscosities and target weights.

Configure the equipment to meet your process needs

The following images (Figure 7 to 14) show the flexibility of the system to achieve various configuration options, tailored to meet your individual process needs. With a range of manifolds and hardware configurations available, end users are able to fill up to 320 biocontainers and/or bottles per batch.

Fig 7. Installing an all-in-one biocontainer bag system on the weighing platform.

Scalable platform for biocontainers showing all-in-one and tower systems

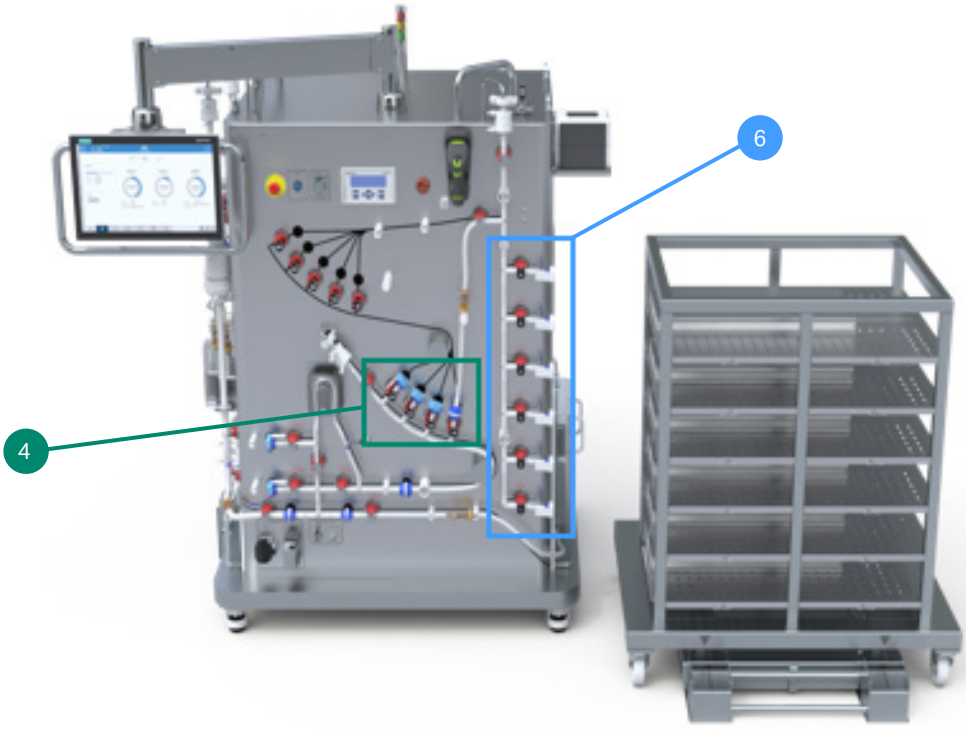


Fig 8. 4 × 6 filling 24 biocontainers.

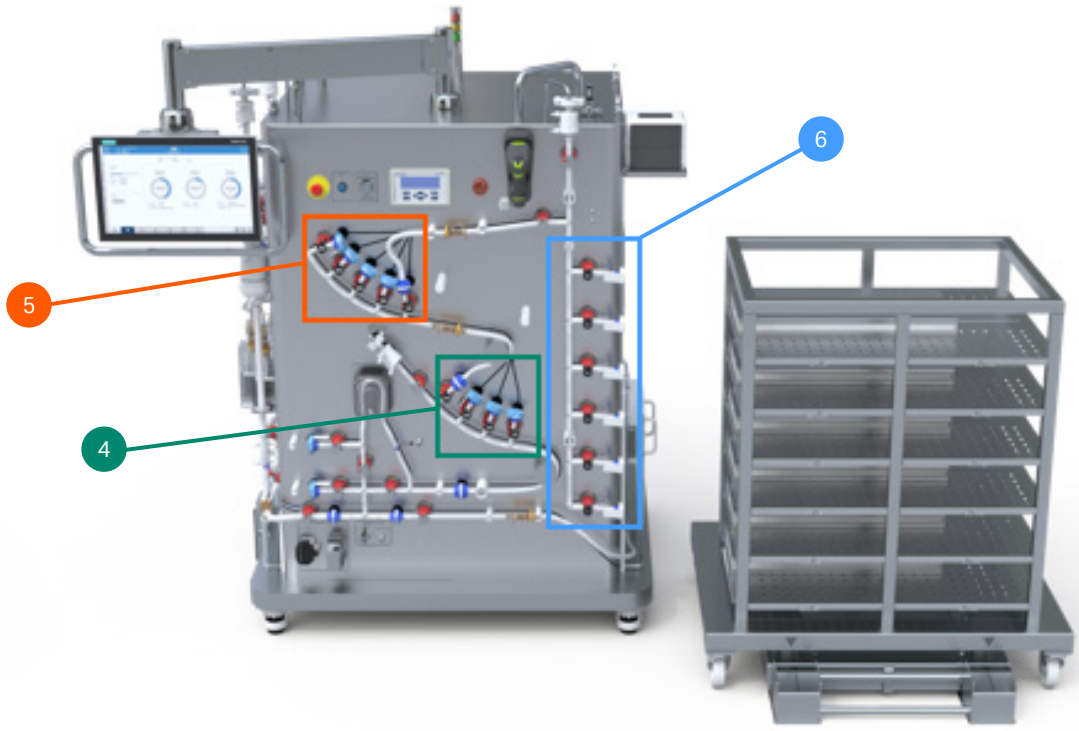


Fig 9. 4 × 5 × 6 filling 120 biocontainers.

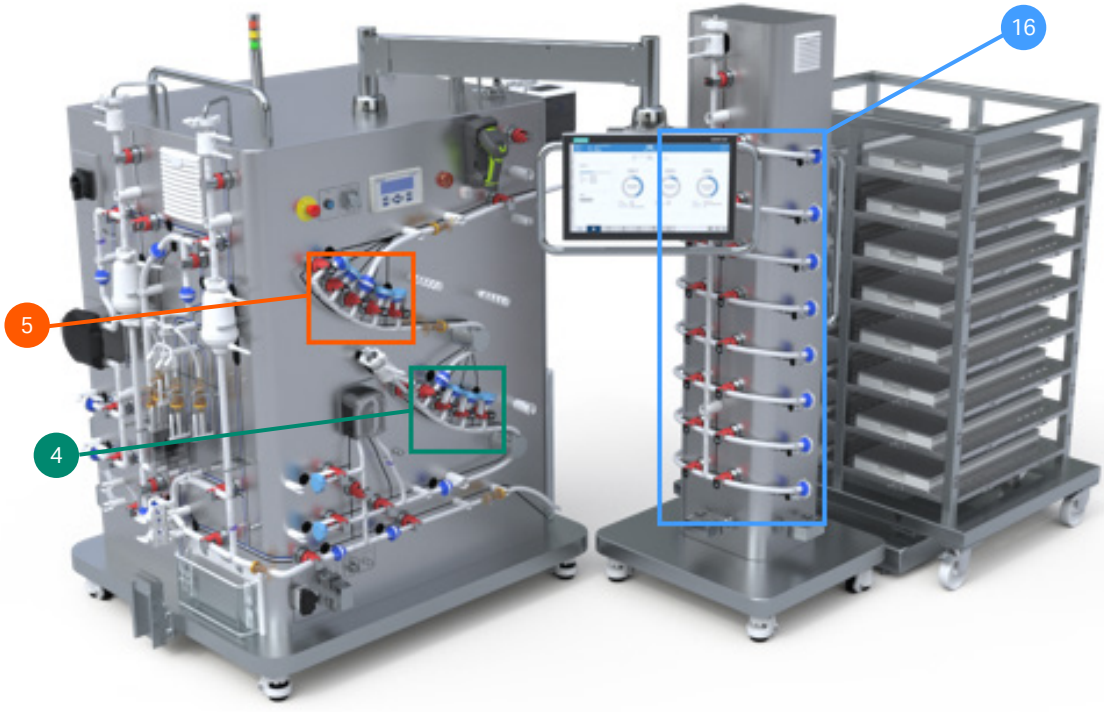


Fig 10. 4 × 5 × 16 filling 320 biocontainers [3].

[3] Additional weighing scale and 16-biocontainer workstation required for 10 L and 20 L biocontainers.

Scalable platform for bottles showing all-in-one and tower systems

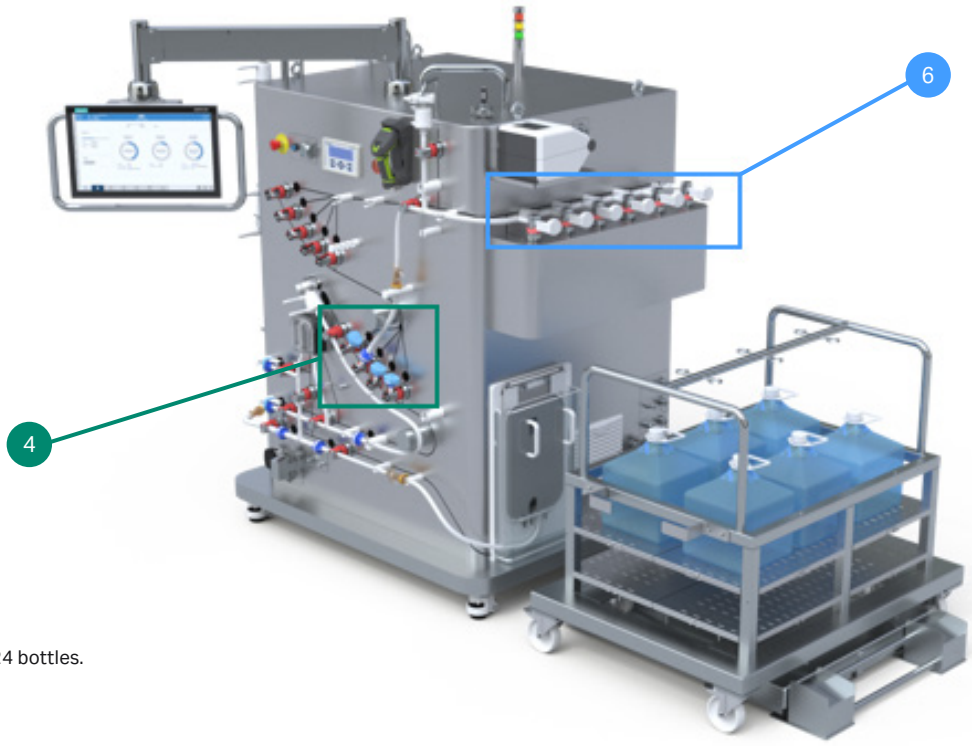


Fig 11. 4 × 5 × 6 filling 24 bottles.

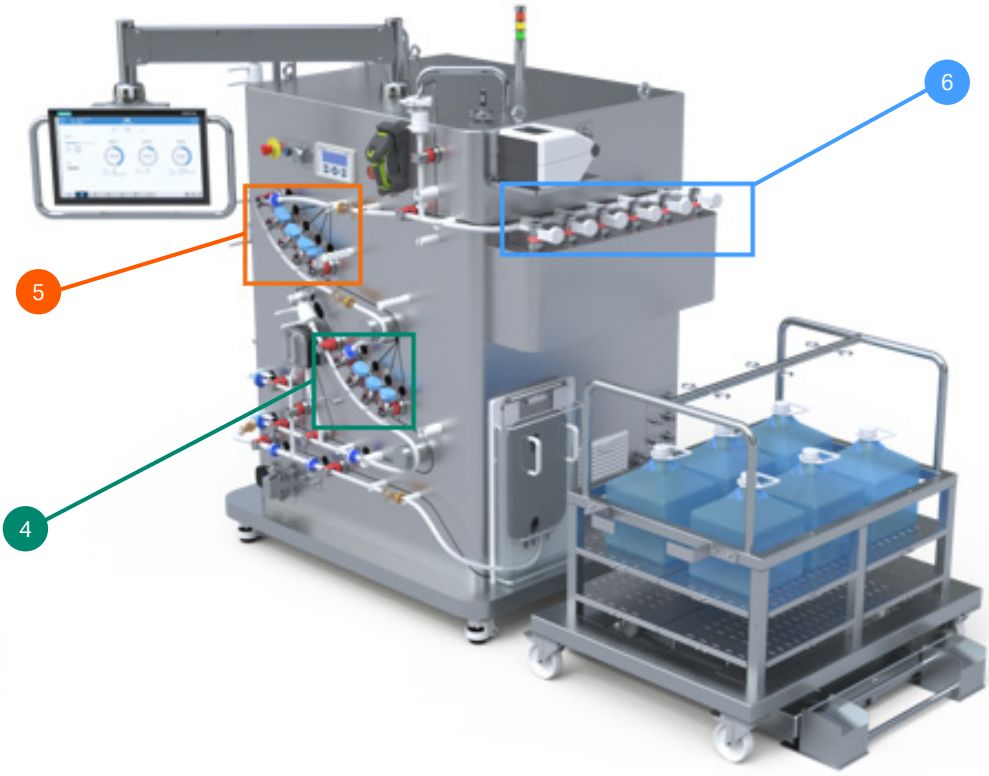


Fig 12. 4 × 5 × 16 filling 120 bottles.

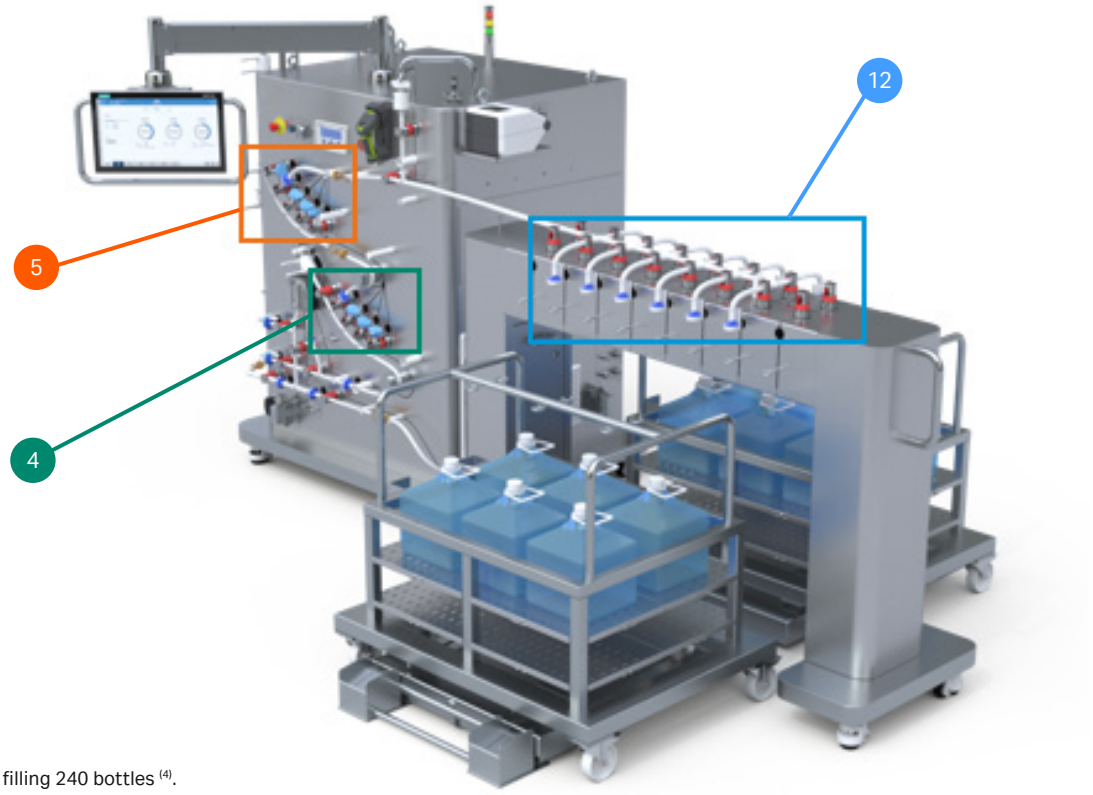


Fig 13. 4 × 5 × 12 filling 240 bottles [4].

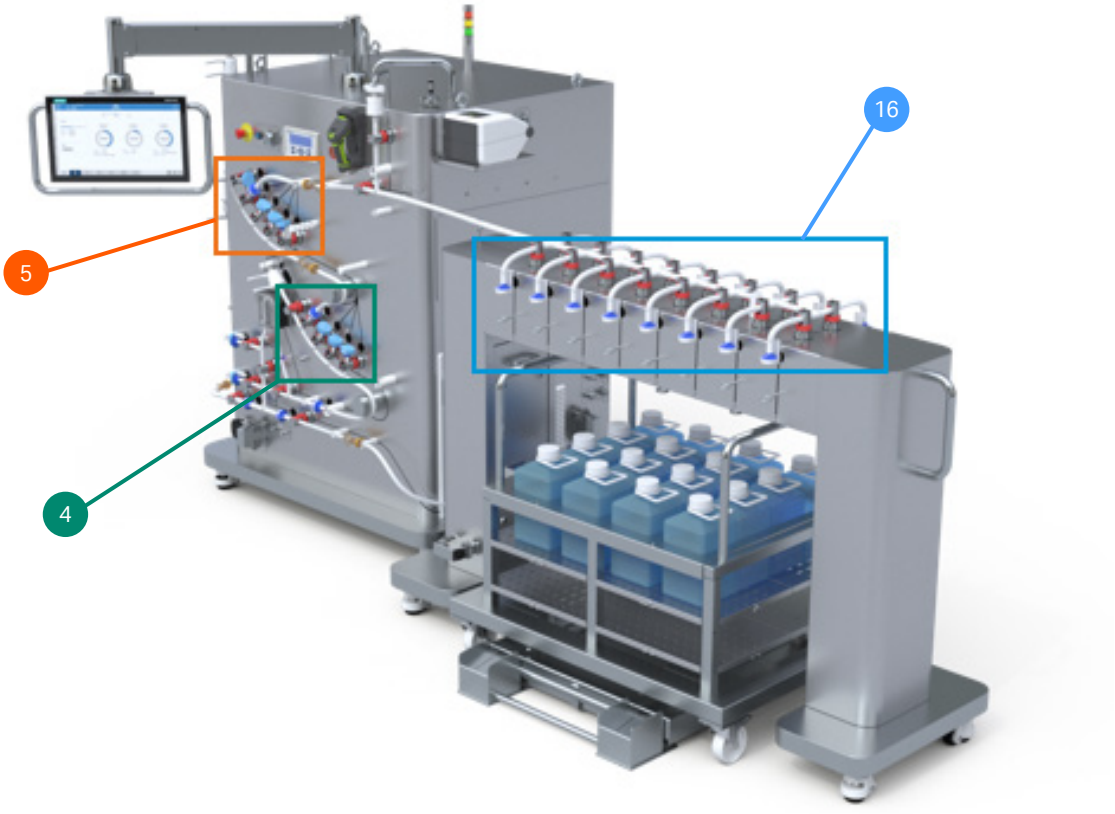


Fig 14. 4 × 5 × 16 filling 320 bottles [5].

[4] Applicable for 10 L and 20 L bottles with 12-bottles workstation (2 trolley + 2 scale). [5] Applicable for 1 L to 5 L bottles with 16-bottle workstation (1 trolley + 1 scale).

Automated manifold leak test and filter integrity test

Automatic leak testing and filter integrity testing completed by the integrated Palltronic Flowstar LGR integrity test instrument, with human machine interface (HMI) visualization of the test progress running from pressurization, stabilization, measurement, venting and results (Figure 15).

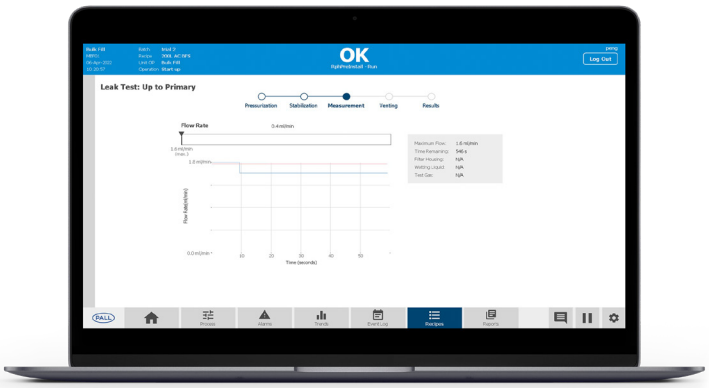


Fig 15. System leak test screen on HMI.

Configurable filtration options

Fig 16. No filtration.

Fig 17. Single filtration.

Fig 18. Serial filtration.

Fig 19. Parallel filtration.

Minimizing non-recoverable volumes of high-value products

Accuracy

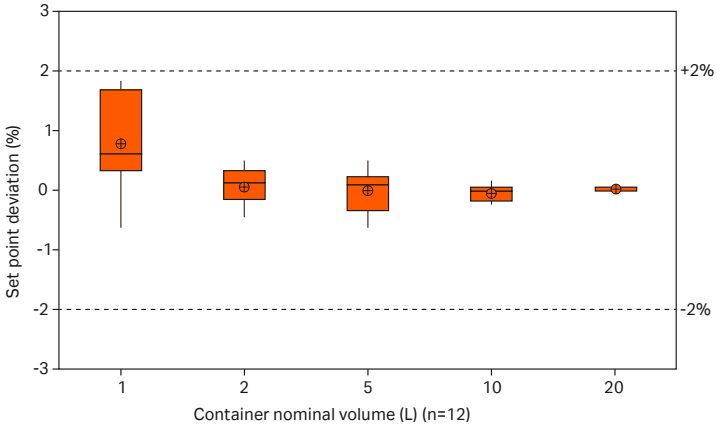


Fig 20. Filling accuracy over a range of container sizes.

Consistency

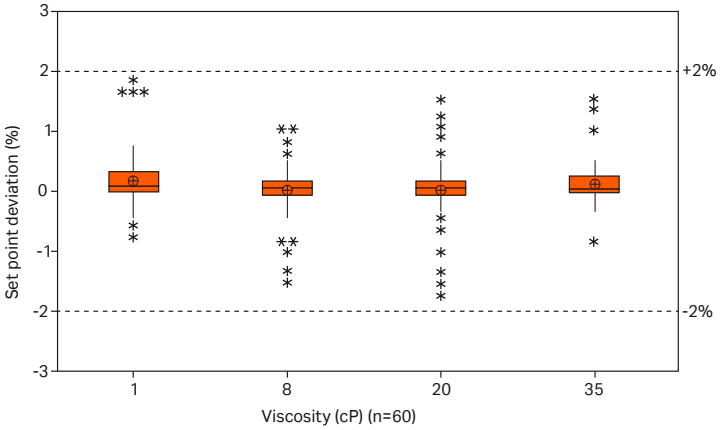


Fig 21. Filling accuracy over varied drug substance viscosity.

Biocontainers and bottles filled to 60% and 80% nominal volume, respectively. Figure 20 and 21 show the accuracy is within ± 2% of the target fill weight for all container sizes and various types of viscous feed stream.

A solution for all bulk filling scenarios

Reliability

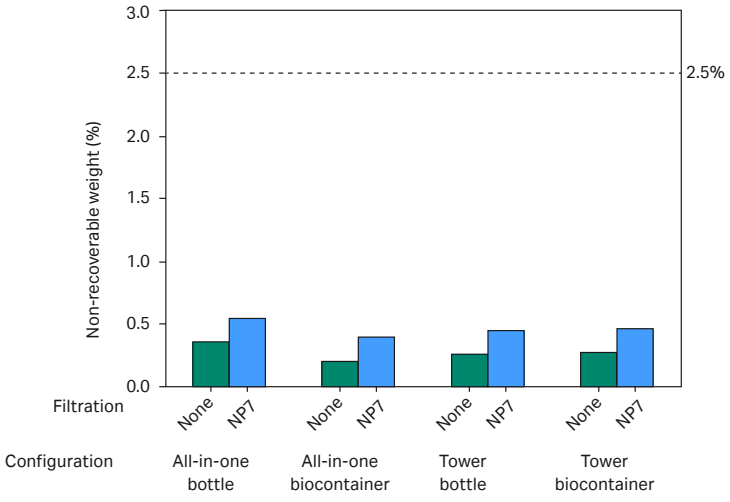


Fig 22. Non-recoverable product weight by hardware and filtration configuration.

Range

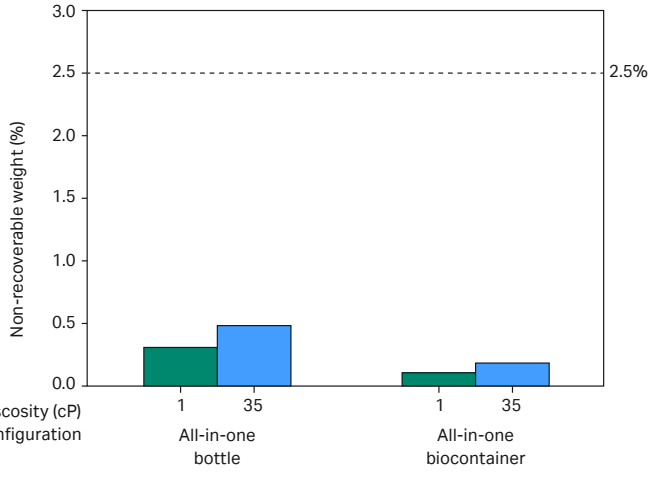


Fig 23. Non-recoverable product weight by drug substance viscosity.

Non-recoverable batch weight shown for a 200 L batch, filling 120 containers with each system set-up and feed type (Figure 22 and 23)

A no-filtration configuration was used unless otherwise specified. The non-recoverable volume stayed < 2.5% with different system configuration and with the best-case and worst-case viscosity feed stream (Figure 22 and 23).

Scale the equipment to meet your process needs

Maximizing productivity

The Allegro Connect bulk fill system utilizes single-use technology (SUT) to achieve faster turnaround times between product batches, eliminating the need for clean-in-place (CIP) and sterilization-in-place (SIP) operations and associated cleaning validation. This reduces maintenance cost and system downtime, helping with improved facility throughput.

The entire flow path is designed for easy installation and removal, with clearly marked connections and a shadow board to visibly guide the user and reduce the installation error (Figure 24 and 25).
Minimal hold-up-volume and optimized flow path design, ensures minimized non-recoverable volumes.

Increased assurance

The Allegro Connect bulk fill system is supported by a comprehensive validation package including:

- Sterile claim
- Extractables per BPOG
- Particulates requirement per USP <788> aligned with industry expectations (for data refer to regulatory dossier)

Consistency across different batches is achieved through automation and a recipe-driven approach. All batch data is recorded electronically to eliminate any transcription errors.

Fig 24. Shadow board concept on the Allegro Connect bulk fill system.

Fig 25. Shadow board visibly guides the user and reduces installation errors.

Designed for ease of use

The Allegro Connect bulk fill system has undergone extensive usability trials, to ensure the system is simple and intuitive to use.

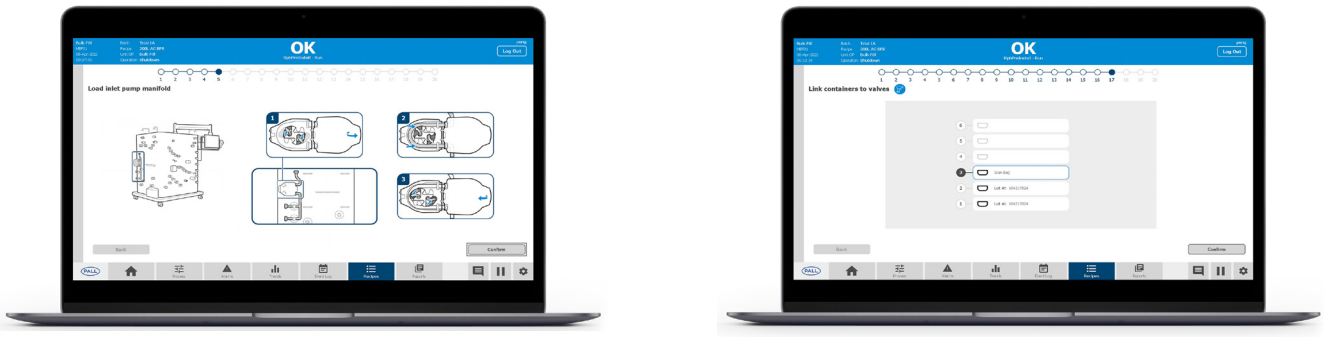


Fig 26. HMI screens showing example of guided installation instructions (left), and bulk containers assigned to valves (right).

Guided Instructions for Installation (IFI), where the operator is instructed by the recipe to perform the distribution manifold connection onto the correct valve (Figure 26).

The bulk containers can be assigned to respective valves with the help of the handheld scanner for seamless labeling post filling.

Fig 27. Product container labels printed out by system printer.

The product container labels are printed with the valve numbers shown in bold font, significantly reducing risk of human error (Figure 27).

A total bulk fill solution

The Allegro Connect bulk fill system can also be connected with some of our other single-use systems to provide a total bulk fill solution for your process, such as the LevMixer™ system or Allegro mixers as a feed tank and intermediate tank, and the Allegro buffer totes for buffer or water for injection (WFI) storage (Figure 28).

System options

The Allegro Connect bulk fill system is available with three types of automation options (Fig 29):

- PLC (Rockwell or Siemens) and HMI for local stand-alone control
- Remote I/O (no PLC) for integration into a DCS or SCADA system
- Remote I/O (no PLC) controlled by centralized PLC system

The automation architecture is based on either Siemens S7 PLC or Rockwell CompactLogix PLC, an industrial PC, and a 22 in. thin client which is applied across our range of Allegro Connect bioprocessing systems enabling a truly modular 'plug-and-play' concept, with the ability to control single or multiple unit operations from one centralized cabinet.

The Allegro Connect bulk fill system is compatible with our single-use mixing technology and can also be integrated with most mixing equipment from other suppliers.

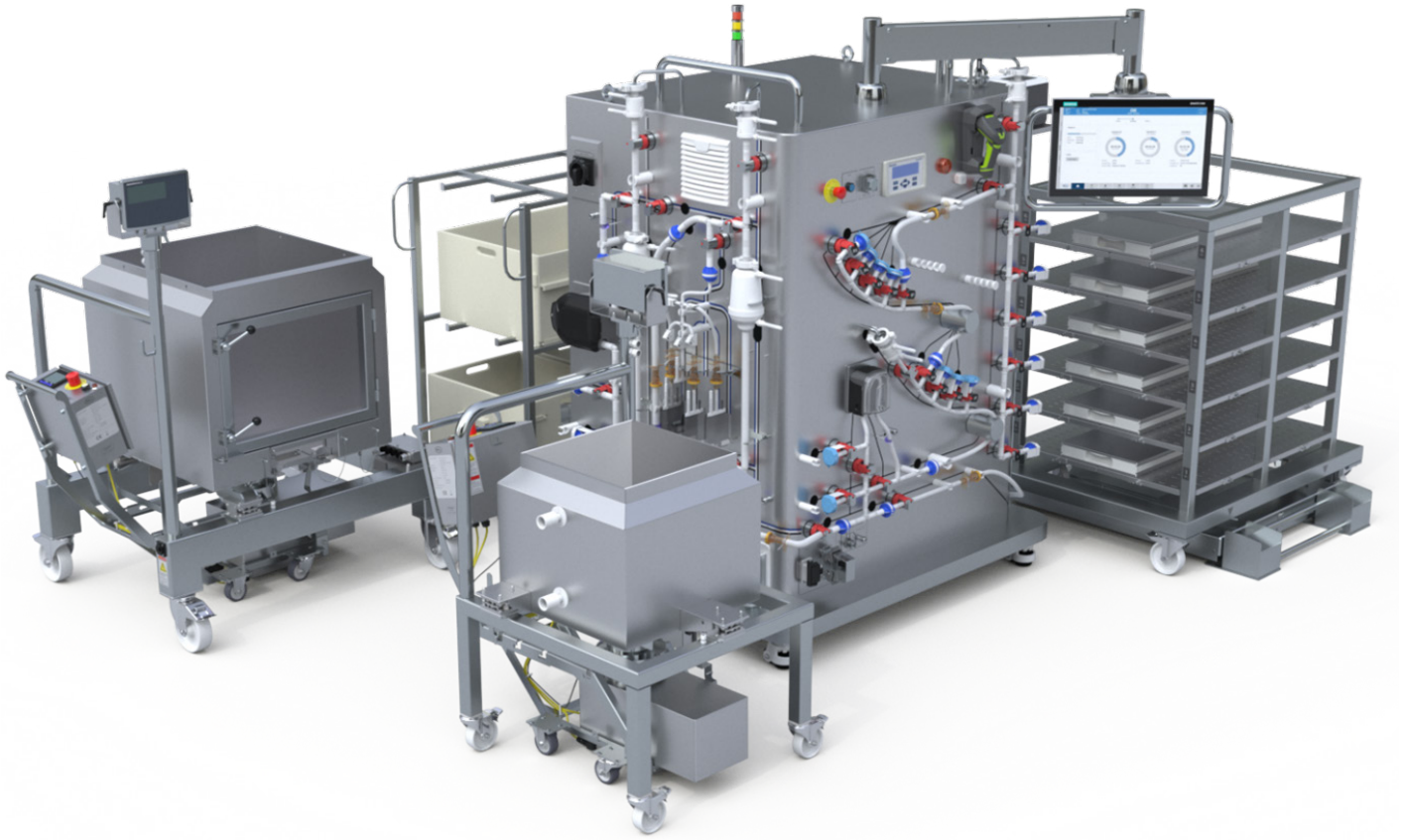


Fig 28. The Allegro Connect bulk fill system.

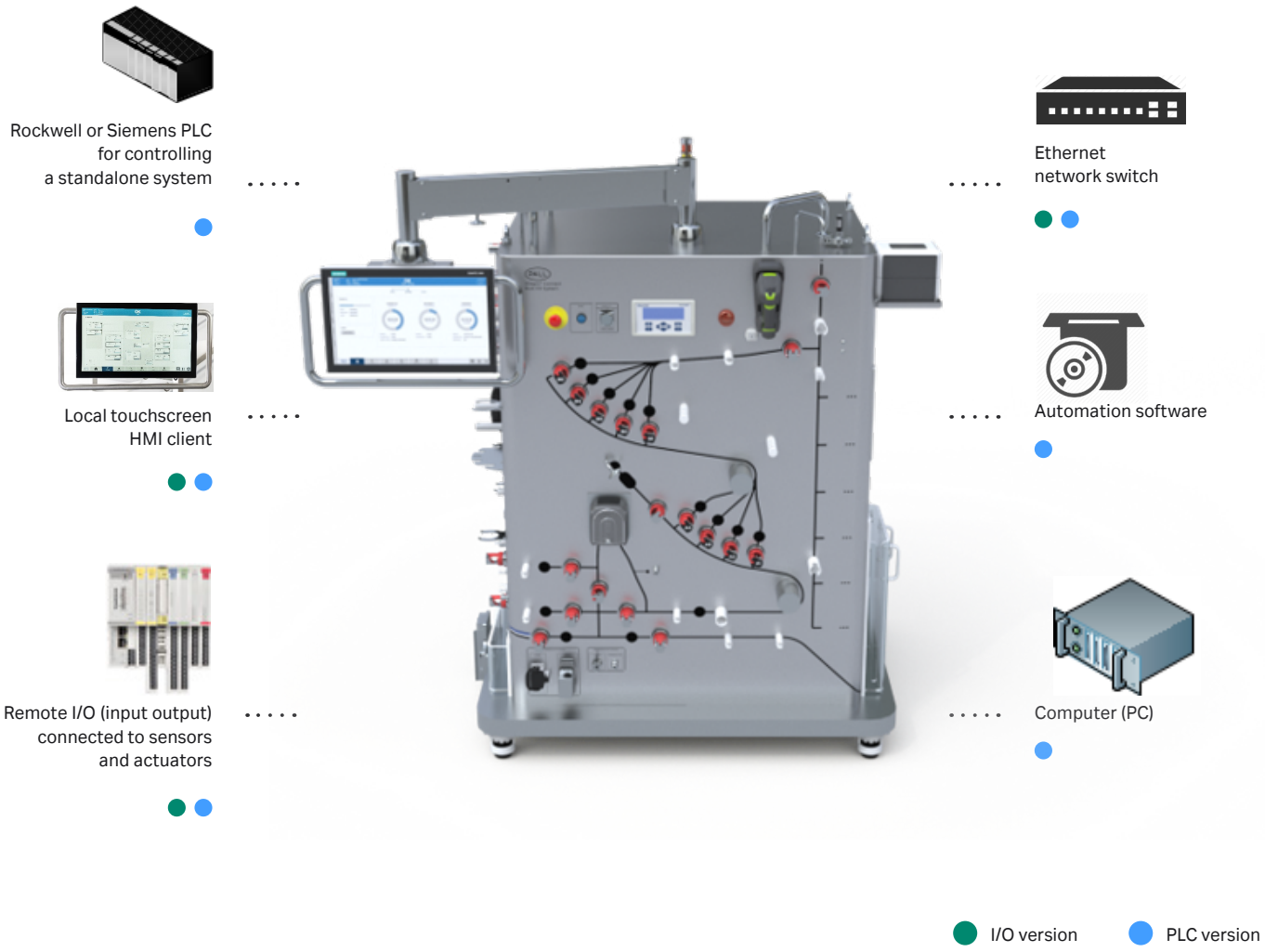


Fig 29. Automation options.

Quality standards

The Allegro Connect bulk fill system provides a detailed validation package for all configurations according to ASTM 2500 Standards (a standard guide for specification, design, and verification of pharmaceutical and biopharmaceutical manufacturing systems and equipment).

The regulatory dossier includes:

- Regulatory compliance ROHS I to ROHS III directives.
- Raw material compliance data (USP Standards).
- Packaging and packaging waste directive 94/62/EC.
- System designed in accordance with the American Society of Civil Engineers (ASCE), ASCE 7, Minimum Design Loads and Associated Criteria for Buildings and Other Structures.

The Allegro Connect automation platform enables compliance with 21 CFR Part 11 and follows the GAMP V life cycle for software development.

Technical specifications

Process specifications

Equipment	Specification
Functionality	Filtration and/or filling
Filtration configurations	No filter; single; serial or parallel/redundant
Minimum liquid filter capsule size	~ 25 mm (1 in.)
Maximum liquid filter capsule size	~ 508 mm (20 in.)
Number of pumps	2
Pump 1 flow rate range	0.15 to 8.5 L/min
Pump 2 flow rate range	0.12 to 3.5 L/min
Number of inlets	2 (1 × WFI/buffer and 1 × product)
Number of outlets	Filling: maximum of 16 active outlets, Waste: 2 process waste outlets
Container types to be filled	Biocontainers and/or bottles
Tube dimension	Combination of ¼ in. (bottle cap manifold, 1 L and 2 L biocontainers), ½ in. and 1 in. internal diameter (ID)
Flow path operating pressure	0 to 1.5 bar (0 to 22 psi)
Integrity test pressure [6]	Up to 5.7 bar (83 psi) for maximum exposure ≤10 hours
Flow path operating temperature range	4 to 40 °C
Pressure sensor	Up to 4 (1 after each pump with integrated pressure switch; 1 before and after each liquid filter)
External connections	9 (6 × weighing platforms, 2 × mixers, 1 × distribution tower)

[6] Acceptable pressure rating of the air filter

System specifications

System	Specification
Main system dimensions [7] (W × D × H)	142 × 122 × 199 cm (56 × 48 × 78 in.)
Main system mass (empty)	750 kg (1654 lb)
12-biocontainer bag workstation dimensions (W × D × H)	120 × 90 × 128 cm (47 × 35 × 50 in.)
12-biocontainer bag workstation weight (empty)	165 kg (363 lb)
16-biocontainer bag workstation dimensions (W × D × H)	120 × 90 × 160 cm (47 × 35 × 63 in.)
16-biocontainer bag workstation weight (empty)	220 kg (485 lb)
Bottle workstation dimensions (W × D × H)	120 × 90 × 103 cm (47 × 35 × 40 in.)
Bottle workstation weight (empty)	100 kg (221 lb)
Biocontainer bag distribution tower dimensions (W × D × H)	80 × 70 × 200 cm (31 × 27 × 79 in.)
Biocontainer bag distribution tower weight (empty)	440 kg (970 lb)
Bottle distribution tower dimensions (W × D × H)	210 × 70 × 133 cm (83 × 27 × 52 in.)
Bottle distribution tower weight (empty)	350 kg (772 lb)
Main system floor clearance	115 mm (4.5 in.)
Environmental conditions	5 to 30 °C, relative humidity 10 to 70% (non-condensing)
Materials of construction	Stainless steel 304
Surface finish	Cold rolled steel (typically Ra < 1 µm)
Ingress protection rating	IP54 (main, outer panel or chassis)

[7] Main system dimensions exclude the weighing platform. Weighing platform forms part of workstation dimensions.

Utility specifications

Utilities	Specification
Electrical supply	230 VAC – 50 Hz (European), 208 VAC – 60 Hz (North American)
Operating voltage control	24 VDC – 20 A
Ingress protection for internal electrical cabinets	IP 56 (European), NEMA 4x (North American)
Recommended FI switch	RCD 30 mA, Type B
Power consumption	≤ 2.4 kVA
Amperage	10 A
Motor power	300 W (Primary pump), 140 W (Secondary pump)
Process air	Minimum pressure = highest integrity/leak test pressure + 1 bar , Maximum pressure = 10 bar, manual pressure regulator, pressure safety valve and Palltronic Flowstar LGR integrity test instrument
Instrument air	6 bar minimum, 10 bar maximum, 40 m^3/h minimum flow rate, instrument air, clean, dry and oil free, pressure reducer and ON/OFF valve

Component specifications

Component specifications, and sensor range and accuracies are as per OEM datasheets and correct at the time of compiling this proposal. We do not accept any responsibility in the case of deviation from the specifications outlined below.

Process equipment	Type	Specification
Primary pump	Watson-Marlow 620R pump head	Flow: 0.15 to 8.5 L/min
Secondary pump	Watson Marlow Drivesure 520R2	Flow: 0.12 to 3.5 L/min
Process valves	Gemü Q30	Pneumatically operated pinch valve
Pressure	PendoTECH – single-use sensor with pressure sensitivity chip	Range: -0.48 to 5.2 bar Accuracy: ± 2% from 0 to 0.41 bar, ± 3% from 0.41 to 2.07 bar, ± 5% from 2.07 to 4.1 bar
Level detector	Rechner – capacitive sensor	Operating distance: 0.5 mm (min.), – 15 mm (max.)
Recovery tote	Plastic tray to support 5 L 2D biocontainer	High density polyethylene (HDPE)
Printer	Zebra ZD420c – HC	Thermal transfer, 203 dpi, 15 to 108 mm label width
Handheld scanner	Zebra DS3678-HD3RF50BS1W	Wireless, Bluetooth Class 1, image sensor 1280 × 800 pixels
Weighing platform	Mettler Toledo PFK989 C600 Floor Platform	600 kg (max. capacity), recommended readability 1 g Accuracy: ± 0.5% at 1 kg [8], ± 0.001% at 600 kg
Integrity test instrument	Palltronic Flowstar LGR integrity test instrument	Forward flow test: 0.1 to 1000 mL/ min., ± 3% of value or ± 0.05 mL/min, whichever is the greater

Recommended process equipment and fittings

Process equipment	Recommendation
Product inlet mixer	LevMixer stainless steel cubical tank (ASME available upon request)
Product inlet mixer drive	LevMixer drive unit IV (LMG403)
Buffer flush feed tote	Allegro 100 L HDPE tote
Buffer flush waste tote	Allegro 50 L plastic 3D tote
Bioprocessing workstation	Allegro bioprocessing workstation (LGRTTBSC)
Intermediate mixer	Allegro 50 L standard mixer and weigh platform

[8] Please note that the container workstation is ≥ 100 kg

Automation specification

The system is equipped with Wonderware® batch management and Wonderware system platform, which enables you to create recipes based on your individual process needs. Recipes are created using operations that are comprised of predefined phases. Each phase is configured to allow you to tailor the recipes as per your requirements.

The system also provides flexible phases, that allow for a fully manual creation of recipes.

Automation architecture is based on either Siemens S7 PLC or Rockwell CompactLogix PLC, an industrial PC, and a 22 in. touch screen HMI.

The automation platform allows the end user to create an unlimited number of recipes.

An OPC UA client is installed if a communication link is desired with the unit operation. The automation platform enables compliance with 21 CFR Part 11 and follows the GAMP V life cycle for software development.

Automation options

- PLC (Rockwell or Siemens) and HMI for local stand-alone control
- Remote I/O (no PLC) for integration into a DCS o SCADA system
- Remote I/O (no PLC) controlled by centralized PLC system

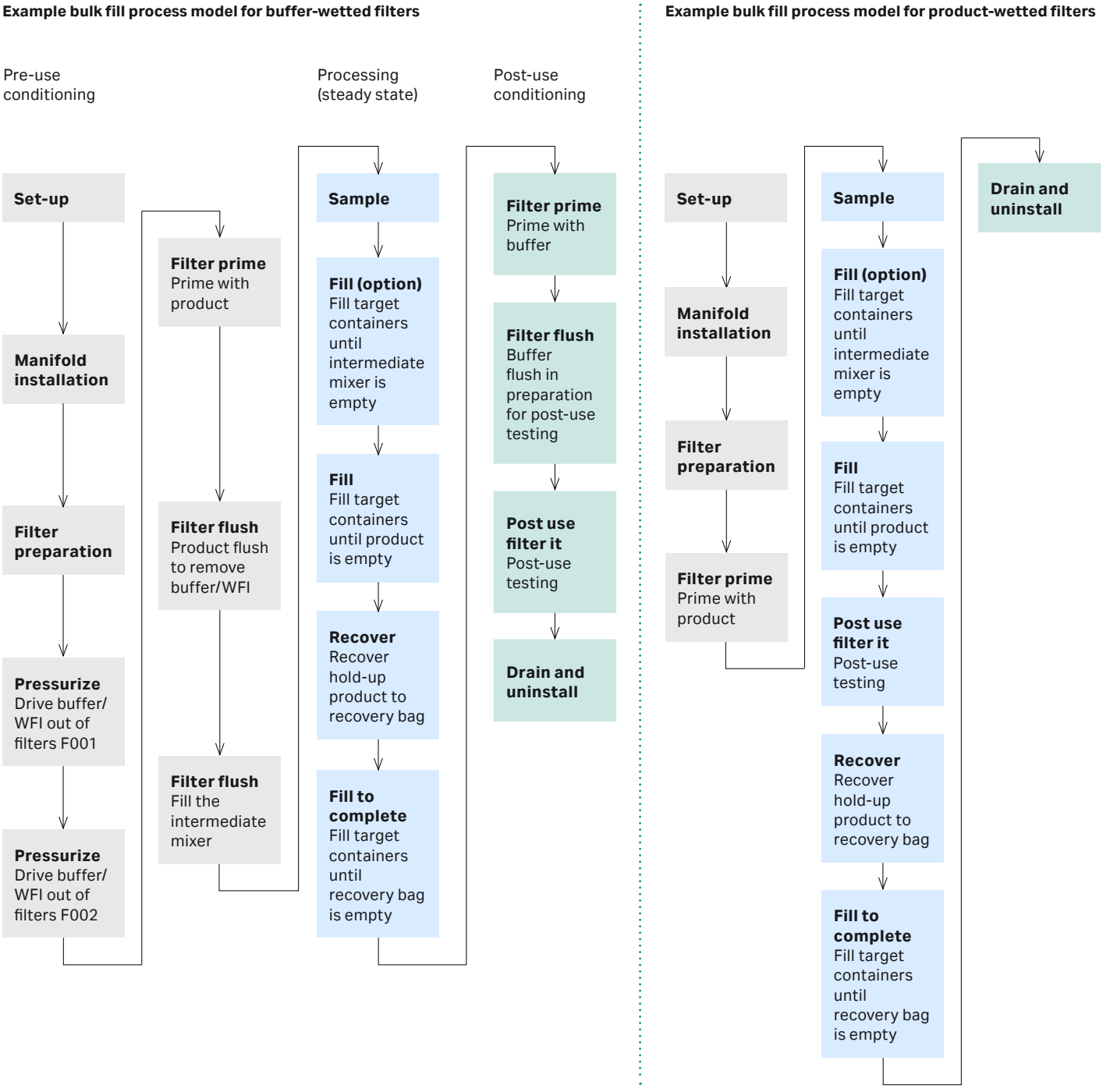
Automation hardware specification [9]

Utilities	Specification
PLC vendor (option 1)	Siemens
PLC model (option 1)	SIMATIC® S7-1500, CPU 1516-3 PN/DP
PLC software (option 1)	Siemens TIA V16
PLC vendor (option 2)	Rockwell
PLC model (option 2)	5069-L380ERM
PLC software (option 2)	Rockwell Studio 5000 V32
Database	SQL Server
Operating system	Windows server 2016
Batch engine	Wonderware batch management
Historian	Wonderware historian
Reporting	Dream Reports / Wonderware system platform
HMI	SIMATIC ITC2200 V3 PRO, industrial thin client, 22
Panel PC	INDUSTRY PC Stratus ztC Edge 200i
UPS	QUINT-UPS/ 24DC
Remote I/O	Turck BL20 series
Ethernet switches	Phoenix Contact 8 port (managed switch)
OPC server	ArchestrA Client

[9] Technical equivalent replacements are possible depending on market availability, refer to the Turnover Package (TOP) documentation for Allegro Connect systems.

Process sequence

The chart below shows the separate process operations and process actions of the standard bulk fill process. Configurable phases are provided to cover these process steps. Examples are shown for both buffer and product-wet filter testing scenarios:



Additional phases which may be used to build custom recipes:

Distribution installation	Intermediate manifold installation	Manifold prime	SU test	Intermediate setup
(Un-) Installation of secondary multiplier/distribution manifolds	Distribution installation and testing of newly installed components	Prime multipliers and distribution manifold	Perform testing with Palltronic Flowstar integrity test instrument with multiple attempts	Change fill parameters during recipe

Key:

Descriptive phase name

Process description and/or configuration

Fig 30. Bulk fill process for buffer- and product-wetted filters.

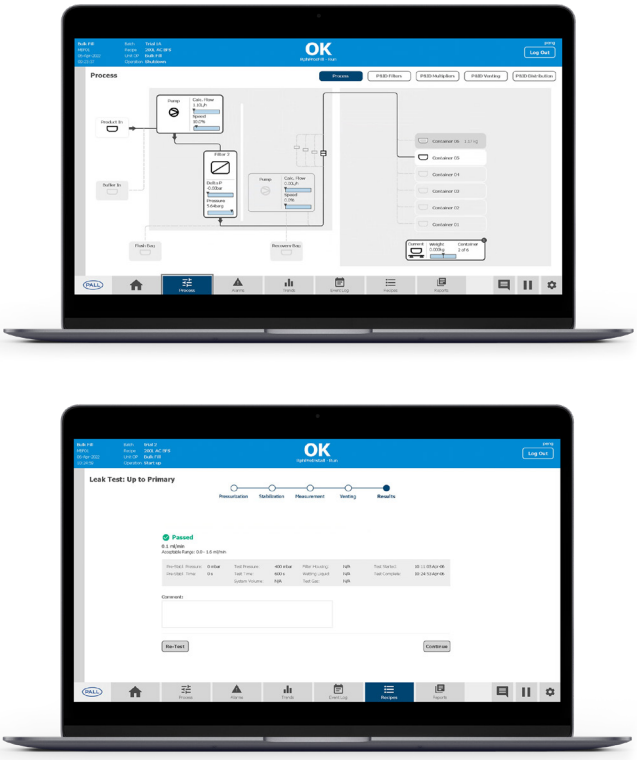
Instructions for installation screens

The IFI have been created and are accessible via the HMI screen, providing you with a step-by-step guide to installing the single-use flow paths and making the relevant fluid connections. Sample IFI screens can be seen in Figure 31:

Fig 31. Typical IFI (left) and process (right) screens on HMI.

Process screens

Process screens have been created to summarize and expand on critical process information throughout the operation. The Palltronic Flowstar LGR integrity test instrument will also be controlled via the system HMI when performing filter integrity testing and/or pre-use manifold leak testing – sample screens of this procedure are also shown below.



Batch report

Upon operator selection, batch reports will be generated automatically at the end of a batch for each single step. Both a summary and detailed batch report is generated, and the content of these batch reports is predefined. Batch reports can be configured to specific needs by the end user via Wonderware Dream Reports. Sample batch reports can be provided upon request.

Predefined batch records contain the following major information:

- General batch information, phase information and transition conditions
- Global and recipe parameters including controller configuration
- Audit trails excerpt
- Alarms summary
- List of single-use manifold details that were registered during recipe execution
- Sample container list (including sample weight)
- Filled container list (including product weight)
- Trends for differential pressure across filters
- Trends for input weights
- Trends for filling weights

Ordering information

Main system

Allegro Connect bulk fill system can be provided with PLC or I/O, and with software automation or no automation. Seismic leveling feet are available for the system, biocontainer bag tower and bottle tower.

Factory acceptance test (FAT)

FAT for Allegro Connect bulk fill system is available as 2.5 days or 5 days for extended FAT.

Contact your Cytiva sales representative for more information or for UL61010 certification requirement.

Ordering guide suggestion for system hardware

Fig 32. All-in-one biocontainers.

Fig 33. All-in-one bottles.

Fig 34. Tower biocontainers

Fig 35. Tower bottles.

Fig 36. All-in-one hybrid (biocontainers and bottles)*

* Towers can also be used with hybrid system

Ordering steps

Step 1: choose the central unit (with or without automation) [11]

Central bulk fill unit for CE region with automation	Central bulk fill unit for CE region without automation	Central bulk fill unit for UL region with automation	Central bulk fill unit for UL region without automation
ACBFSCEPLC	ACBFSCEIO	ACBFSULPLC	ACBFSULIO

[11] 1 × label roll and 1 × printer cartridge are included with the system. For additional quantity please place the order with Codeway Ltd (England) for vendor P/N: 8000T CryoCool (labels) and 4800 Resin (cartridge).

Step 2: choose the system configuration for biocontainers/bottles/hybrid based on container size and number of fills

All-in-one biocontainer(s) for 1 to 20 L container size up to 120 fills	All-in-one bottle for 1 to 20 L container size up to 120 fills	All-in-one hybrid (biocontainer(s) and bottle) for 1 to 20 L container size up to 120 fills	Bottle distribution tower for 1 to 5 L container size from 121 to 320 fills
ACBFSBCREXT	ACBFSBTLEXT	ACBFSBCREXT and ACBFSBTLEXT	ACBFSBTLTWRCE/ ACBFSBTLTWRUL
ACBFSPFK9C600	ACBFSPFK9C600	ACBFSPFK9C600	ACBFSPFK9C600
ACBFS12BCRWKSN	ACBFSBTLWKSN [12]	ACBFS12BCRWKSN and ACBFSBTLWKSN [12]	ACBFSBTLWKSN [12]
Bottle distribution tower for 10 L and 20 L container size from 121 to 240 fills	**Biocontainer(s) distribution tower for 1 to 5 L container size from 121 to 320 fills**	**Biocontainer(s) distribution tower for 10 L and 20 L container size from 121 to 320 fills**	
ACBFSBTLTWRCE/ ACBFSBTLTWRUL	ACBFSBCRTWRCE/ ACBFSBCRTWRUL	ACBFSBCRTWRCE/ ACBFSBCRTWRUL	
2 × ACBFSPFK9C600	ACBFSPFK9C600	2 × ACBFSPFK9C600	
2 × ACBFSBTLWKSN [12]	ACBFS16BCRWKSN [12]	2 × ACBFS16BCRWKSN [12]	

[12] Proceed to step 2A to choose complementary trays/inlays. Step 2A and Step 3 are only applicable for bottle filling configuration.

Step 2A: choose 2 complementary single bottle trays (inlays) or 1 complementary dual bottle tray/inlay for each ACBFSBTLWKSN depending on the size of the bottles used in the process

Available sizes	Product code	Available sizes	Product code
Single bottle tray/inlay		Dual bottle tray/inlay	
6 × 1 L	ACBFS1LSQTRAY6	16 × 5 L	ACBFS5LSQTRAY16
6 × 2 L	ACBFS2LSQTRAY6	12 × 10 L	ACBFS10LSQTRAY12
6 × 5 L	ACBFS5LSQTRAY6	12 × 20 L	ACBFS20LSQTRAY12
6 × 10 L	ACBFS10LSQTRAY6	N/A	N/A
6 × 20 L	ACBFS20LSQTRAY6	N/A	N/A
16 × 1 L	ACBFS1LSQTRAY16	N/A	N/A
16 × 2 L	ACBFS2LSQTRAY16	N/A	N/A

Step 3 (optional): choose additional bottle trays/inlays as required

Available sizes	Product code	Available sizes	Product code
Single bottle tray/inlay		Dual bottle tray/inlay	
6 × 1 L	ACBFS1LSQTRAY6	16 × 5 L	ACBFS5LSQTRAY16
6 × 2 L	ACBFS2LSQTRAY6	12 × 10 L	ACBFS10LSQTRAY12
6 × 5 L	ACBFS5LSQTRAY6	12 × 20 L	ACBFS20LSQTRAY12
6 × 10 L	ACBFS10LSQTRAY6	N/A	N/A
6 × 20 L	ACBFS20LSQTRAY6	N/A	N/A
16 × 1 L	ACBFS1LSQTRAY16	N/A	N/A
16 × 2 L	ACBFS2LSQTRAY16	N/A	N/A

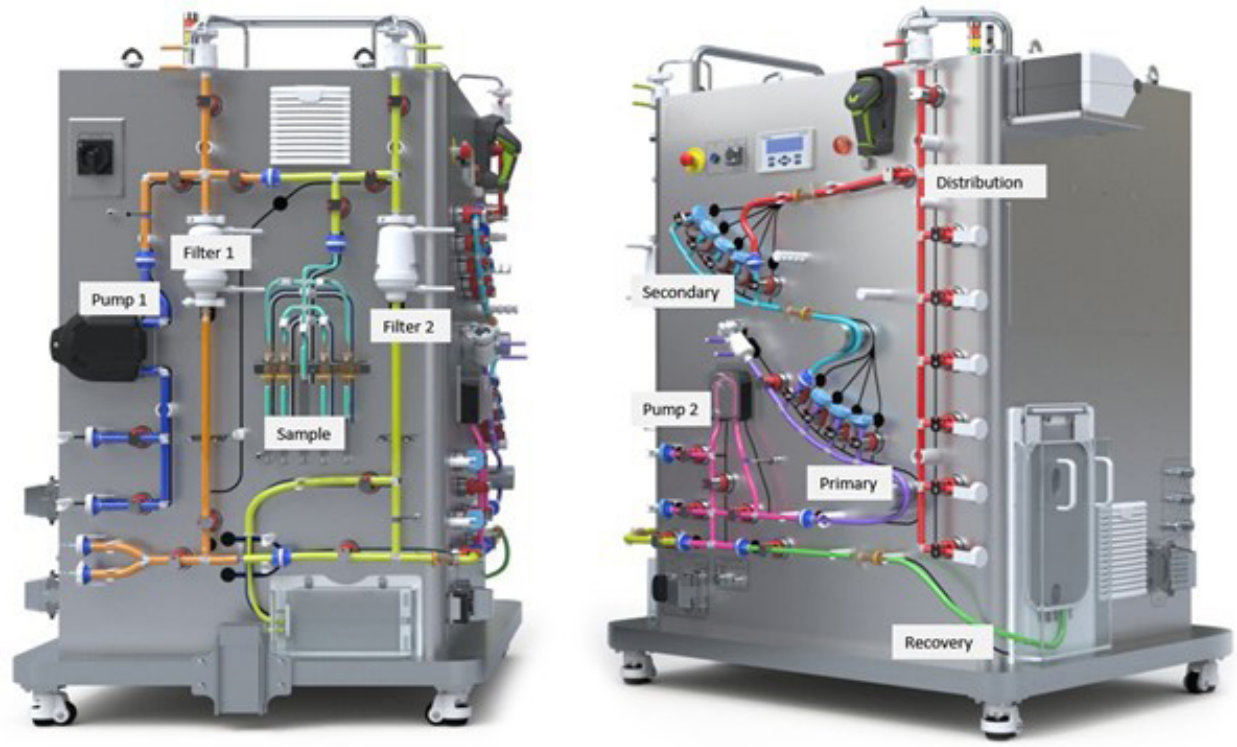


Fig 37. Schematics showing location of the manifold types.

Product code matrix

The flow path selection table shown below lists the standard product codes of the our products designed and approved to support the Allegro Connect bulk fill system. Due to the configurability of the system enabling numerous combinations of the filter capsules (membrane and size), we are only able to list a limited number of the possible filtration assemblies in the table below. Filtration combination sets, which do not appear in this table but are within the scope of the system, are available from us, on request.

Flow path selection	Product	Product code
Step 1: choose pump 1 manifold		
Pump 1	Pump 1 manifold with Kleenpak™ Presto sterile connector	9496-1356Z
Step 2: choose what type of filtration manifold is required for the process		
No filtration		
Bypass manifold	Filter interlink manifold with Kleenpak Presto sterile connector	9496-1579R
Sampling manifold	Sampling manifold with 4 × 50 mL biocontainers	9496-1376Z
	Serial 2 manifold with no filter	9496-1579S
Single filtration (select bypass and sampling manifold. Select a serial 2 filter)		
Bypass manifold	Filter interlink manifold with Kleenpak Presto sterile connector	9496-1579R
Sampling manifold	Sampling manifold with 4 × 50 mL biocontainers	9496-1376Z
	Serial 2 manifold with KA1EKVP16G filter	9496-1572T
	Serial 2 manifold with NP1LUECVP1G filter	9496-1553W
	Serial 2 manifold with NP5LUECVP16G filter	9496-1561U
	Serial 2 manifold with NP6UECVP1G filter	9496-1579K
	Serial 2 manifold with NP7EKVP16G filter	9496-1358F
	Serial 2 manifold with NP7UECVP1G filter	9496-1581F
	Serial 2 manifold with KA02EKVP1G filter	9496-1800S
	Serial 2 manifold with KA3EKVP16G filter	9496-1785E
Serial filtration (select sampling manifold. Select a serial 1 and serial 2 combination)		
Sampling manifold	Sampling manifold with 4 × 50 mL biocontainers	9496-1376Z
	Serial 1 manifold with KA1EKVP16G filter	9496-1558Q
	Serial 2 manifold with KA1EKVP16G filter	9496-1572T
	Serial 1 manifold with KA3EAVP1G filter	9496-1519F
	Serial 2 manifold with NP1LUECVP1G filter	9496-1553W
	Serial 1 manifold with NP5LUEAVP1G filter	9496-1557E
	Serial 2 manifold with NP5LUECVP16G filter	9496-1561U
	Serial 1 manifold with NP6UEAVP6G filter	9496-1579J
	Serial 2 manifold with NP6UECVP1G filter	9496-1579K
	Serial 1 manifold with NP7UEAVP1G filter	9496-1357E
	Serial 2 manifold with NP7EKVP16G filter	9496-1358F
Parallel filtration (select sampling manifold. Select a parallel 1 and parallel 2 combination)		
Sampling manifold	Sampling manifold with 4 × 50 mL bags	9496-1376Z
	Parallel 1 manifold with KA1EKVP16G filter	9496-1574M
	Parallel 2 manifold with KA1EKVP16G filter	9496-1574P
	Parallel 1 manifold with NP5LUECVP16G filter	9496-1560Z
	Parallel 2 manifold with NP5LUECVP16G filter	9496-1560Y
	Parallel 1 manifold with NP6EKVP6G filter	9496-1579M
	Parallel 2 manifold with NP6EKVP6G filter	9496-1579N
	Parallel 1 manifold with NP7UECVP1G filter	9496-1581H
	Parallel 2 manifold with NP7UECVP1G filter	9496-1581G
	Parallel 1 manifold with NP7EKVP16G filter	9496-1358G
	Parallel 2 manifold with NP7EKVP16G filter	9496-1513S

Step 3: choose pump 2, recovery and multiplier manifolds

Pump 2	Pump 2 intermediate mixer manifold	9496-1362T
Primary	Primary multiplier manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	9496-1577Z
Secondary (if required) [13]	Secondary multiplier manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	9496-1578B
Recovery bag	Recovery bag manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	9496-1402Z

[13] quantity of secondary multiplier manifold varies based on number of containers to be filled

Step 4: choose distribution manifolds (quantity of distribution manifold varies based on number of containers to be filled)

Biocontainer bag distribution ('all-in-one')	6 × biocontainer bag distribution manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	9496-1579F
Bottle distribution ('all-in-one')	6 × bottle distribution manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	9496-1519E
Biocontainer bag tower distribution (≤ 5L)	16 × biocontainer bag distribution manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	9496-1579G
Biocontainer bag tower distribution (> 5L)	12 × biocontainer bag distribution manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	9496-1579T
Bottle tower distribution (≤ 5L) [14]	16 × bottle distribution manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	9496-1513T
Bottle tower distribution (> 5L)	12 × bottle distribution manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	9496-1519D

[14] Manifold can be used for 16 × filling with 10 L and 20 L biocontainers when additional weighing scale and 16-biocontainer bag workstation is used.

Step 5: choose storage biocontainer(s) or bottle cap manifold (quantity of storage containers varies based on the number of containers to be filled)

Biocontainer(s)		
	1 L storage bag manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	7190-1561S
	2 L storage bag manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	7190-1561W
	5 L storage bag manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	7190-1561X
	10 L storage bag manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	7190-1561T
	20 L storage bag manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	7190-1571R
Bottle cap		
Bottle cap manifold for tower	Bottle cap manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector (for tower)	7496-1579U
Bottle cap manifold for all-in-one	All-in-one bottle cap manifold with Kleenpak Presto sterile connector and Kleenpak sterile disconnector	7496-1671Y

In order to reduce our carbon footprint, we strive to provide single-use systems manufactured regionally. However, to ensure security of supply you may receive product from multiple global sites.

cytiva.com

For local office contact information, visit cytiva.com/contact

CY38191-27Nov23-DF