



Asahi Kasei Bioprocess: Advanced Filter Technologies for Bioprocessing Applications

November 25, 2025

Val Brubaker

1. Corporate & Business Overview
2. Planova Virus Removal Filters
3. BioOptimal Microfilters
4. Summary & Q&A

Corporate & Business Overview

Asahi Kasei Corporation

Corporate profile

Trade name Asahi Kasei Corp.

Founding May 25, 1922

Head Office Tokyo, Japan

Paid-in capital ¥103,389 million

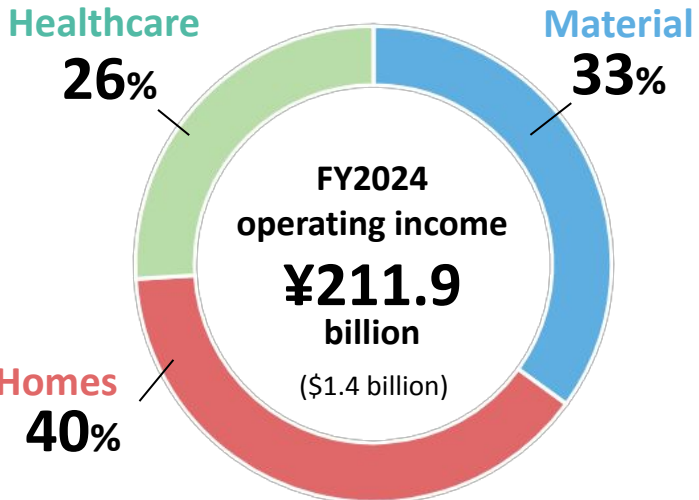
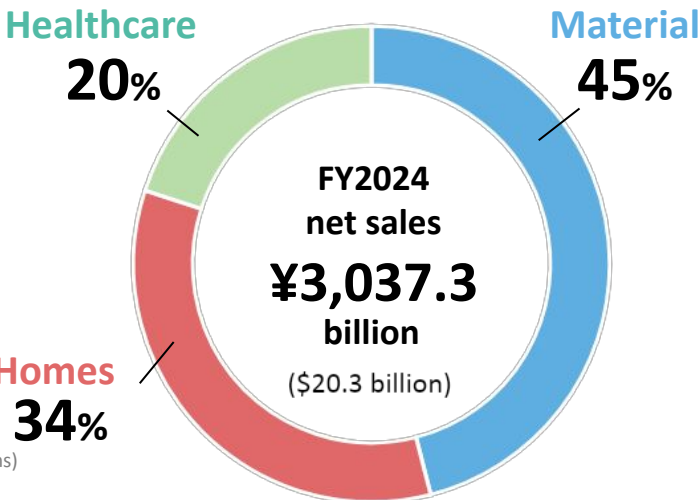
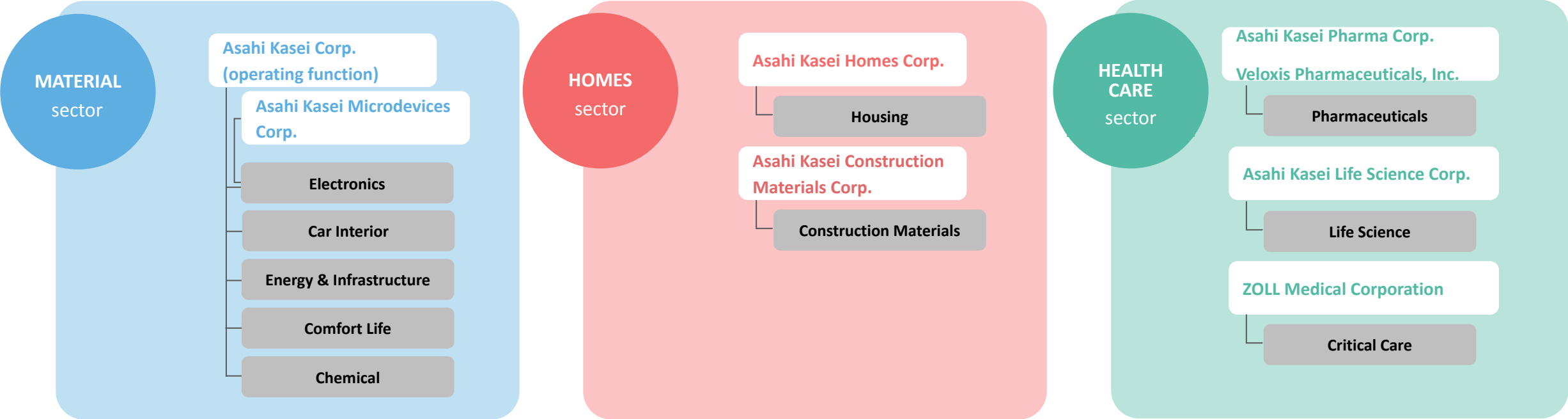
Employees 50,352

(consolidated, as of March 31, 2025)



AsahiKASEI

Asahi Kasei Corp. (Holding company function)



(Percentages excluding corporate expenses and eliminations)

Material sector

Homes sector

Healthcare sector

AsahiKASEI
BIOPROCESS

Electronics

Asahi Kasei Corp.,
Asahi Kasei Microdevices

Product Electronic devices,
Electronic materials, LED etc.

Car Interior

Asahi Kasei Corp.,

Product Artificial suede, etc.

Energy & Infrastructure

Asahi Kasei Corp.,

Product Water treatment membranes,
ion-exchange membrane
chlor-alkali process separators,
etc.

Comfort Life

Asahi Kasei Corp.,

Product Kitchen & household products,
photosensitive materials, fibers,
additives, clads & anchors, etc.

Chemical

(Performance Chemical, Essential Chemical)

Asahi Kasei Corp.,

Product Basic chemicals, monomers,
polymers, synthetic rubber,
elastomers, foamed products,
performance polymers, etc.

Housing

Asahi Kasei Homes

Product Unit homes, apartment buildings, condominiums,
residential land development, etc.

Construction Materials

Asahi Kasei Construction Materials

Product Autoclaved aerated concrete (AAC), thermal insulation,
foundation systems, structural systems and components, etc.

Pharmaceuticals

Asahi Kasei Pharma,
Veloxis Pharmaceuticals

Product Prescription drugs, diagnostic
reagents, etc.

Life Science

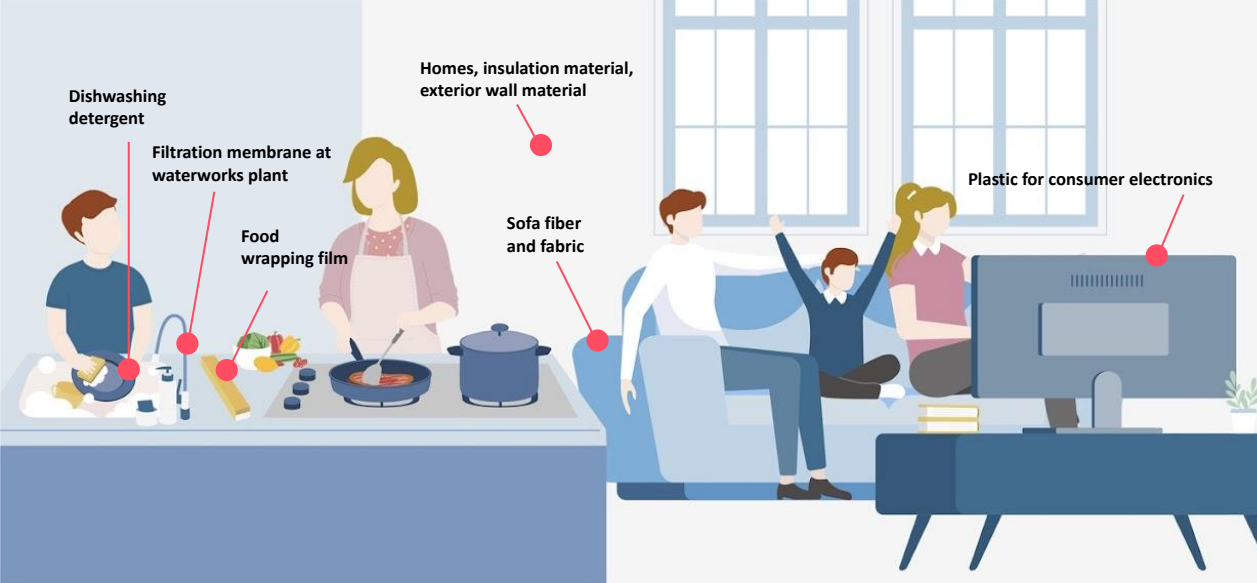
Asahi Kasei Life Science

Product Bioprocess products and services,
etc.

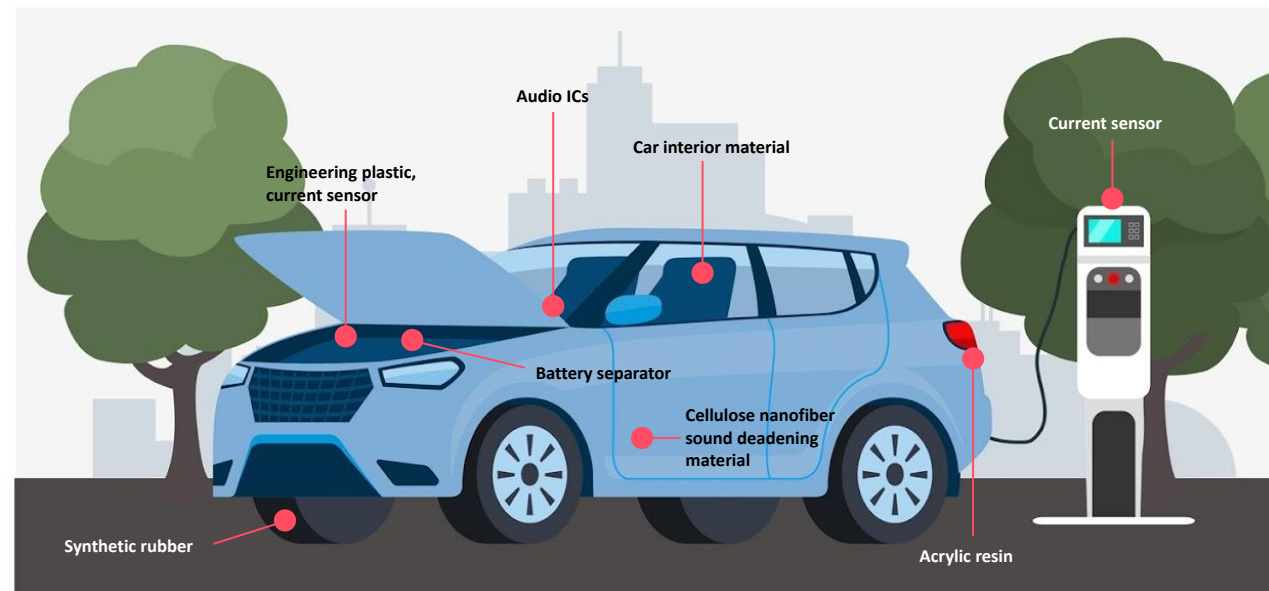
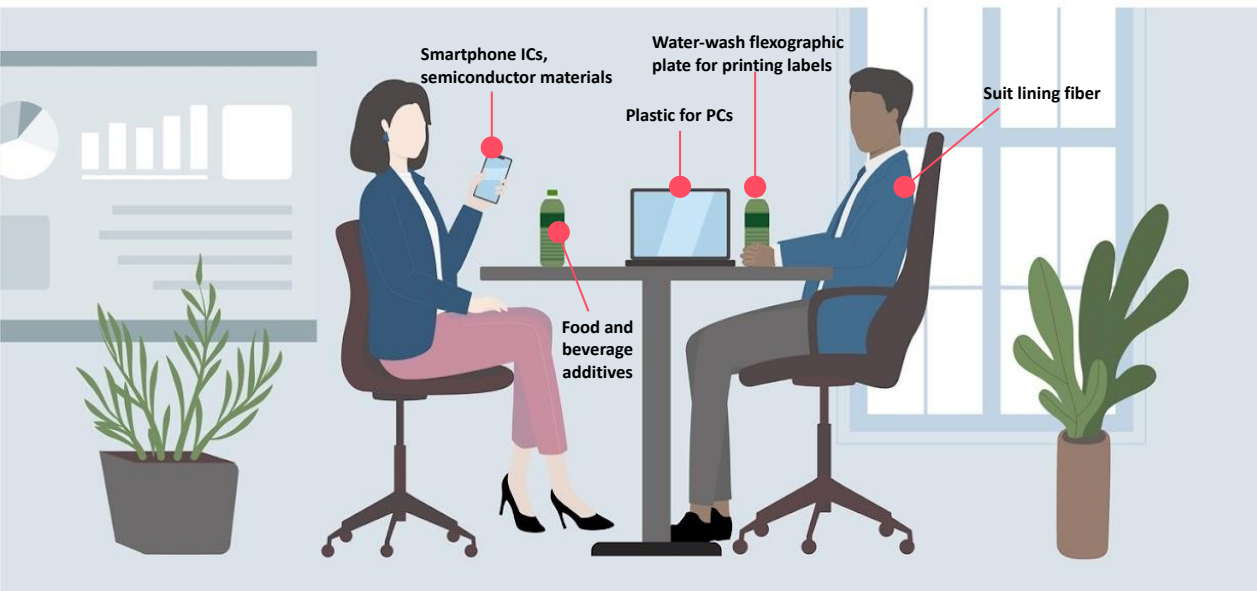
Critical Care

ZOLL

Product Defibrillators, ventilators, home
sleep apnea test, etc.



Asahi Kasei products and technologies that support life and living



Asahi Kasei Bioprocess

PURIFICATION PLANOVA™



Virus Removal Filters
Assurance Beyond Expectation™

BioOptimal™ MF-SL



Microfilters

FLUID MANAGEMENT



THESIS™
Oligonucleotide
Synthesis



MOTIV™
Inline Buffer
Formulation



CURSIV™
Chromatography



VANTIV™
Bioprocess Filtration

Built For You™

BIOSAFETY TESTING SERVICES



Virus/Prion Clearance Studies



Mycoplasma Testing Services

Quality is no coincidence

BIOLOGICS DEVELOPMENT & MANUFACTURING



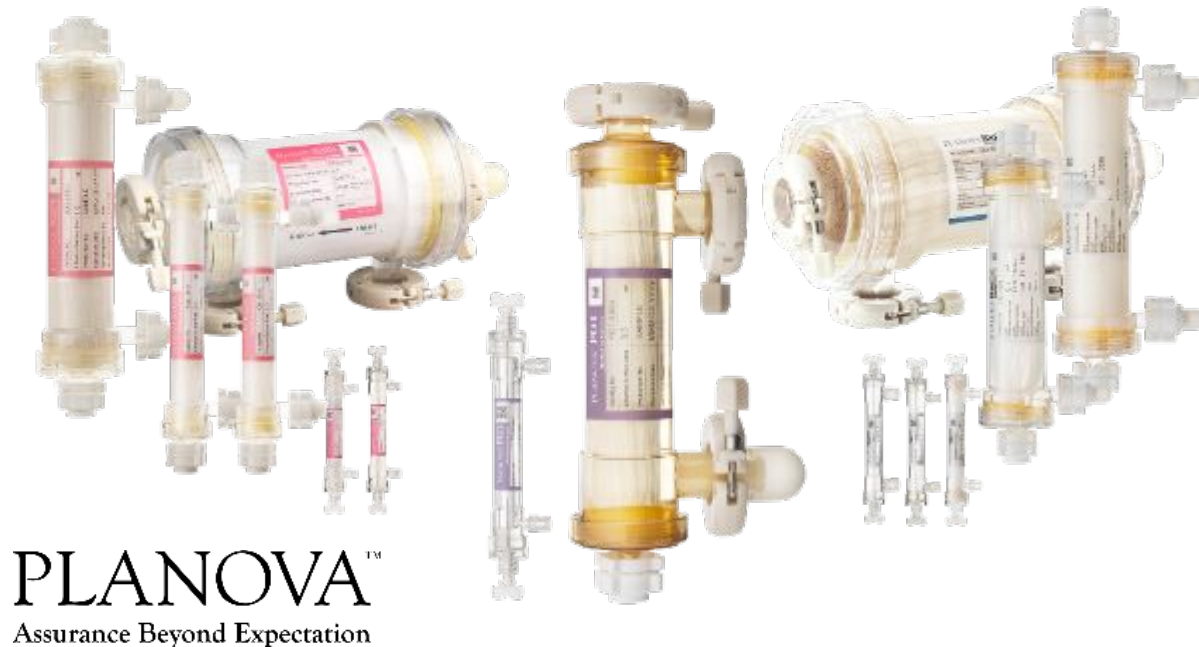
End-to-End Process Development



GMP Manufacturing

Where concept becomes cure

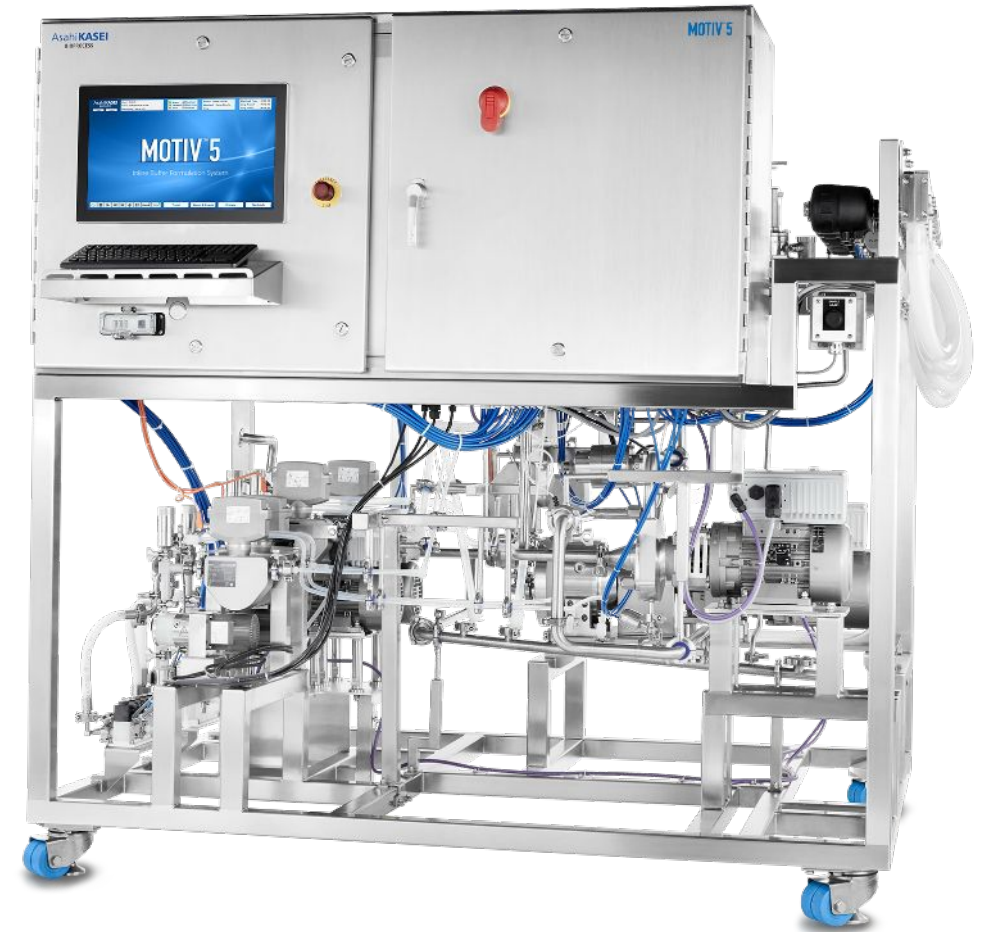
- The Purification Business Unit of Asahi Kasei Bioprocess offers products for your process: Planova and BioOptimal.
- Planova virus removal filters provide assurance beyond expectation for virus safe medication.
- BioOptimal microfilters offer cell clarification and perfusion with high protein recovery with simplicity to support your clarification needs.



BioOptimal™ **MF-SL**

- The Fluid Management Business Unit of Asahi Kasei Bioprocess is devoted to solving therapeutic product safety, efficiency and purity challenges within the pharmaceutical and bioprocessing industries.
- With technology platforms for virus filtration, inline buffer formulation, chromatography and oligonucleotide synthesis, our bioprocessing systems, columns and automation solutions advance GMP manufacturing of critical drug substances around the world.
- Built with pride, built with quality, built to exceed your high expectations. “Built for You.”

Built For You™



The Pioneering Difference

Asahi**KASEI**
BIOPROCESS

Unrivalled Product Quality

Deep Technical Support

Scientific Knowledge Sharing



Pioneering Biologics Safety and Manufacturing Efficiency

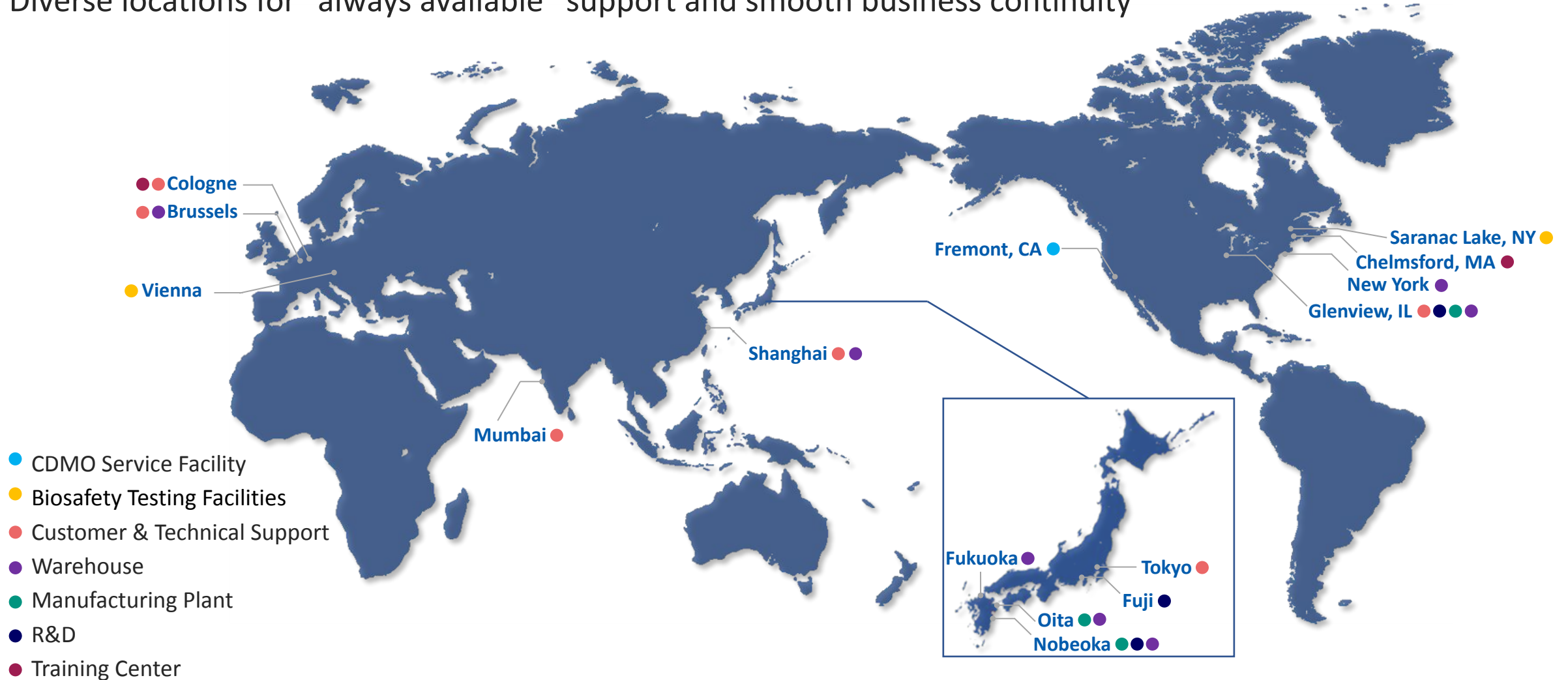
Trustworthy
Quality Management System

A Tradition of Innovation

Dependable
Global Business Network

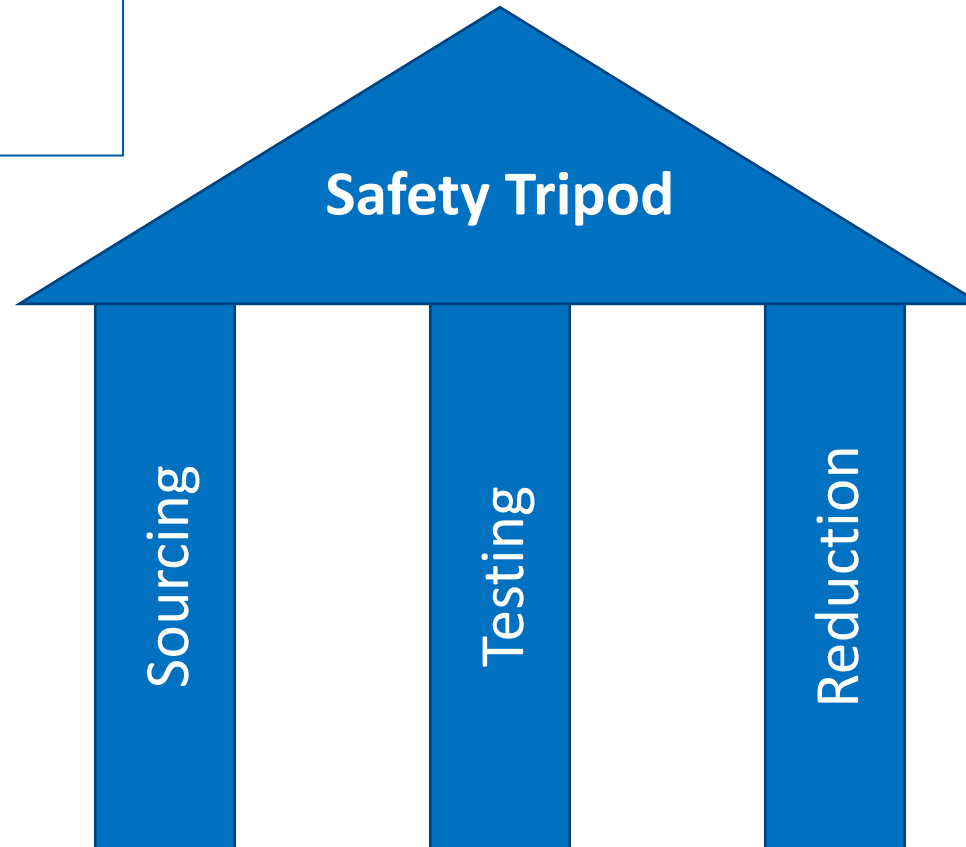
AK Bioprocess Global Network Locations

Diverse locations for “always available” support and smooth business continuity



Planova Virus Removal Filters

Biotherapeutics may be contaminated with pathogens such as viruses



1. Sourcing

- Raw material selection

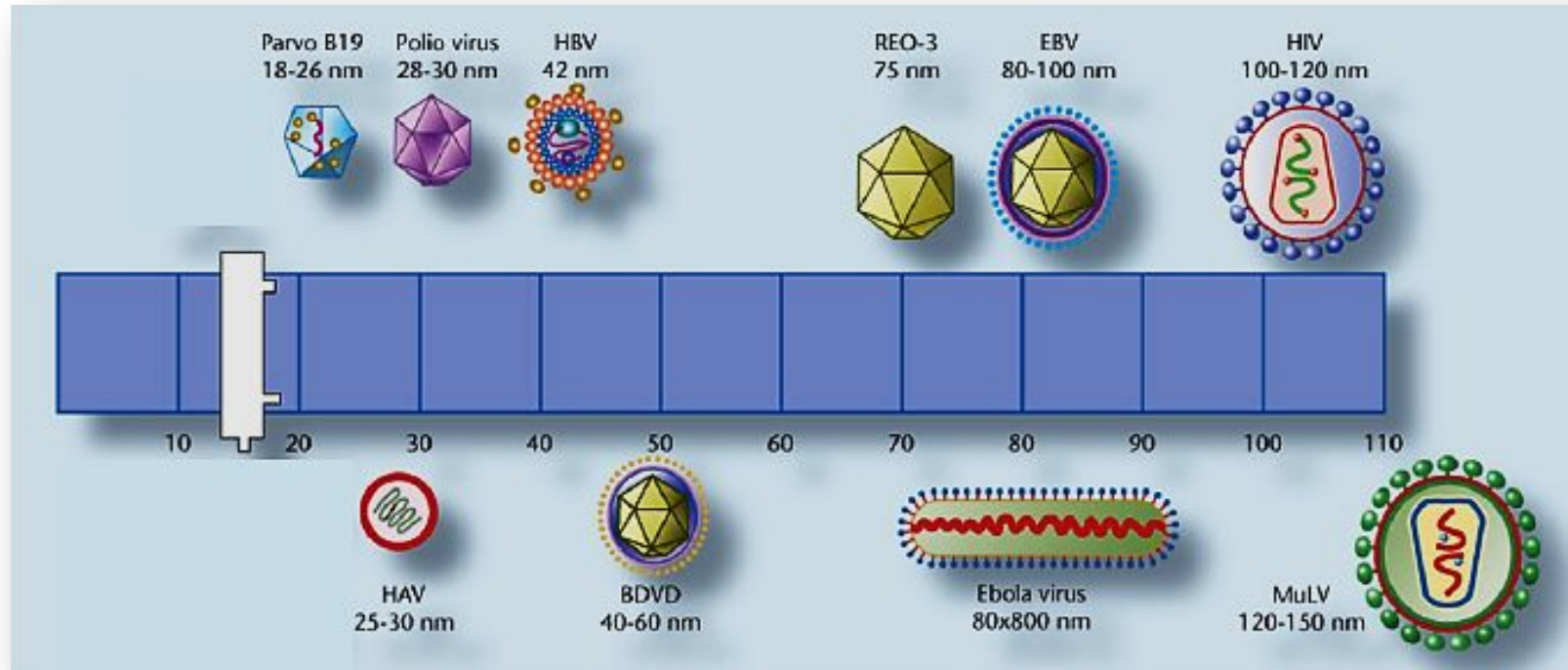
2. Testing

- PCR
- In Vitro and In Vivo

3. Reduction

- Inactivation
- Removal

Broad Diversity of Virus to Filter



- RNA or DNA
- **Enveloped** (genetic material + protein coat + lipid envelop) or **Non Enveloped** (no lipid envelop)
- Variety of shapes and sizes (16 nm → 300 nm)
- “Significant” or “Robust” removal if LRV > 4 log (from 10 000 virus reduced to only 1 virus !)

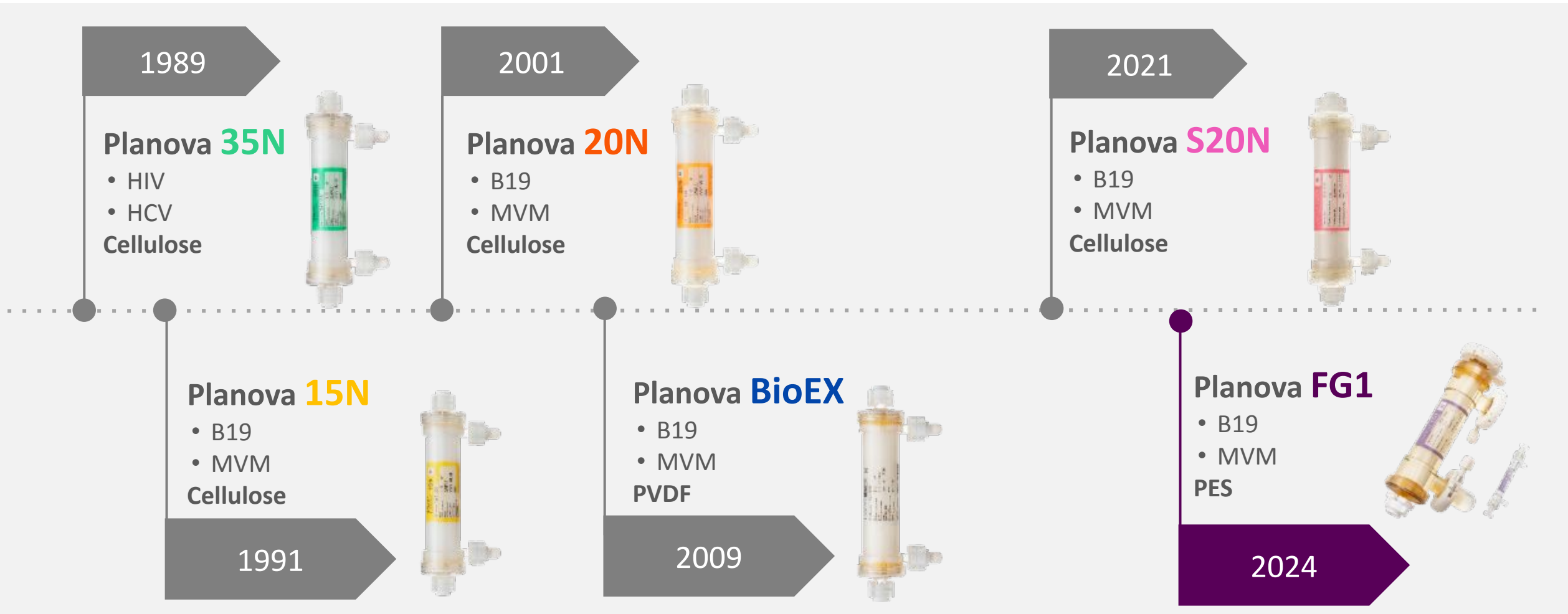
Why Virus Removal Filtration?

- For removal/reduction of viruses from mammalian derived biological products
- Simple mechanism based on size exclusion
- Reproducible and reliable
- Not affected by the nature of virus or product
- No impact on chemical characteristics of the product solution
- No stabilizers or other chemical agents are required
- Robust and consistent



PLANOVA History

■ Pioneering virus removal filtration technology since 1989



Planova Membrane Structure

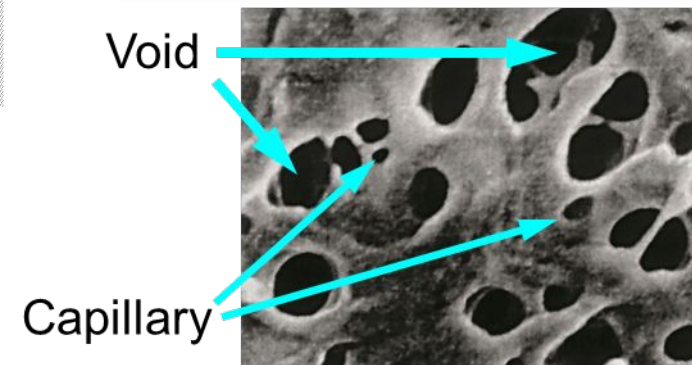
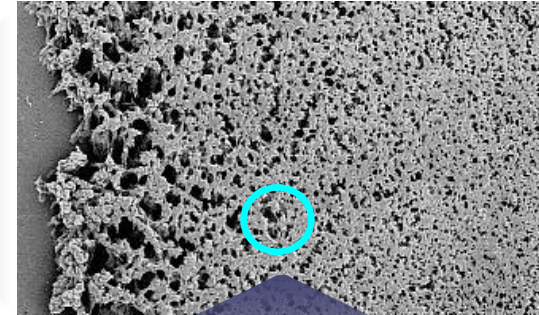
Planova filter



Hollow fiber



Membrane cross-section



Hollow fibers of Planova filters have a three-dimensional network structure consisting of voids connected by capillaries.

Improved Performance

Higher flux and throughput

Water flux: 150 LMH @ 216 kPa

Higher pressure filtration

MAX TMP: 216 kPa

Robust virus LRV

High parvovirus LRV possible

No impact of process pause*

No impact of low-pressure operation*

Improved Operational Efficiency

Simple integrity test (IT)

Leakage test

No GPT



Traditional Planova Qualities

Filtration consistency and reliability

Stable flux with minimal flux decay

Less impacted by pH and conductivity

Robust virus removal

Less impacted by pH, conductivity and flux decay

Excellent product recovery

Excellent scalability and high lot-to-lot consistency

*: Under Asahi's severe conditions

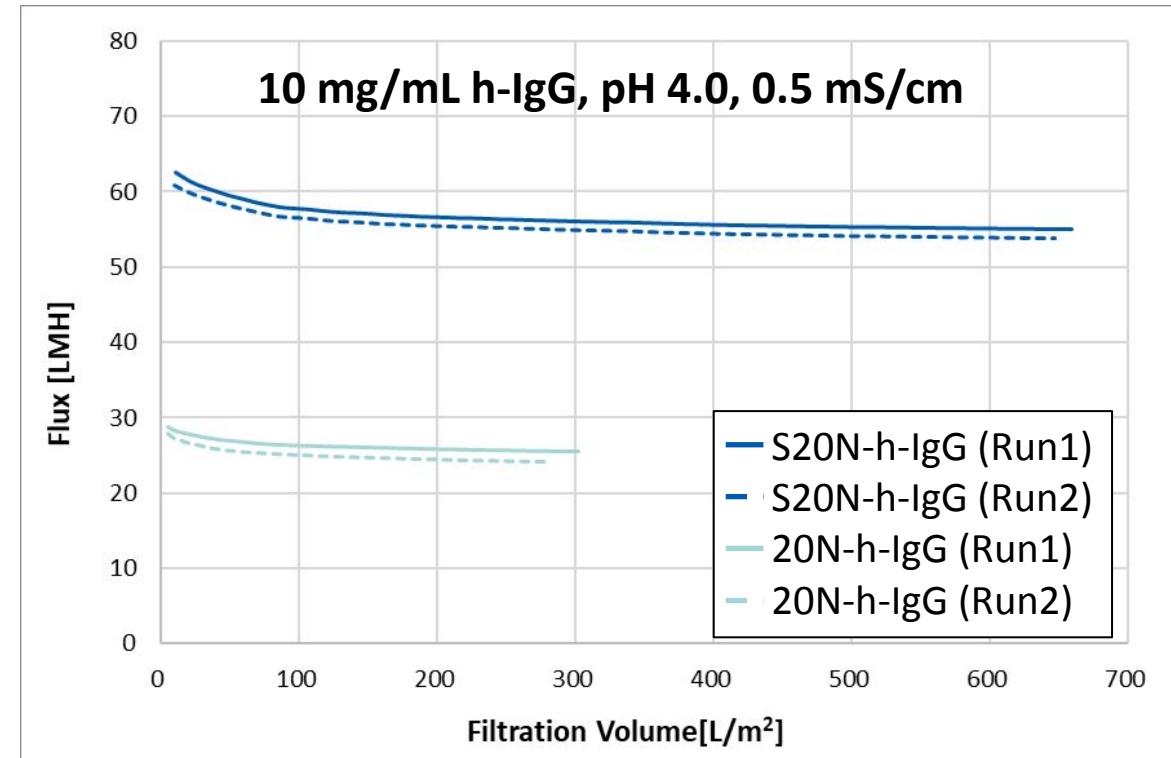
Higher Flux and Throughput

- S20N can provide stable filterability with high flux while resisting to clogging.

Improved performances

Higher flux and throughput

Filter	Pressure (kPa)	Filtration Volume (L/m ²) in 5 hrs	Filtration Volume (L/m ²) in 12 hrs
S20N	196 (28.4 psi)	278	652
20N	98 (14.2 psi)	128	295



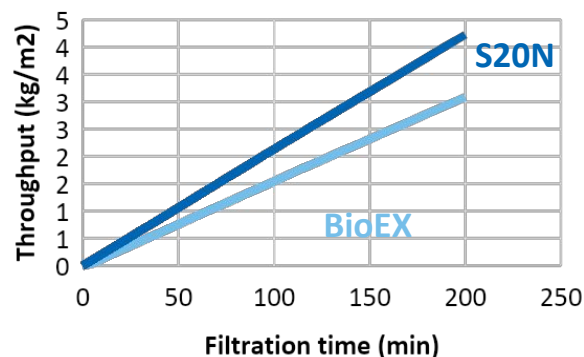
Higher Throughput in Various Buffer Conditions

- Planova S20N can provide stable filtration with higher throughput
- Filterability is not affected by solution condition

Improved Performance
Higher throughput

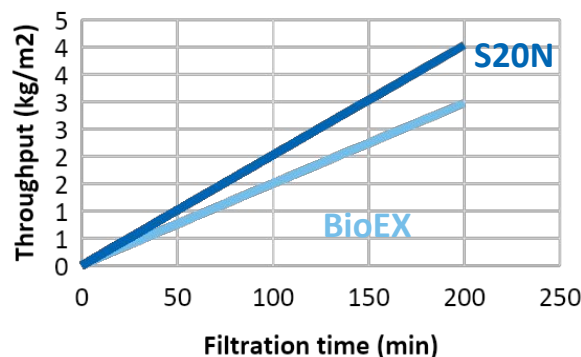
Case 1

25 mM acetate buffer,
pH 5.0, 14 mS/cm



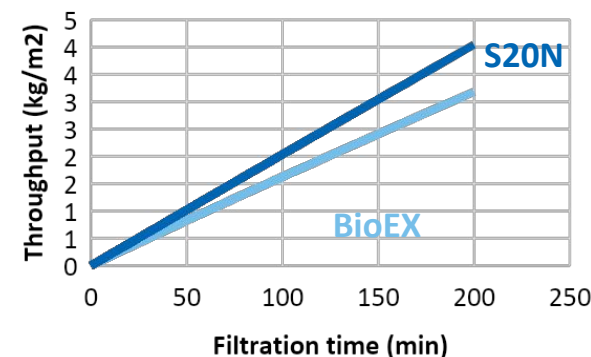
Case 2

25 mM histidine buffer,
pH 6.0, 5 mS/cm



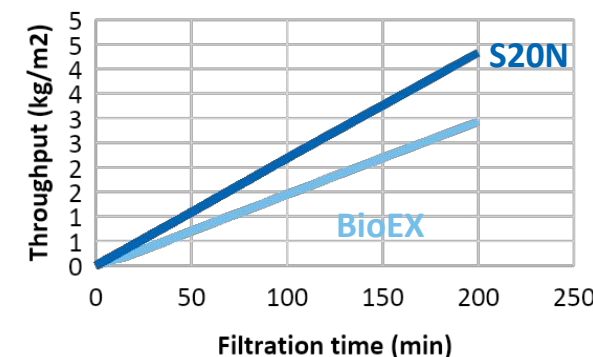
Case 3

25 mM histidine buffer,
pH 6.0, 14 mS/cm



Case 4

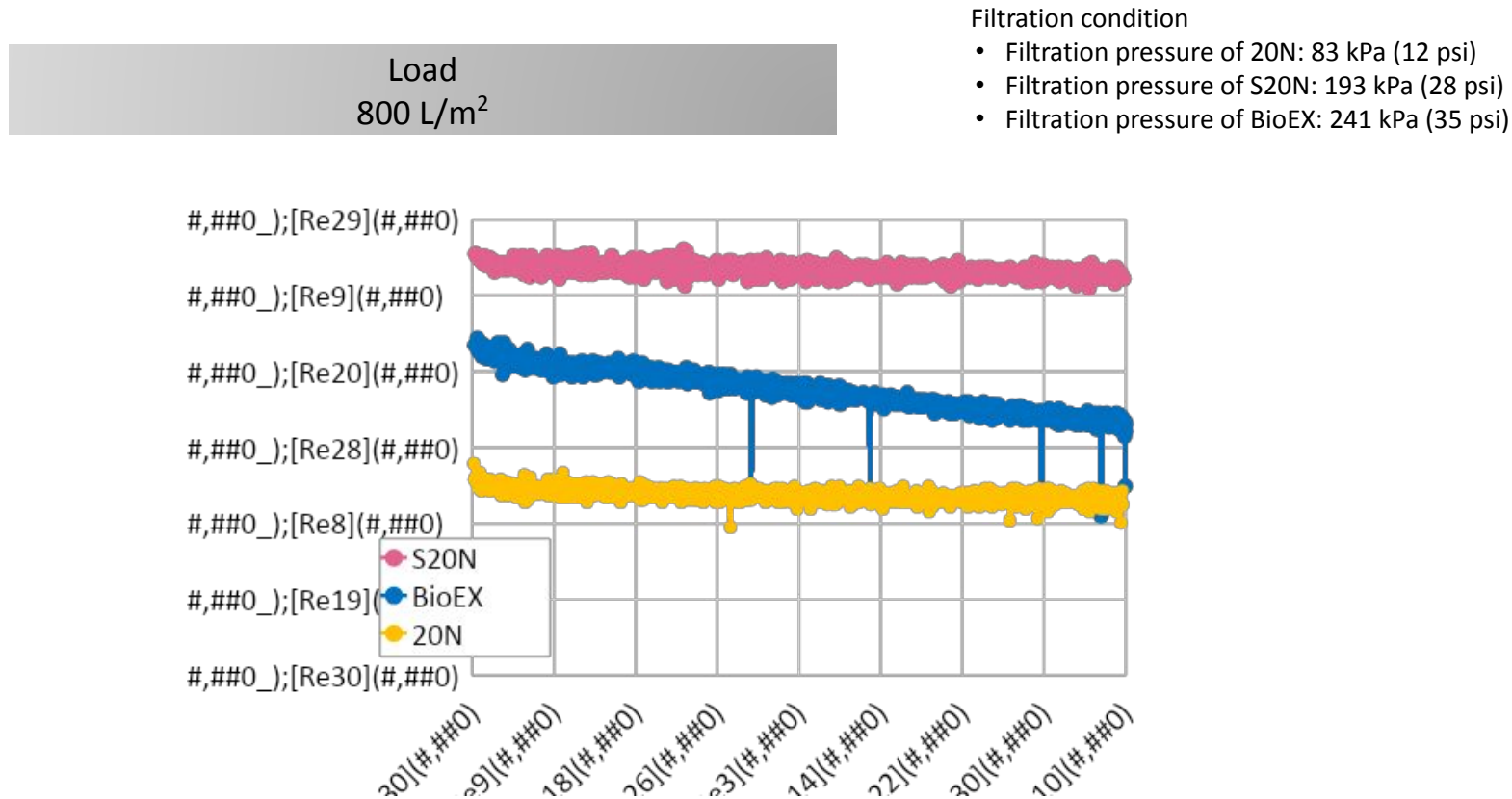
25mM Tris-HCl buffer,
pH 7.2, 5 mS/cm



* mAb concentration in all cases was 10 mg/mL

Filter	Pressure (kPa)	3 h Throughput (kg/m ²)			
		Case 1	Case 2	Case 3	Case 4
S20N	196 (28.4 psi)	3.8	3.6	3.6	3.9
BioEX	196 (28.4 psi)	2.8	2.7	2.9	2.6

- Bristol Myers Squibb evaluated multi-specific antibody on Planova S20N



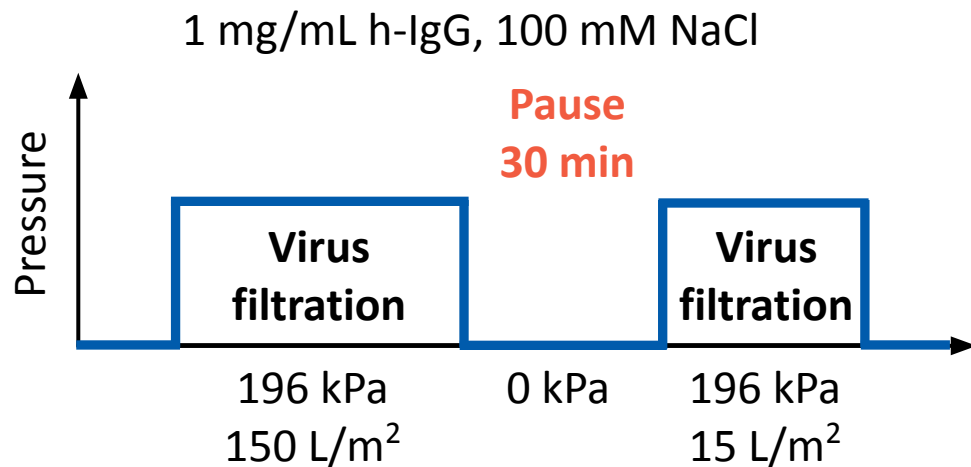
S20N achieved the highest filtration capacity with very minimal decay for a multi-specific antibody without a prefilter.

- High virus LRV for various viruses even with **30 min** process pause

Improved Performance

High virus LRV

High parvovirus LRV possible
with typical model viruses for clearance studies



Virus	Genome	Size (nm)	Virus LRV* ¹
MVM	DNA	18 – 24	≥5.3
PPV	DNA	18 – 24	≥5.8
PRV	DNA	120 – 200	≥5.4* ²
EMCV	RNA	25 – 30	≥5.9* ²
BVDV	RNA	50 – 70	≥5.9
HIV	RNA	80 – 120	≥4.1* ²

*¹Total pool virus LRV after **30 min** process pause

*²CRO was contracted to perform the test. Large volume assay was used to expand the dynamic range of virus testing.

Promise of Unrivalled Performance

Rapid filtration enabling highly efficient processing

- ✓ Unrivalled high flux

Reliable solution for consistent virus removal

- ✓ Robust virus removal capability
- ✓ Compatibility with CIP/SIP
- ✓ Simple integrity test

Traditional Planova Qualities

- ✓ Excellent scalability
- ✓ High lot-to-lot consistency
- ✓ Ready to use



Traditional Planova Qualities - Ready to Use

■ Planova FG1 contributes to shortening manufacturing process time

Just like other Planova filters, Planova FG1 arrives at your site “ready to use”

- Shipped sterilized, available immediately after opening
- No pre-wetting process required (Supplied as filled with purified water)



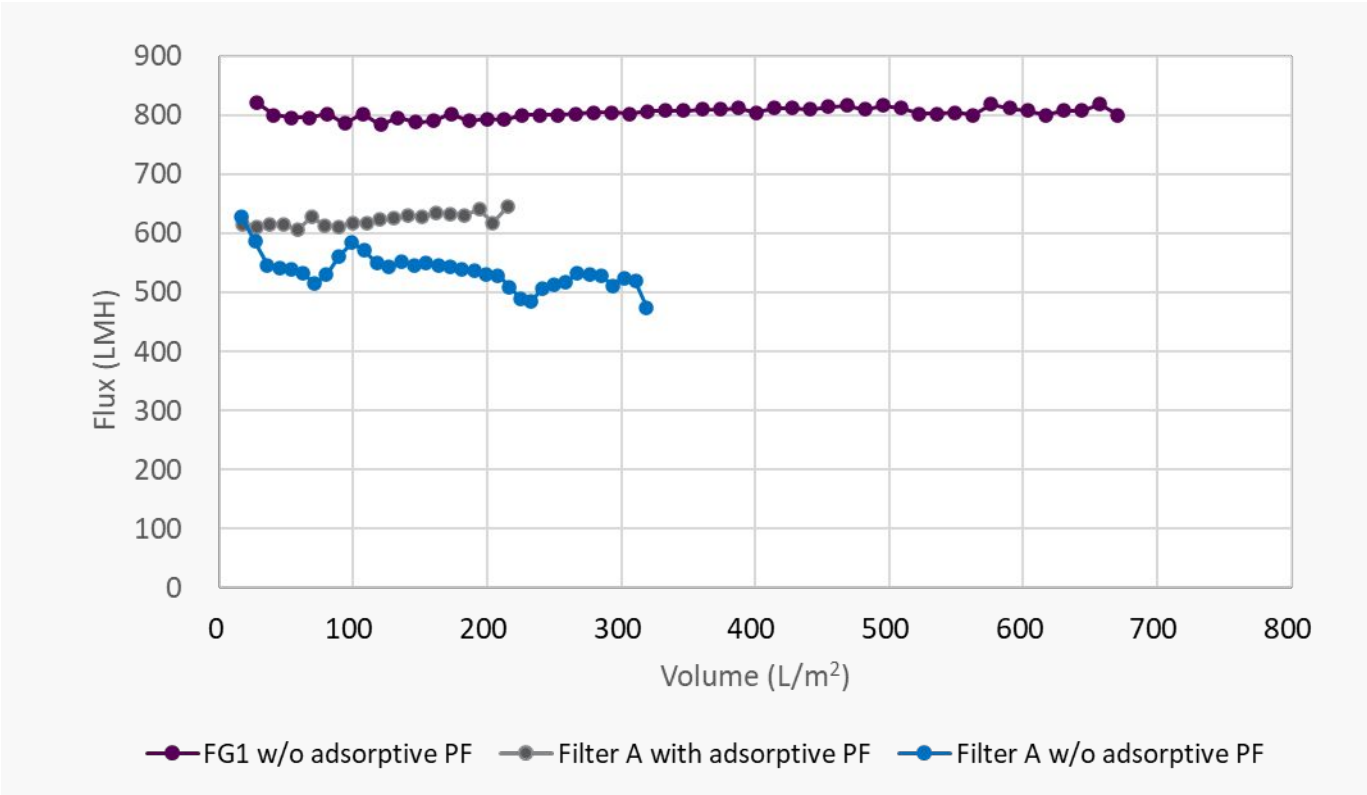
Example of Evaluation: Customer 1

■ FG1 demonstrated a significant increase in flux compared to other filters

Molecule	Conc. (g/L)	Buffer	Filtration pressure
mAb C	10.7	20 mM sodium acetate, pH 6.8	310 kPa (45 psi)

Filterability

- 1.5x higher average flux compared to Filter A without adsorptive prefilter.
- 1.3x higher average flux compared to Filter A with adsorptive prefilter.



*Unpublished data

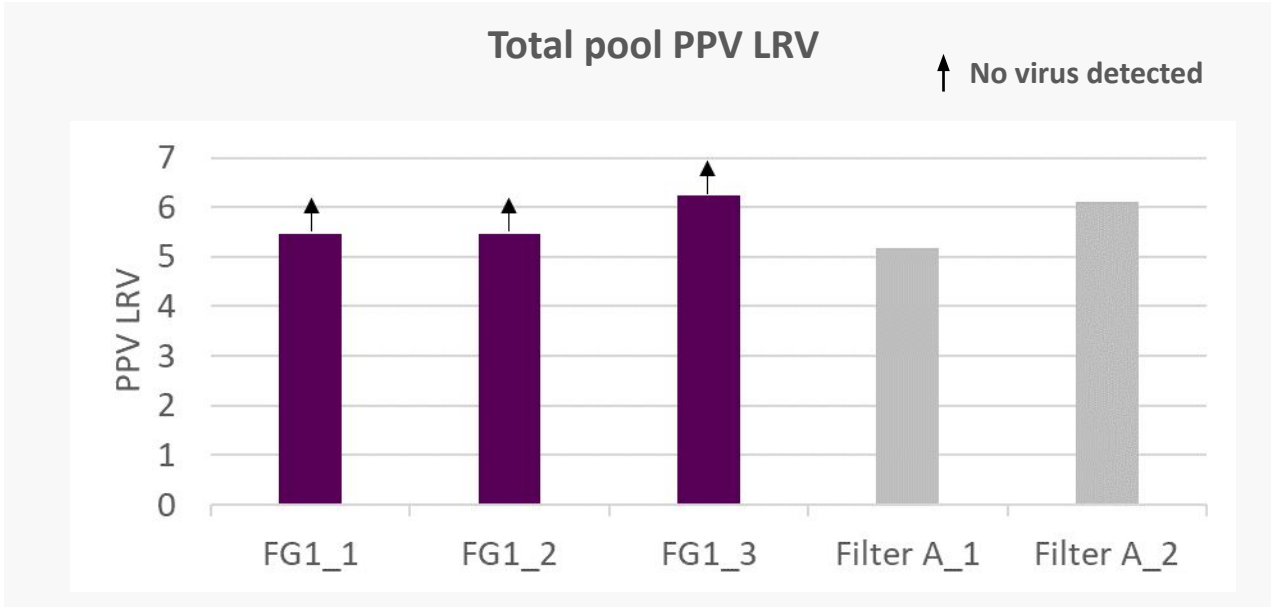
Example of Evaluation: Customer 1

■ FG1 demonstrated robust virus removal capability even after multiple process pauses

Molecule	Conc. (g/L)	Buffer	Filtration pressure
mAb C	10.7	20 mM sodium acetate, pH 6.8	310 kPa (45 psi)

Viral Clearance Study

- mAb C was used for the 2000 L/m² loading challenge spiked with PPV, with three 30 min process pauses
- FG1 achieved high throughput and robust virus removal with no virus detected



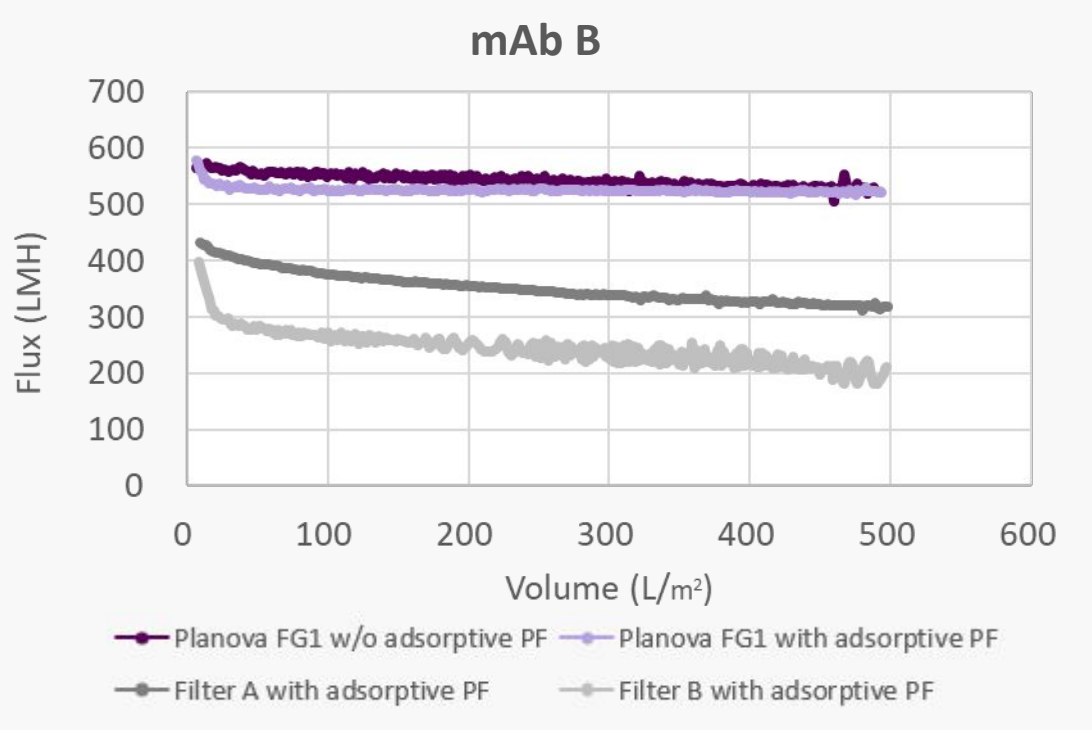
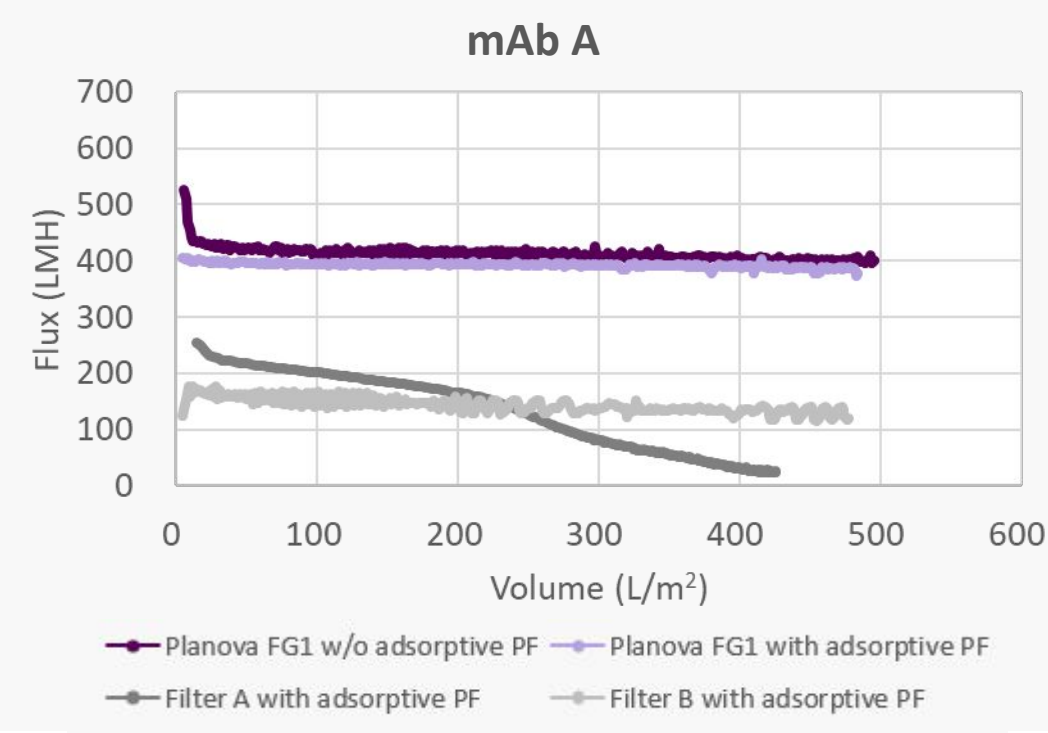
Filter_Run No.	FG1_1	FG1_2	FG1_3	Filter A_1	Filter A_2
Total throughput (L/m ²)	211.3	211.0	2000.3	810.3	785.5
No. of process pause	1	2	3	1	3

*Unpublished data

Example of Evaluation: Customer 2

■ FG1 showed higher and more stable flux than other filters without adsorptive prefilter

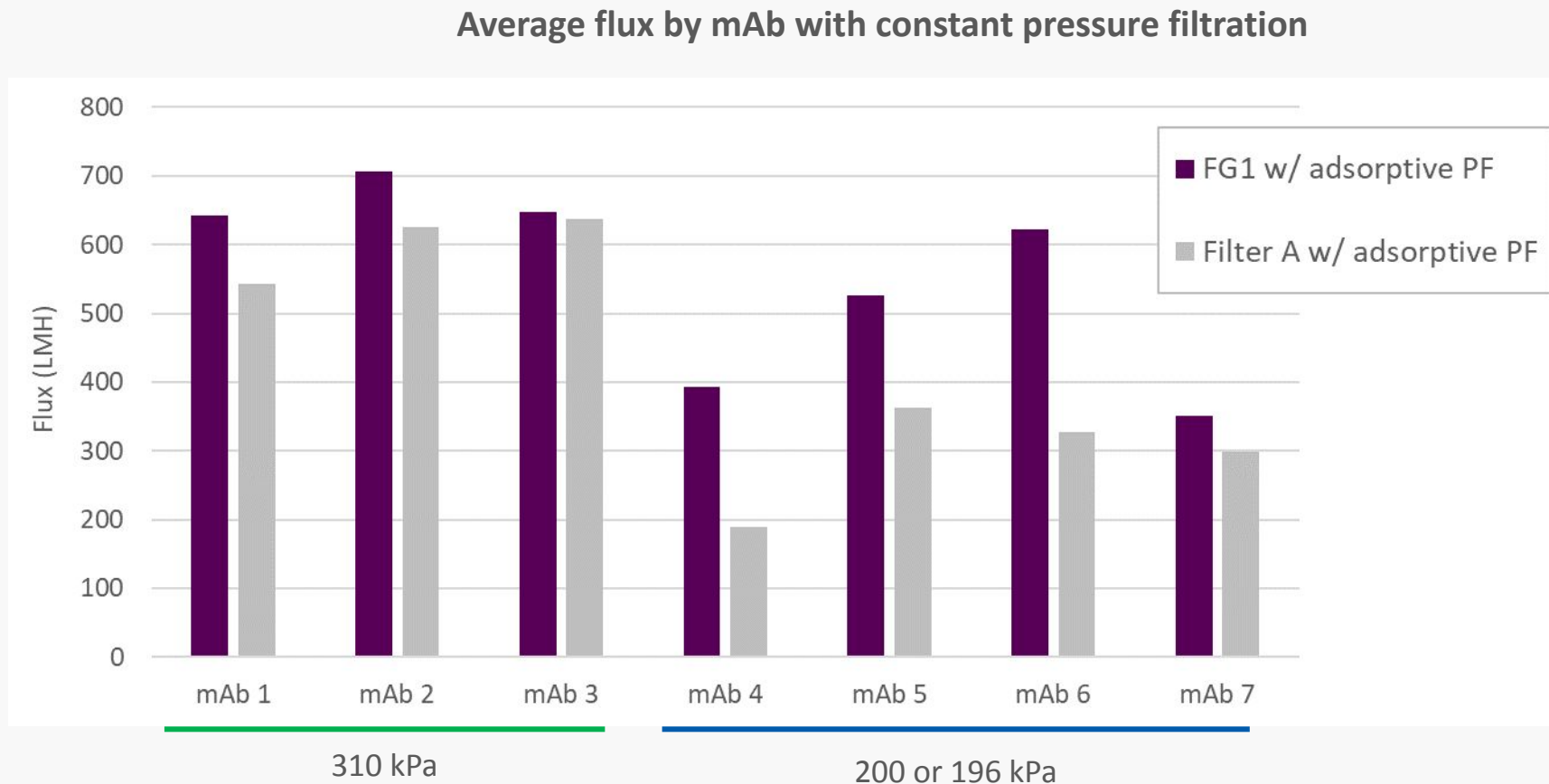
Molecule	Conc. (g/L)	Buffer	Filtration pressure
mAb A	15	20 mM histidine, pH 6	200 kPa (29 psi)
mAb B	2	50mM Tris, 20mM NaCl, pH 7.5	200 kPa (29 psi)



Overall Results of Pre-Launch Customer Evaluations

■ High flux of FG1 was validated in pre-launch customer evaluations

FG1 with adsorptive PF achieved higher average flux than filters from other vendors with adsorptive PF for multiple molecules.



*Results of pre-launch customer evaluations between April 2023 and February 2024.

Planova Filters

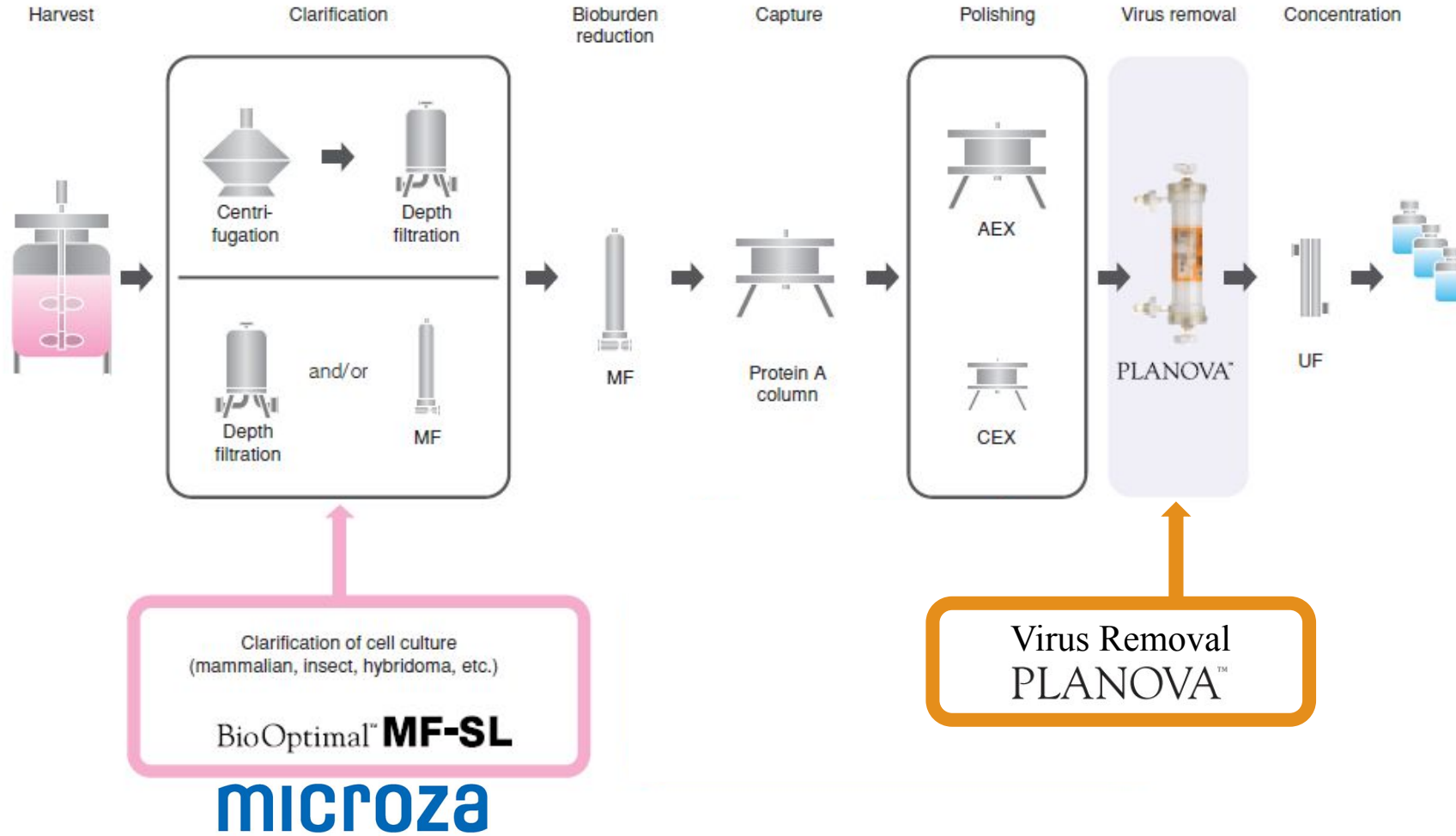


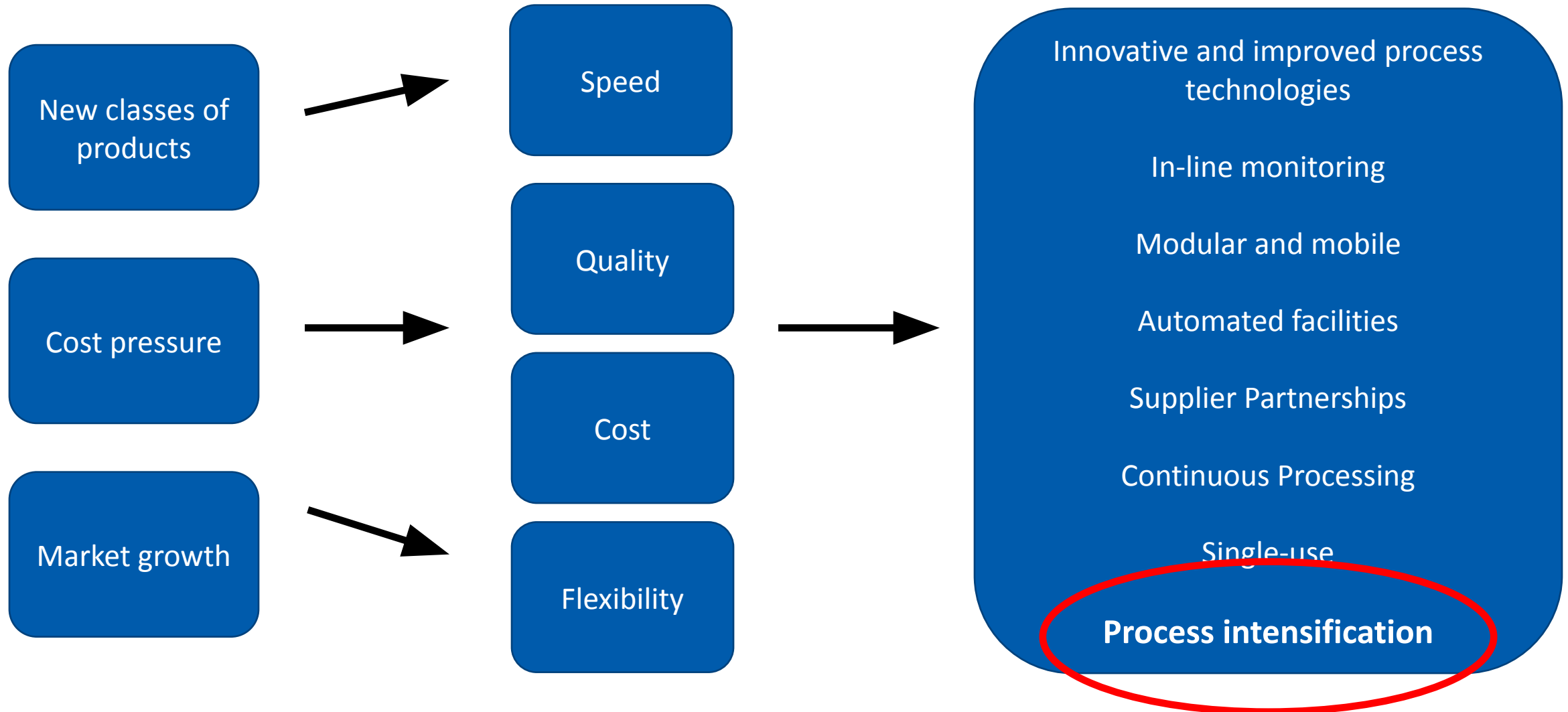
Filter	Planova FG1	Planova S20N	Planova N	Planova BioEX
Hollow fibers	PES	Regenerated cellulose	Regenerated cellulose	PVDF
Mean pore size (nm)	Parvovirus removal	Parvovirus removal	15, 20, 35, (75)	Parvovirus removal
Effective surface area (m ²)	0.3, 0.003, 0.0003 (Plan 1.0, 0.1, 0.03)	4.0, 1.0, 0.3, 0.1, 0.01, 0.001	4.0, 1.0, 0.3, 0.12, 0.01, 0.001	4.0, 1.0, 0.1, 0.01, 0.001, 0.0003
Max TMP	343 kPa (49.7 psi)	216 kPa (31.3 psi)	98 kPa (14.2 psi)	343 kPa (49.7 psi)
Water flux (LMH)	1220^{*a} @ 343 kPa	150 @ 216 kPa	20N: 66 @ 98 kPa	170 @ 343 kPa
SIP	YES	NO	NO	YES
CIP with NaOH	YES	NO	NO	NO
Post-use integrity test	Leakage test	Leakage test	Leakage test + Gold particle test	Leakage test

^{*a}Based on the filtration with lab scale filters

BioOptimal Microfilters

Typical mab production process





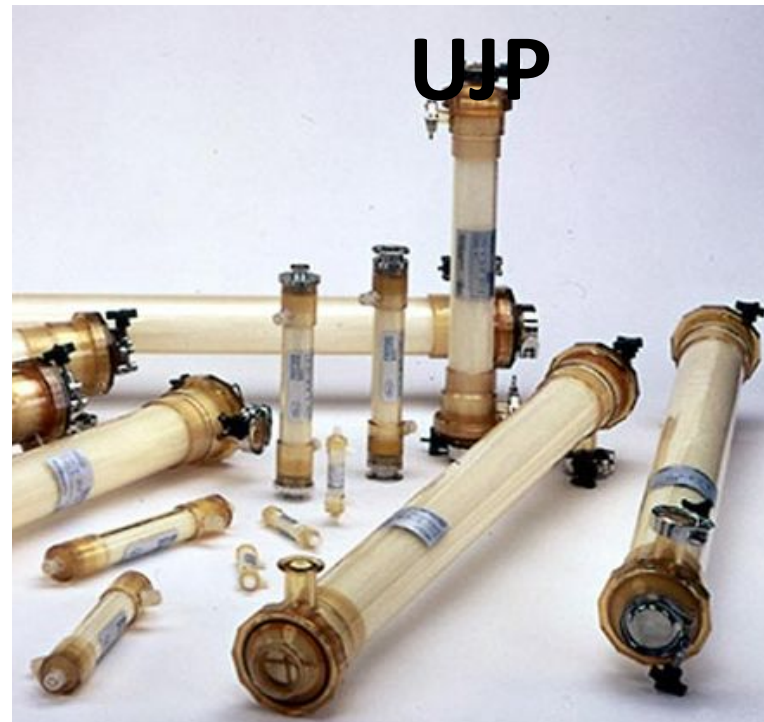
Asahi's BioOptimal microfilters improve performance of harvest or perfusion by:

- **Higher resistance to membrane clogging**
- **Higher product sieving**

BioOptimal **MF-SL**

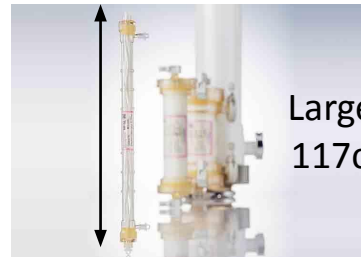
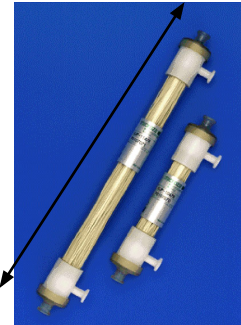


microza UMP, UJP

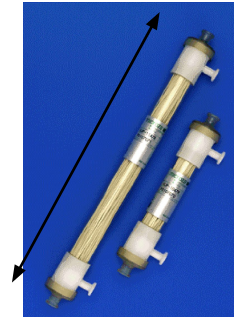


Our Microfilter Portfolio

Largest
113 cm

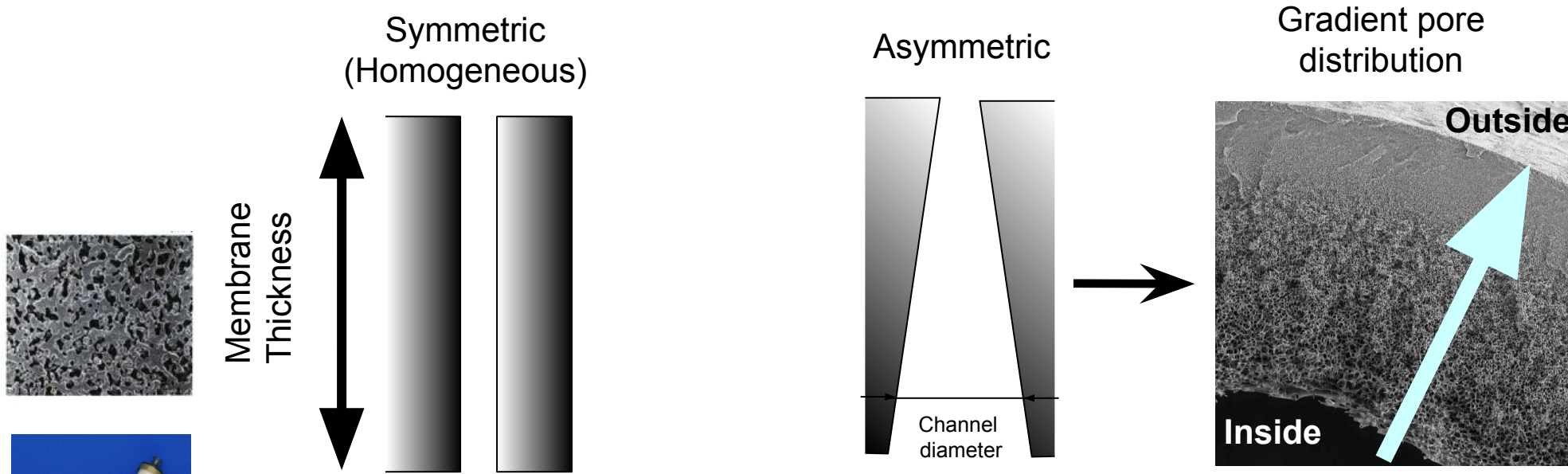


Largest
117cm



Largest
113 cm

Filter	UMP	MF-SL	UJP
Hollow fibers	PVDF	PS	PVDF
Pore Structure	Homogeneous	Asymmetric	Homogeneous
Approximate pore size (μm)	0.2	0.4	0.65
I.D. (mm)	1.4	1.4	1.1
Effective surface area (m ²)	0.02 – 4.05	0.005 – 8.0	0.02 – 3.8
Max Operating pressure (psi)	43	29	43
CIP	YES	YES	YES
SIP (autoclaving)	YES	YES	YES



UJP and UMP Microfilters

- Good for perfusion processing
- Low TMP (gentle on cells)
- Low fouling
- High protein permeability – **LESS FILTER CHANGEOUTS**
- Low permeate turbidity – eliminate additional clarification (UMP 0.2um)

MF-SL Microfilters

- Good for perfusion processing and harvest clarification
- Low TMP and high flux
- Low fouling
- High protein permeability – **LESS FILTER CHANGEOUTS**
- Low permeate turbidity – no additional clarification needed prior to column chromatography



Introducing UMP (0.2um) and UIP (0.65um) TFF Microfilters



Applications

- Perfusion cell culture applications as a cell retention device
- Size-based exclusion removal of impurities before further processing

Features

- High throughput capability
- Excellent protein transmission during N and N-1 perfusion
- Gentle on cells due to low transmembrane pressure (TMP)
- Scalable

- Planova virus removal filters

Different membrane chemistries for wide range of product types and user goals

Hollow fiber design for consistency & scalability

Robust virus removal even under varying conditions (pressure, pH, conductivity, process pause, protein concentration)

Newest filters (BioEX, S20N & FG1) have simplified integrity tests

PLANOVA™
Assurance Beyond Expectation



- BioOptimal microfilters

Different pore structures for either perfusion or harvest applications

High product sieving (protein transmission)

Low TMP (less shear stress & gentler on cells)



BioOptimal™ **MF-SL**
Hollow Fiber Microfilter

Asahi Kasei Bioprocess offers the following services to support customers:



- Technical consultation on virus filtration process development, scale-up, optimization and filter operation
- Virus filter operator training for development
- Virus filter operator training for manufacturing
- Technical consultation on filtration and integrity test process automation

Save the Date!

Asahi**KASEI**
BIOPROCESS



THE 27TH PLANOVATM WORKSHOP

SEATTLE | OCT. 22 - 23, 2026

Asahi**KASEI**
BIOPROCESS

Questions?

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Regional Manager
Valerie.Brubaker@ak-bio.com

<https://planova.ak-bio.com/>

AsahiKASEI

BIOPROCESS

감사합니다

Gracias

Danke

Благодаря

谢谢

Tack

धन्यवाद

Dziękuję

Спасибо

Thank You

Obrigado

Děkuju

Grazie

Ευχαριστώ

Merci

Köszönöm

ありがとうございました

Teşekkür ederim