



01 who, what is MERCK ?

MERCK

FOUNDED
IN **1668**
WORLD'S
OLDEST
CHEMICAL &
PHARMACEUTICAL
COMPANY

1.6 M
LIFE SCIENCE
CUSTOMERS
GLOBALLY

~100 M
UNIQUE
VISITS
TO OUR
LIFE
SCIENCE
WEBSITE

~28,400
EMPLOYEES

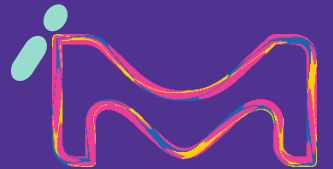
€10.4bn
TOTAL
REVENUE
IN 2022

>100 LIFE SCIENCE
DISTRIBUTION
CENTERS

PRESENCE IN
66 COUNTRIES

>300,000
LIFE SCIENCE
PRODUCTS

60 MANUFACTURING
SITES WORLDWIDE





Headquarter in Darmstadt, Hessian State, DE

Our Financials

2022 Financials



Total revenue
in 2022

€10.4 B



EBITDA pre
exceptionals

€3.7 B



R&D costs

€399 M



Net sales in 2022

€10.3 M

LS 2022 net sales per region

North America

€3,931
million

Asia-Pacific

€2,536
million

Europe

€3,445
million

Latin America

€353
million

Middle East and
Africa

€116
million



MERCK'S systems portfolio for bioprocessing

Learn & Connect Day
Q4 2024

Presented by
Joachim Regel



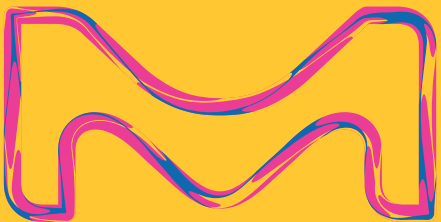
MERCK

Biologics production today and beyond our next steps to our journey to the facility 4.0

MERCK

Joachim Regel
October 2024

With Content from
F. Balbin, Merckgroup LS/PS
Prof. Dr. Michelangelo Canzoneri, Merck KGaA



The life science business of Merck operates
as MilliporeSigma in the U.S. and Canada.

Millipore®

Preparation, Separation,
Filtration & Monitoring Products

Agenda

1. Short History of Biologic Productionsschemes/Processes
2. Multi Modality playground
3. Merck's Systems Portfolio - A solution for every step
4. Evolution towards intensified and continuous processing
5. Digitalisation of the Biotech-Production



Part of a

VIBRANT SCIENCE AND TECHNOLOGY

company with over 355
years of history.

At Merck, science is at the heart
of everything we do. It drives
the discoveries we make and the
technologies we create.

Three High-tech Businesses Competing in Attractive Markets

Healthcare

As One for Patients

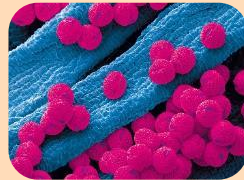


Leading among
SPECIALTY PHARMA
markets

- Biologics and small-molecule **prescription medicines** against cancer, multiple sclerosis, infertility
- **Research** focus: Oncology, Immunology & Immuno-Oncology

Life Science

Impacting Life and
Health with Science



A leading
LIFE SCIENCE
business

- Tools and services for **biotech research and production**
- **Tools and laboratory supply** for academic research and industrial testing

Electronics

Advancing Digital Living



A leading business in
HIGH-TECH SOLUTIONS

- Semiconductors
- Displays
- Surfaces



SCIENCE & LAB SOLUTIONS

Seamless customer experience & scientific expertise; access to one of the **broadest portfolios** in the industry

Customer Focus:

- Pharma & Biotech Discovery, Contract Research Organizations (CROs)
- Diagnostics
- Industrial & Testing
- Academic & Government



TOGETHER, WE
IMPACT **LIFE**
AND HEALTH
WITH
SCIENCE

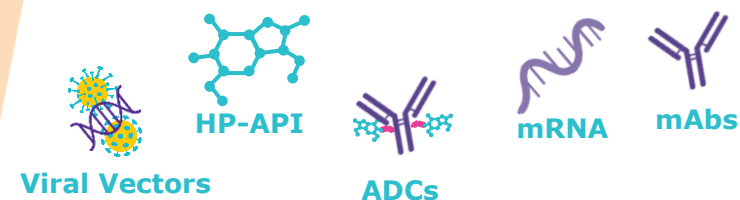


LIFE SCIENCE SERVICES

Fully integrated service organization for development & manufacture of traditional & novel modalities, as well as testing services; focus on **end-to-end** solutions, **best-in-class services**

Customer Focus:

- Pharma & Biotech Development
- Pharma & Biotech Manufacturing



PROCESS SOLUTIONS

Best-in-class products focused on pharma development, manufacturing; product **innovation** for BioProcessing, Process & Formulation Materials

Customer Focus:

- Biopharma & Biotech Development & manufacturing
- CDMOs & CMOs



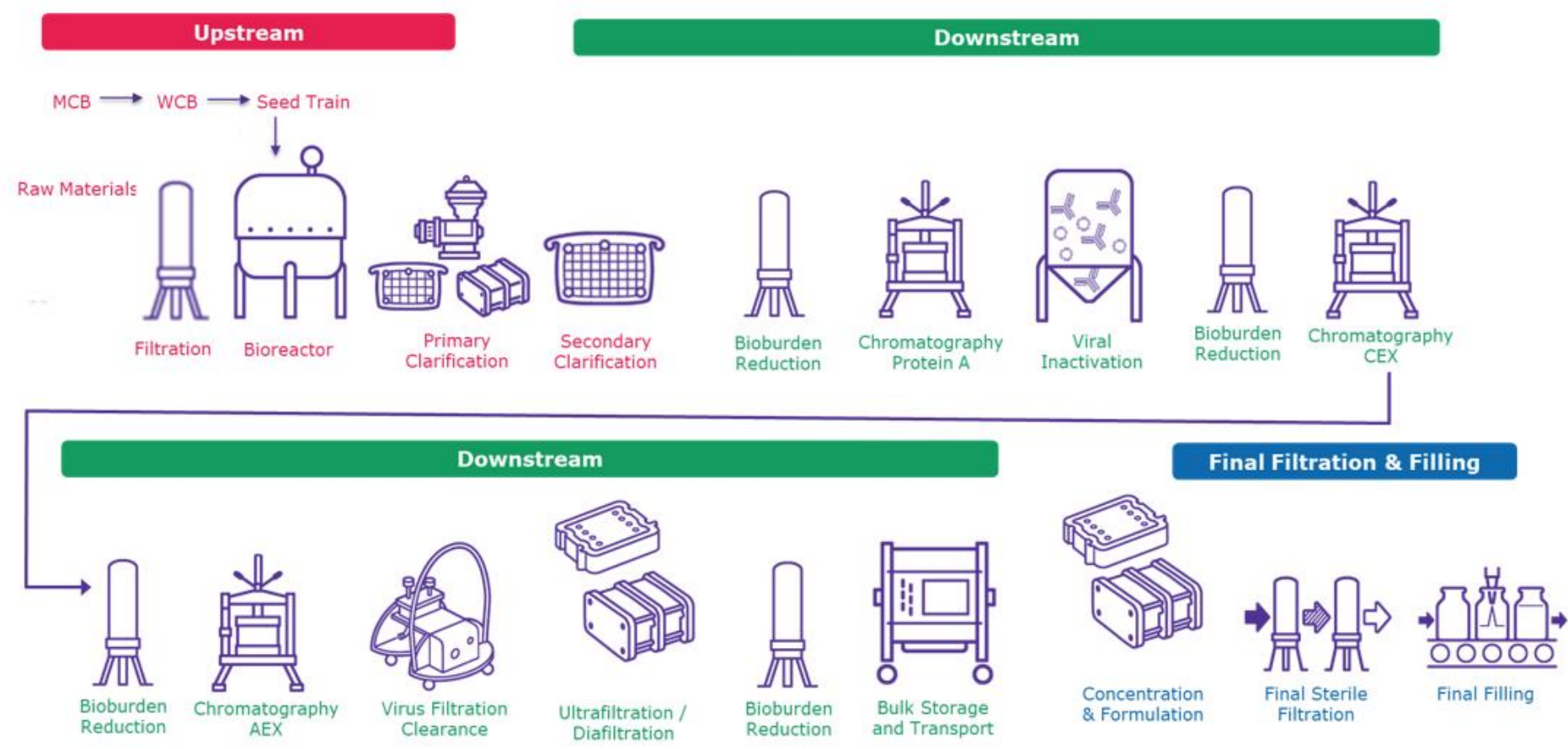
MERCK



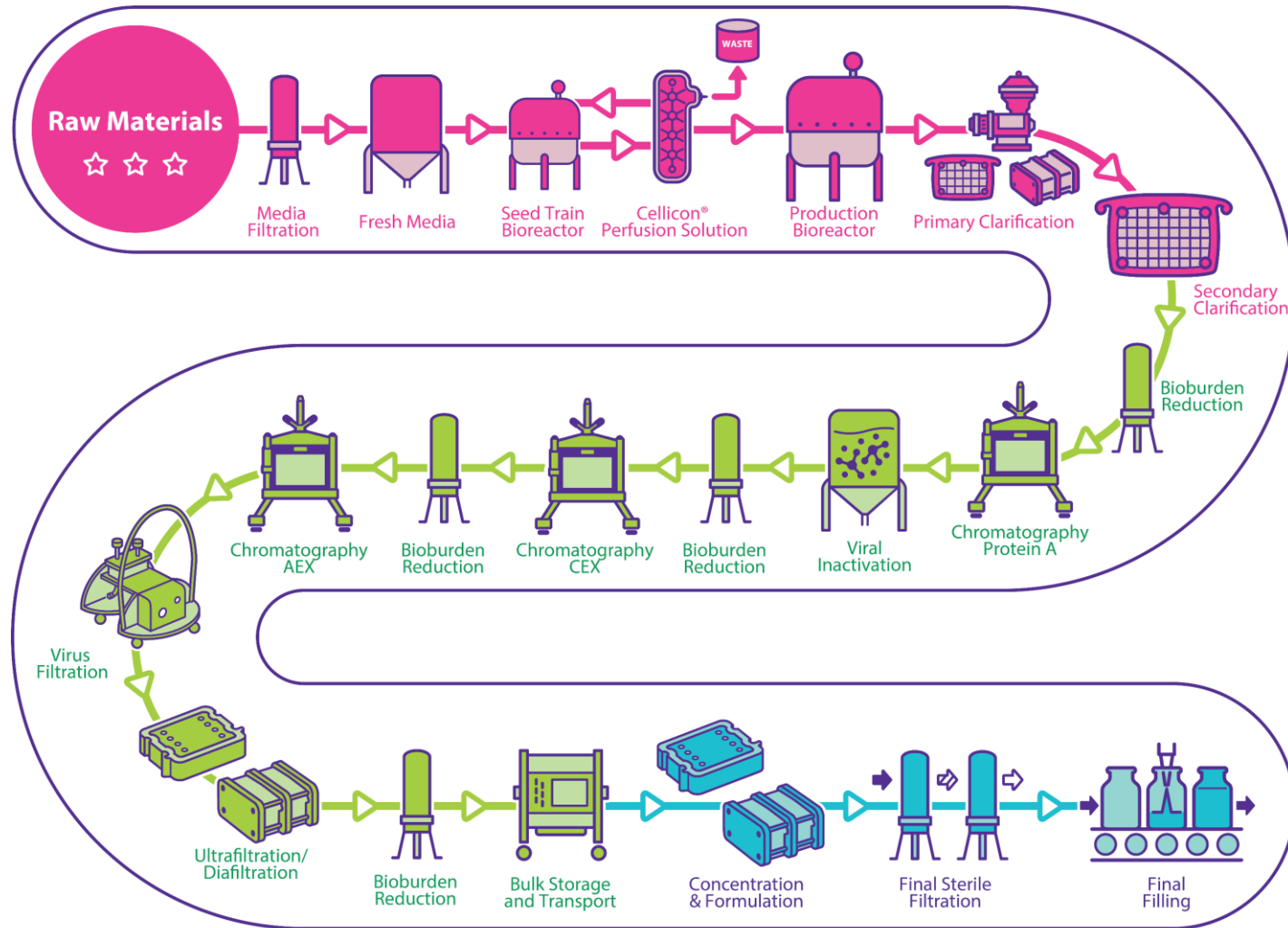
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Biologics and Biotech plants today and in the future

Generic Biologics Process Template



Typical proces template – A solution for every steps, at all scales



Upstream

Prevent bioreactor contamination

Downstream

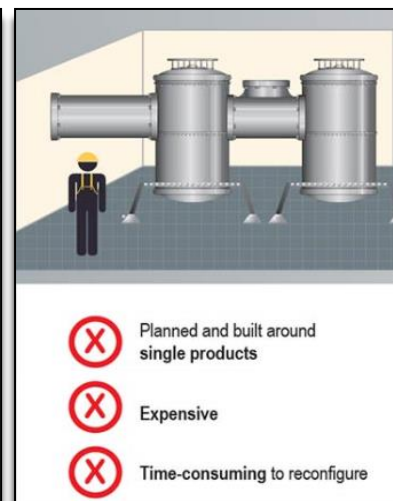
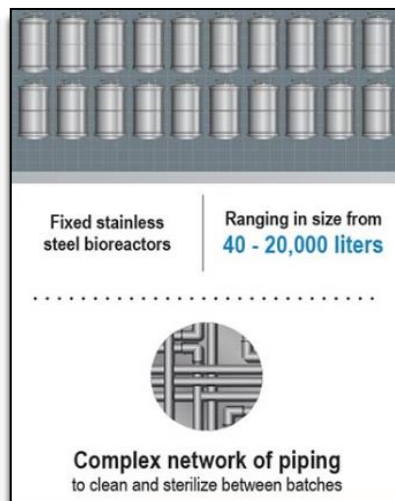
Prevent bioburden ingress and maintain low bioburden

Final Fill

Sterile filtration and aseptic processing for patient safety.

Traditional facility construction approach in today's industry's needs

- High CAPEX (>\$500M)
- Long time before the first product run; 3-4 years
- Product dedicated
- Inflexible – no scalability
- Building size is based on pre-release product sales forecast
- Extensive qualification process



Courtesy: Amgen

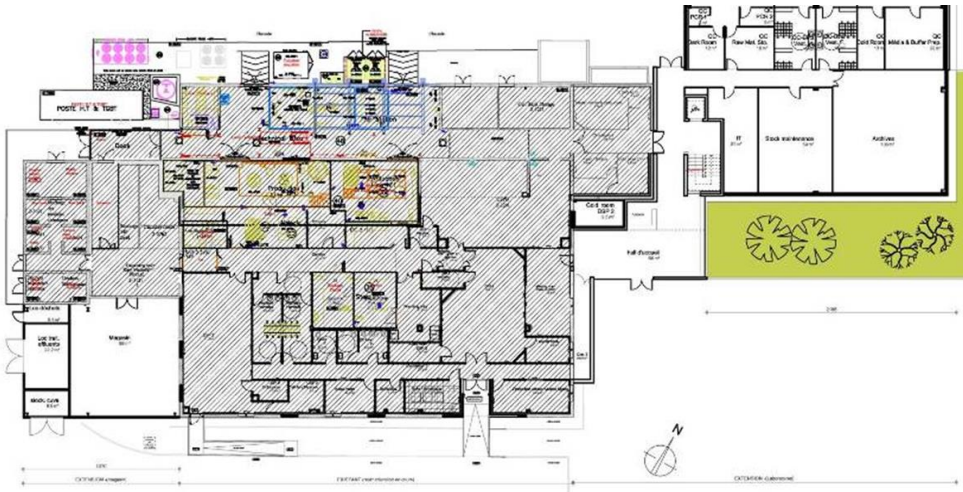


Modular plant-flexible?



Courtesy: Pharmadule

Full dedicated Biotech plant



Ballroom concept: “A large manufacturing area that has no fixed equipment and minimal segregation due to the use of functionally closed systems.”

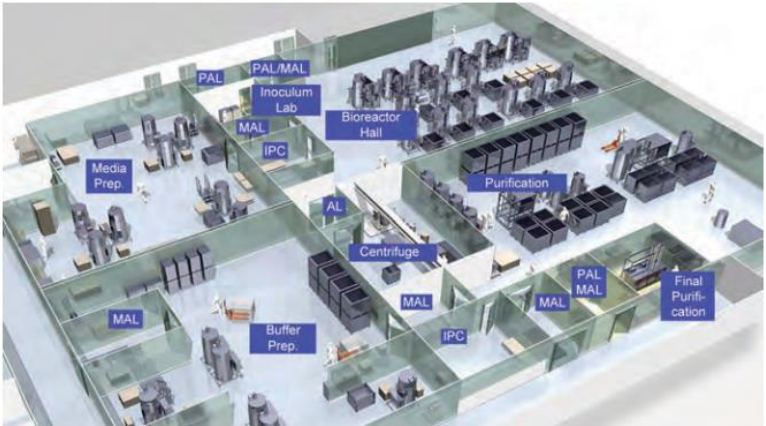


Figure 1. 3D model of a ballroom type facility.

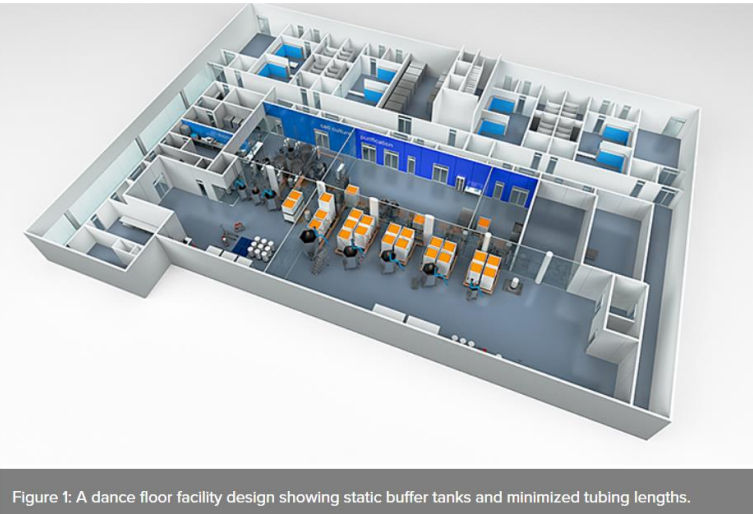


Figure 1: A dance floor facility design showing static buffer tanks and minimized tubing lengths.

Dance floor concept: “Mix of static elements like buffer tanks/Bags with flexible, SU based manufacturing technologies. Movement of liquids is done with small volumes only”

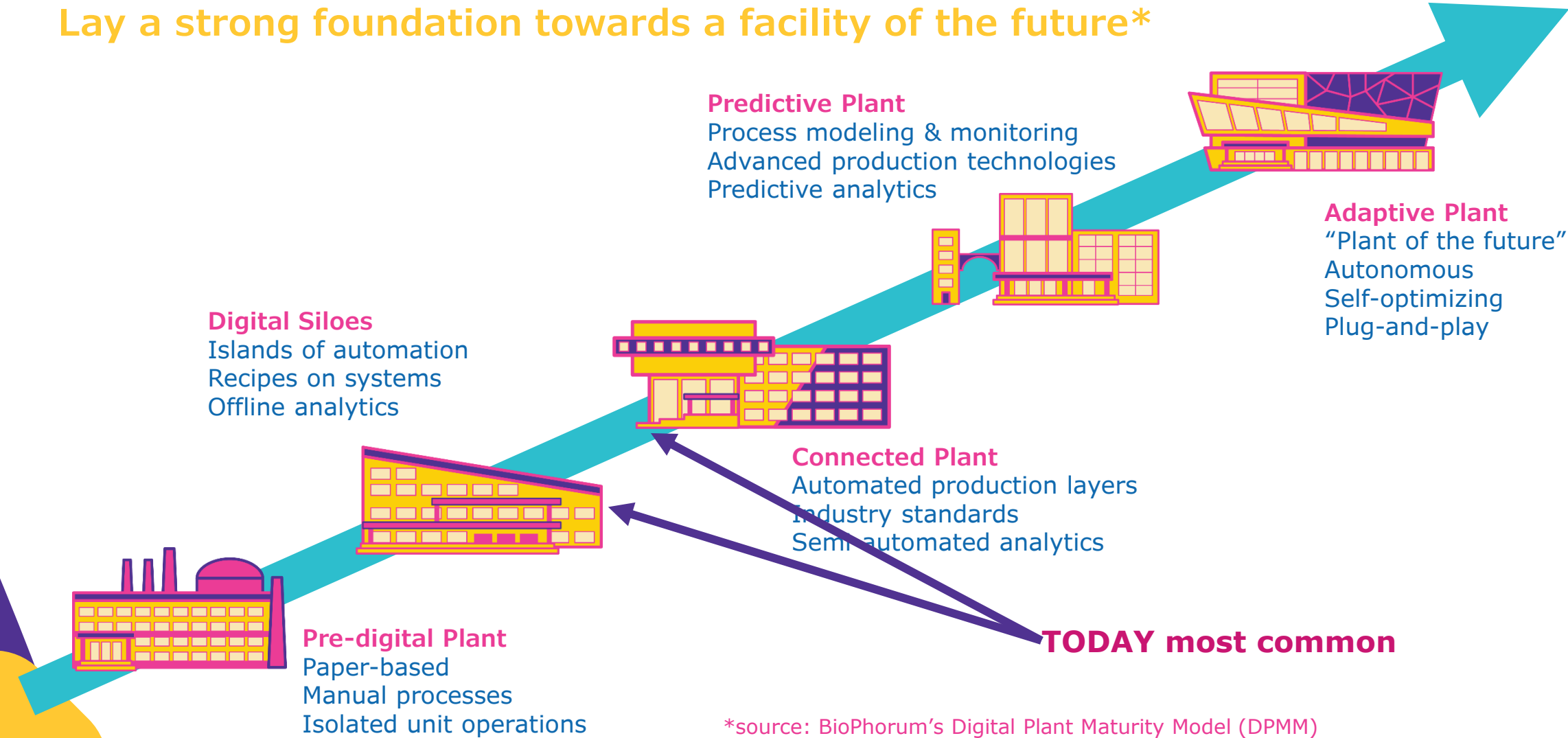


Parenteral Formulation plant

Source: ISPE; Pharmaceutical Engineering July August 2014. D. Wolton/A. Rayner; ISPE Online Nov 2019/2020 D. Wolton/ T. Rohrer

Begin Your Digital Transformation

Lay a strong foundation towards a facility of the future*



*source: BioPhorum’s Digital Plant Maturity Model (DPMM)

90%

less footprint

90%

Less capital

70%

reduction in construction time

60%

reduction OPEX

90%

Reduction in cost of quality

Paradigm Shift:
The **Factory of the Future** will require a transformation in how biologics are developed and manufactured

Process

Intensified

Connected

Continuous

Format

Single Use

Closed

Sterile

Analytics

Inline

Real Time

Predictive

Digital

Controlled

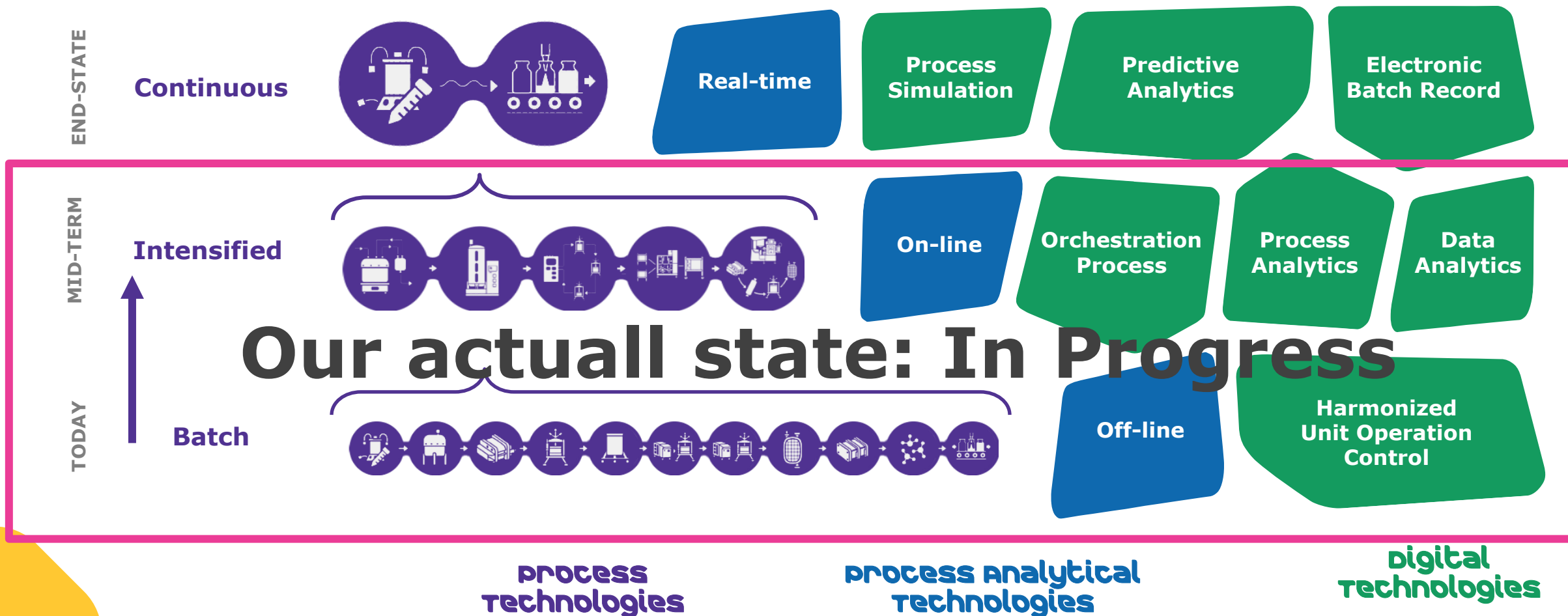
Integrated

Autonomous



How Do We Address The Need for Paradigm Shift?

Convergence of Evolving Process, Analytics & Digital Technologies





02 internal MERCK example

How to ensure sustainability in the frame of new Biomanufacturing facility ?



Total Surface:
2700m²

Investment : 30m€

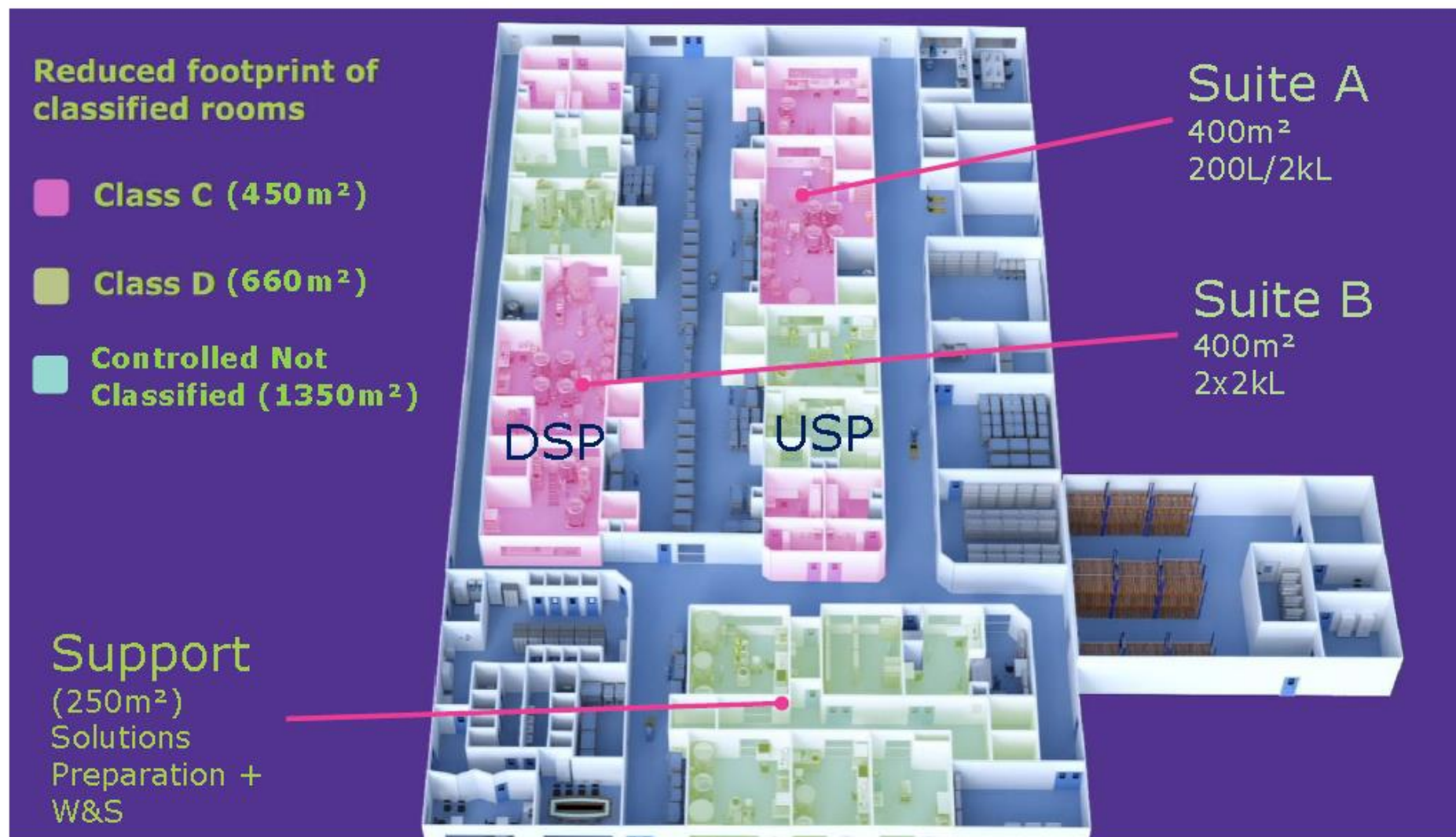
Mamalian Plateform

Scale:
200L/2KL/2x2kL

Capacity:
45batches/year

150 additional
employees

Sustainability by Design Overall Concept



USP Martillac
2018



DSP Martillac 2018



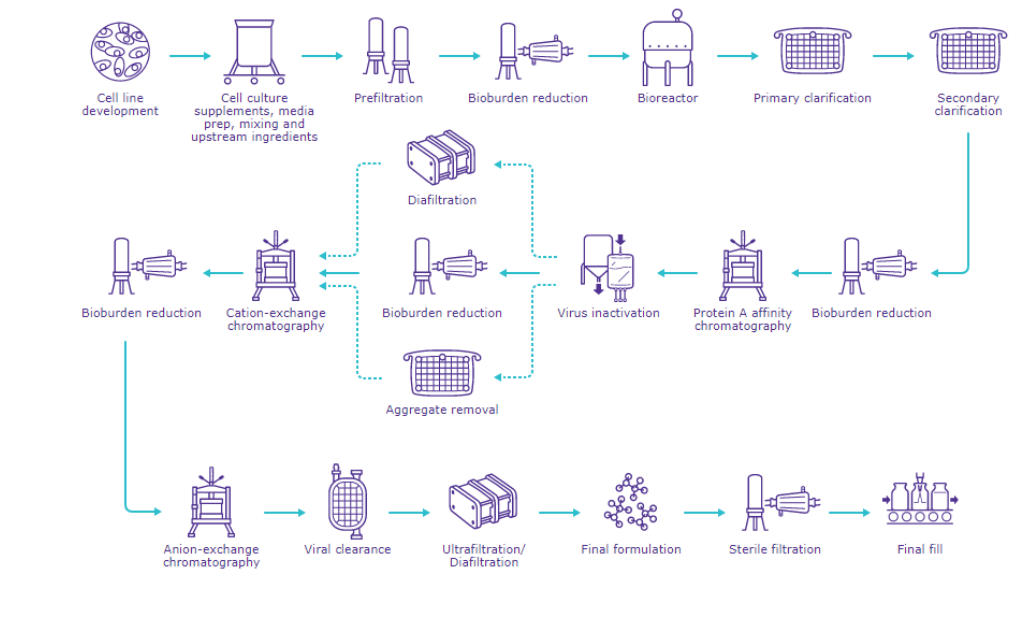
DSP



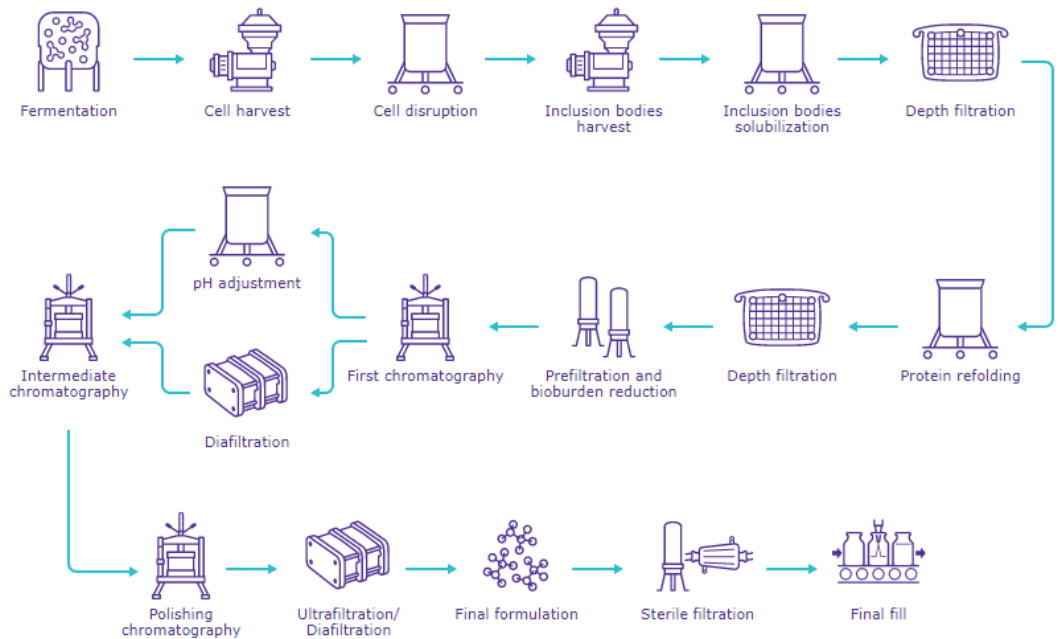
03 Multi Modality playground

THE biotech processes

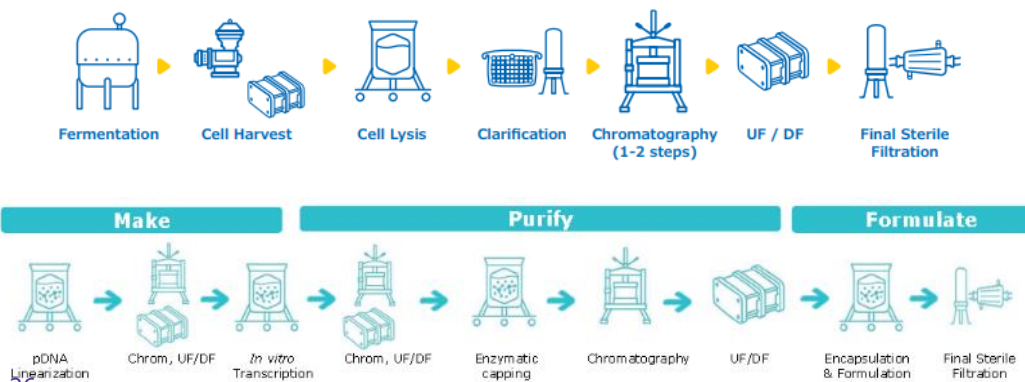
Monoclonal Antibody template



Microbial Process template



pDNA and mRNA template



AAV Process Flow

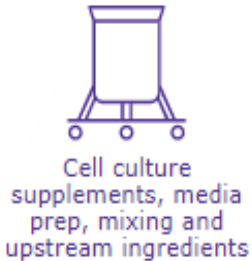


The Merck Purification Systems portfolio is agnostic to the modality

UPSTREAM

Cell Culture Media Preparation

- mAbs
- VGT
- Microbial
- Vaccines



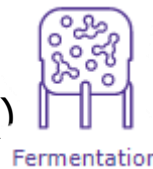
Mammalian Cell Culture

- mAbs (CHO)
- Some VGT (HEK 293)
- Vaccines (MDCK)



Bacterial Cell Fermentation

- Microbial (*E.coli*)
- pDNA (*E.coli*)



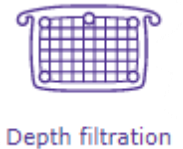
Cell Lysis

- *E.coli*
- Some AAV



Clarification

- mAbs
- Microbial
- Vaccines
- Plasma
- VGT



The Merck Purification Systems portfolio is agnostic to the modality

DOWNSTREAM

Nucleic Acid Digestion

- VGT
- Vaccines



Affinity Chromatography

- mAbs
- VGT



IEX Chromatography

- mAbs
- Microbial
- Vaccines
- Plasma
- VGT
- ADC



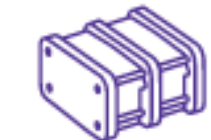
Formulation and Filling

- mAbs
- Microbial
- Vaccines
- Plasma
- VGT
- ADC



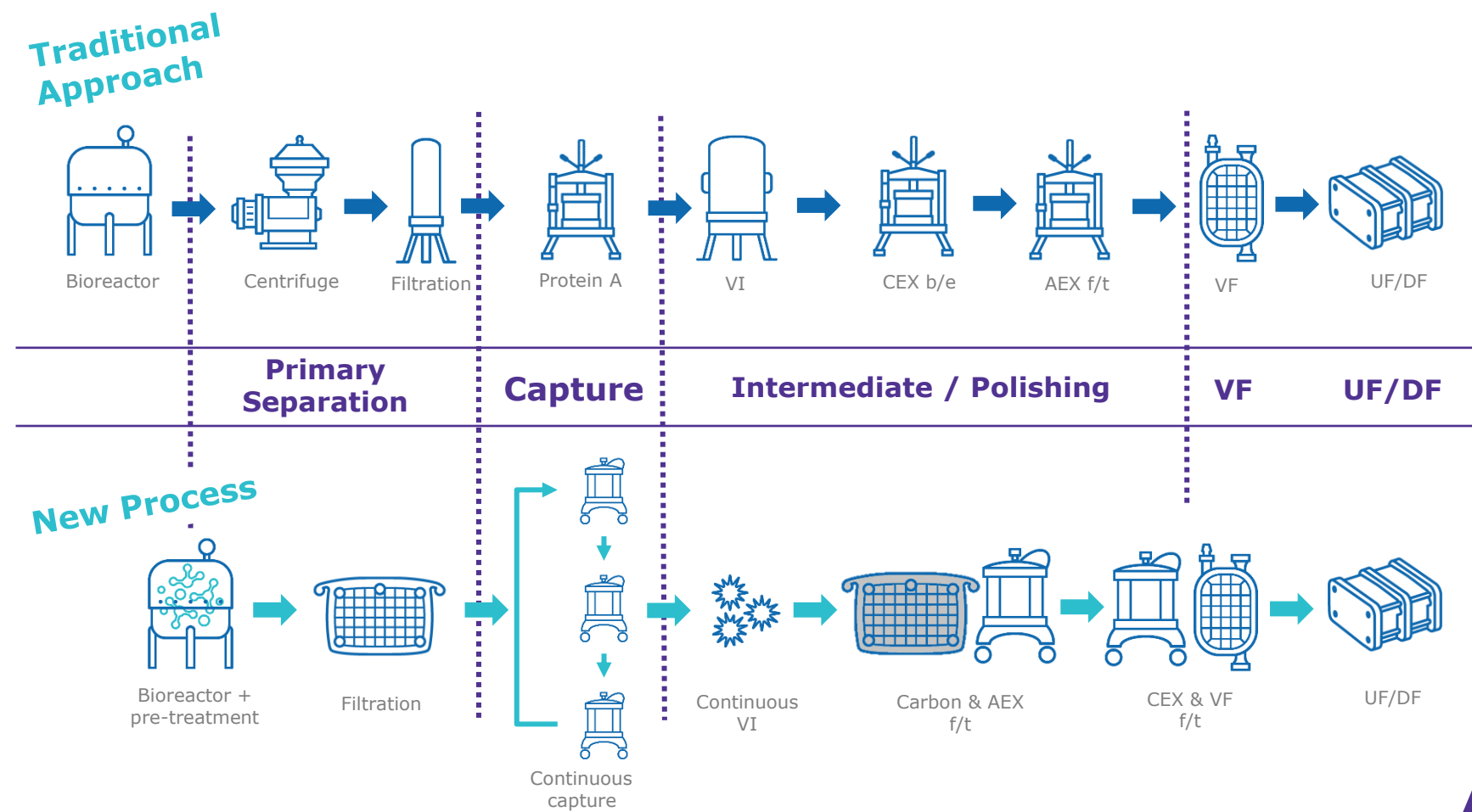
TFF

- mAbs
- Microbial
- Vaccines
- Plasma
- VGT
- ADC

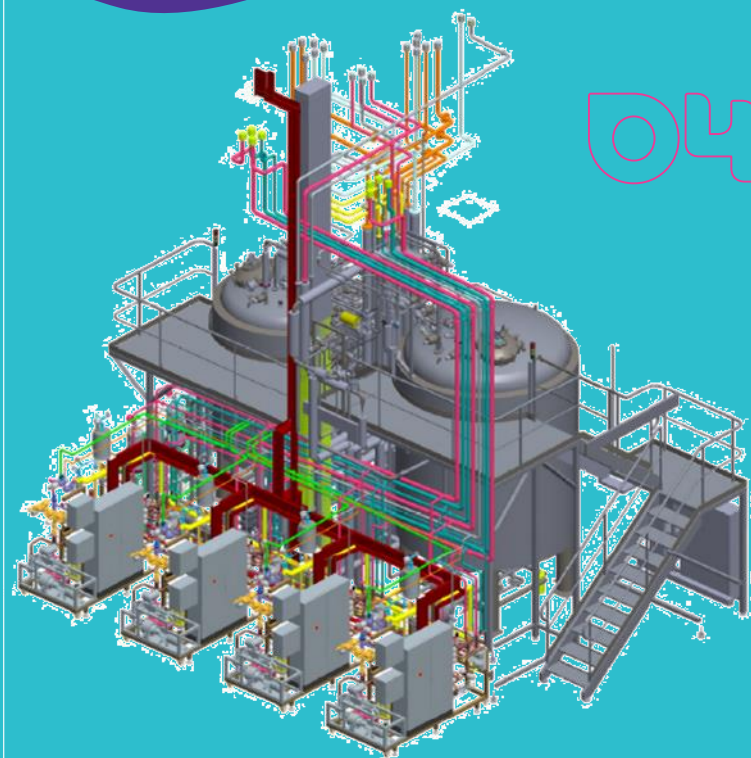


Optimizing Biopharmaceutical Downstream Processing

Moving from batch chromatography to continuous

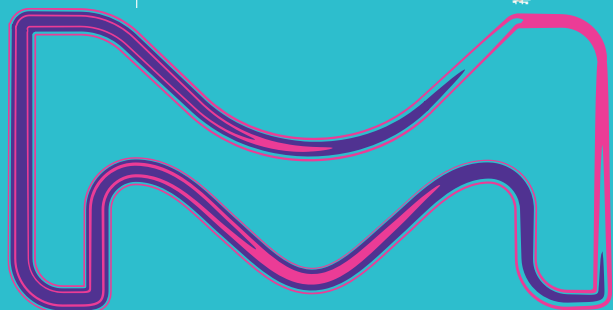


The first step towards a continuous downstream purification train



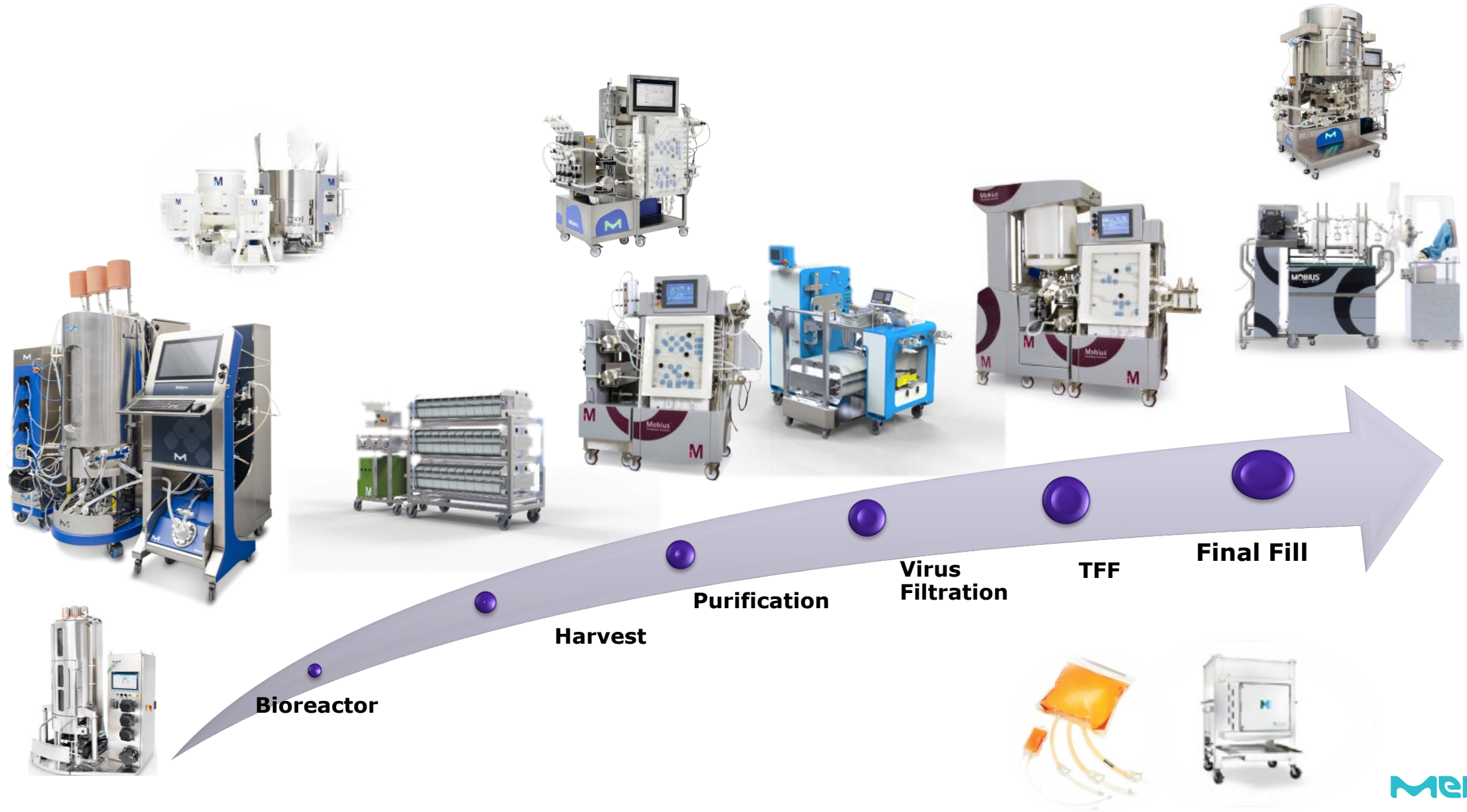
04

50 years experience
Enabling Multi-use and
single-use facilities

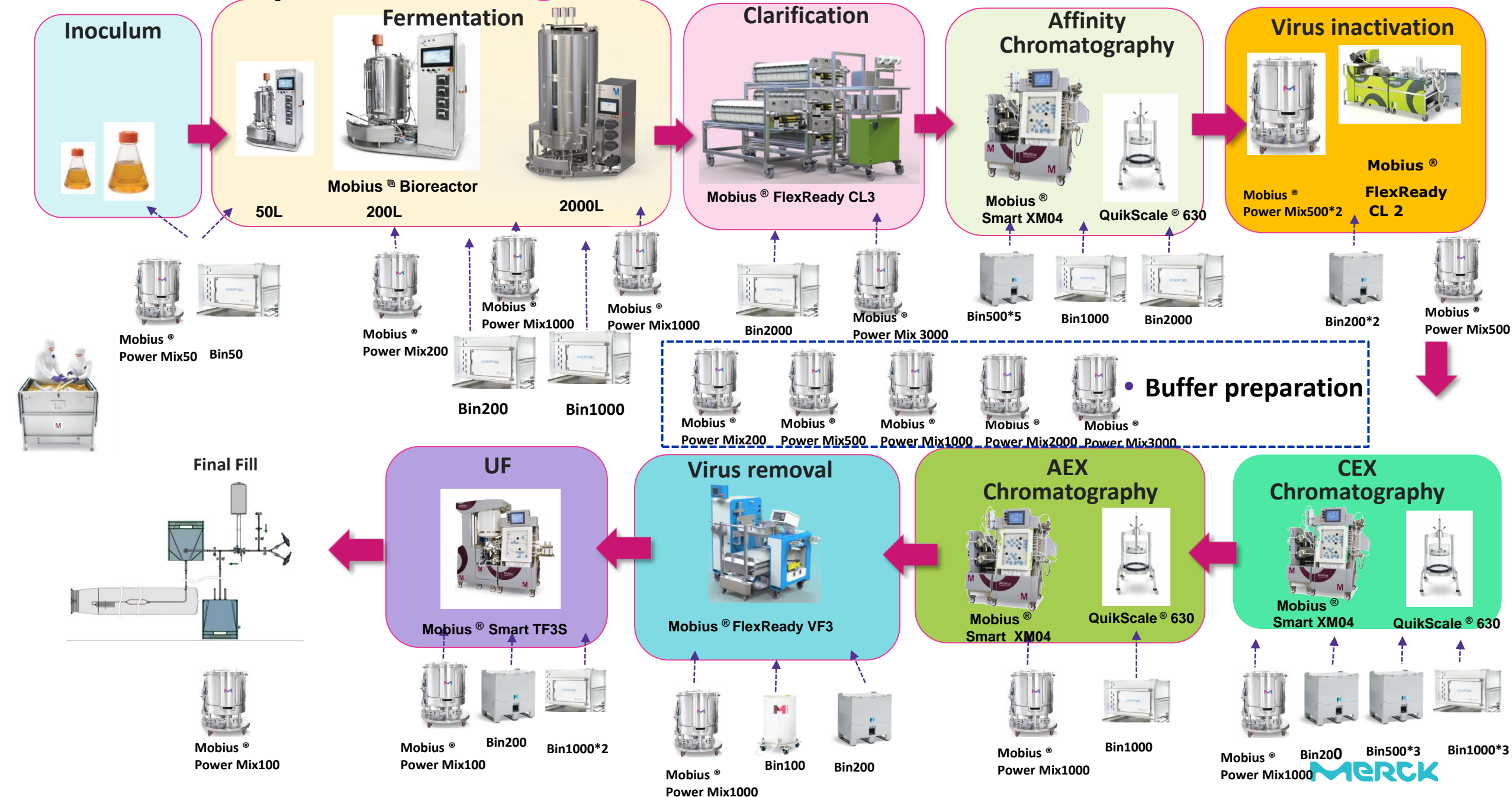


MERCK

Complete Single-use Process up to 2000 L Scale Harmonized fluid handling



Mab Process template -2000L Single Use version





06 MERCK'S SYSTEMS PORTFOLIO - A SOLUTION FOR EVERY STEP

USP

Mobius® single-use Bioreactors: Scalable from 3L to 2000 L

- Easy bag installation: only 2 operators and <2h for large SUBs
- Optimal mixing capabilities with bottom-mounted impeller and baffle : high k_{LA} with less shear
- 5:1 turn-down ratio : allows maximum flexibility in working volumes
- Demonstrated scalability from 3L up to 2,000L scale



Mobius® Single-Use Bioreactor Platform

Mobius® 50L Bioreactor

Oversized Vent filter heater (up to 80 LPM at 17 mbar)

Primary & back-up vent connections
on bag assembly for added security

6 x MFCs

HMI with CCP software:

15" Siemens Touch Screen

Bioreactor Tank

- Fully jacketed tank (incl. base)
- Door
- Viewing window

PC : B&R APC910

PLC : Allen-Bradley

I/Os : Murr Elektronik

Gateway

(field bus exchange)

UPS

Bottom Mount Agitation

- Levitating impeller
- 5:1 Turn down

4 pumps:

Watson Marlow
(several options)

Mobius® SensorReady Monitoring & Sampling Loop

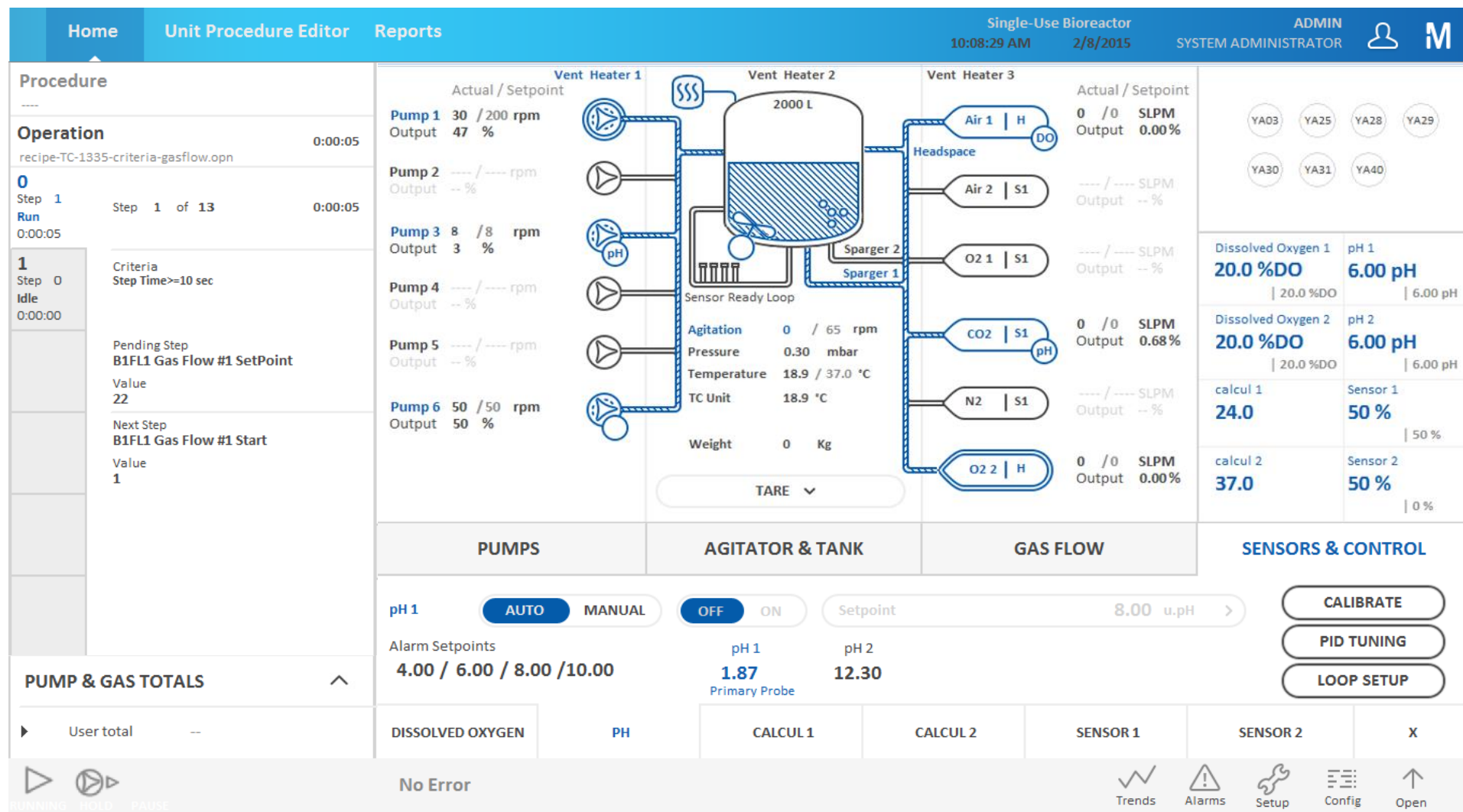
Positioned for easy access

Flexibility in number of probes, without customization



Mobius® Single-Use Bioreactor Platform

CCP® Software: designed for intuitive navigation



07

MERCK'S SYSTEMS portfolio - A solution for every step

USP
perfusion
cellretention

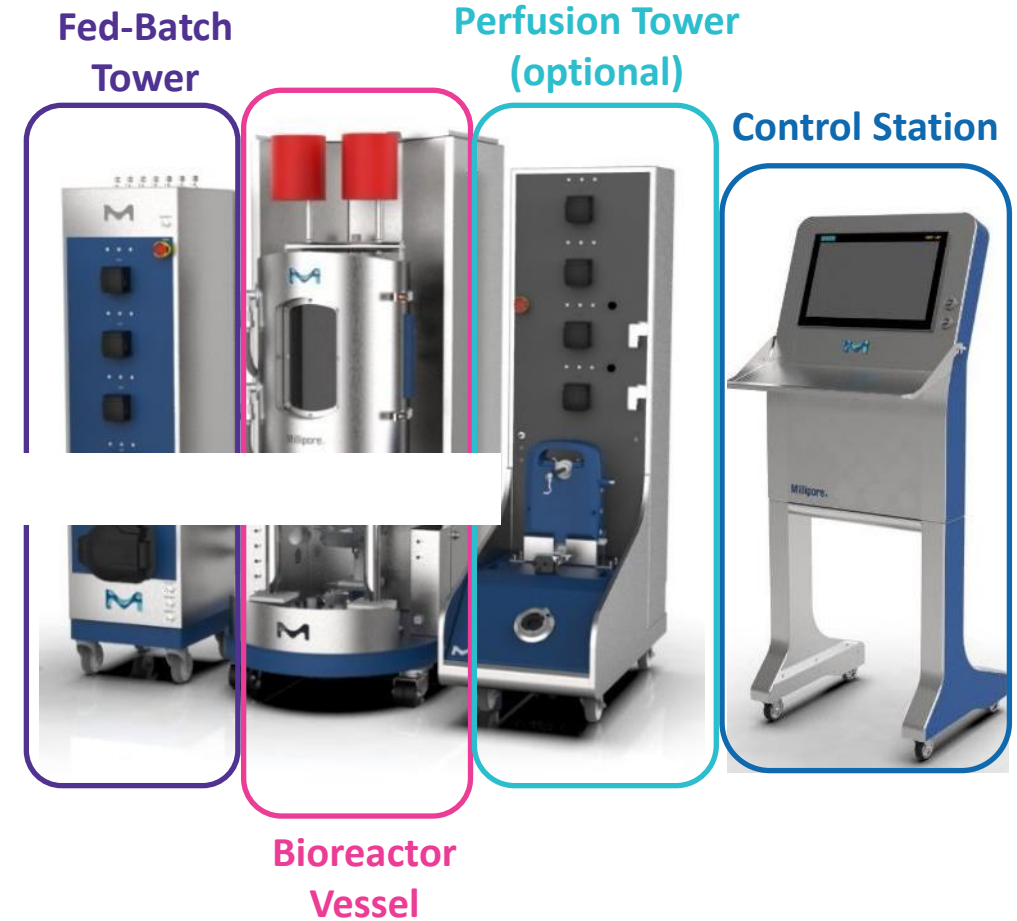
New **Mobius® iFlex** Bioreactors

Flexibility to operate in fed-batch or perfusion mode

- Can be used for **fed-batch or perfusion** (perfusion tower can be purchased later)
- Perfusion tower uses Cellicon® Filter Assembly, controlled by the bioreactor software – one only HMI

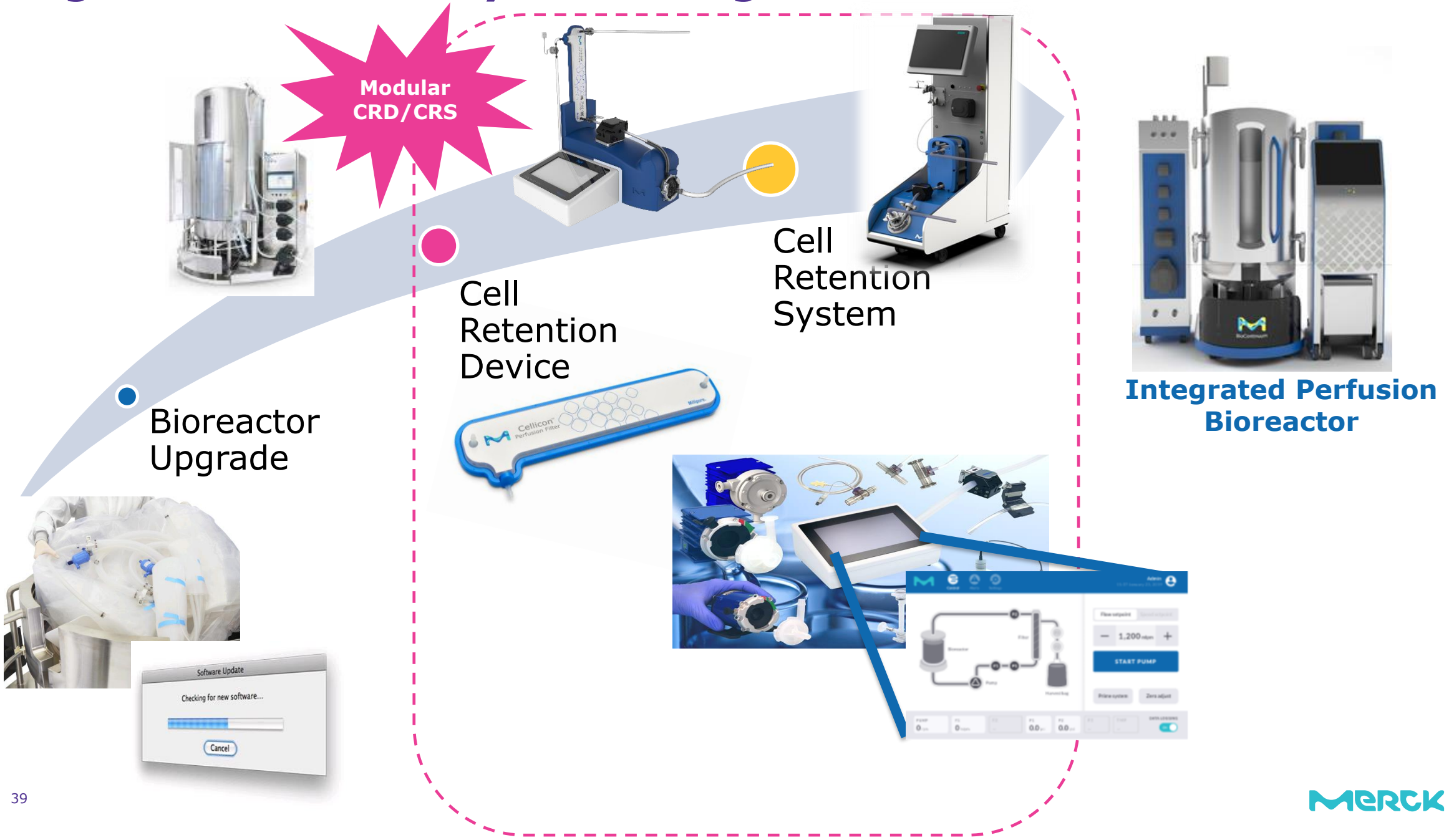
Highlights:

- Use of **Ultimus® film** for the bag to reduce leakage
- pH, DO, VCD and pCO₂ probes directly inserted into vessel (choice for MU or SU probes for pH, DO and VCD)
- **Bag ready to connect to MAST and ProCellics**
- **New impeller and sparger design** to support higher cell densities and longer cell culture duration
- **3 spargers in one bioreactor bag** :
 - ✓ sparger 1 = open pipe
 - ✓ sparger 2 = drilled-hole
 - ✓ sparger 3 = high performance
- **Improved Mixing time** <40 secs
- **High Power per volume (P/V)** : up to 100 W/m³



Launching soon!

Integrated Perfusion Systems Program



Perfusion adoption starts in process development

Enabling perfusion PD is critical to realizing Merck's BRX GMP perfusion ambition

cell Line & Early
process
development



Breez
2 mL

Late process
development &
Tech transfer



**3L Mobius with
Cellicon CRS & CRD**
3 L

GMP perfusion portfolio launches 2022+



IPB
50 L



IPB
200 L



IPB
500 L

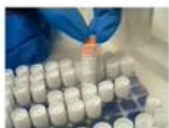


IPB
2000 L

process scalability: critical process parameters will match across platforms

engineering scalability: linear system design ensures successful scale-up

Early process development
Ecosystem offering



CHO cell lines incl.
CHOZN® GS



EX-CELL® & Cellvento®
Perfusion media

Late process development Ecosystem offering



EX-CELL® & Cellvento®
Perfusion media



3L Controller (Concept
Stage)



MAST Auto-sampling



Procellics Raman

erbi Breez supports scalable culture performance & cpps to L-scale BRX and CRS

iFlex systems overview

Batch-Fed Batch and perfusion runs



Performance Specifications

Attribute	Targeted Specification
Cell Density	100-200 e6 cells/mL
Operating duration	30 days continuous (nice to have : 40 days)
Impeller	Bottom mounted impeller (15°)
Mixing	Mixing Power per volume (P/V): 15 to 100 W/m³
Mixing	Impeller tip speed < 2,5 m/s
Mixing	Mixing time <40 secs
Spargers	3 spargers in one bioreactor bag : - sparger 1 = open pipe (1.5mm) - sparger 2 - sparger 3
Gas exit velocity	30 m/s at slpm for max kLa (spargers design criteria)
Oxygenation	kLa: ≥ 40 h⁻¹ in all sizes at a defined P/V and vvm, ideally ≥ 50 h⁻¹
Perfusion range	0.25 to 3 VVD
Perfusion device	Bioreactor can be used with CRD or ATF perfusion devices
Perfusion Tower	Optional Perfusion Tower incl. Cell Retention System & Device, fully integrated (HW, FLW and SW)
Perfusion Tower	Perfusion Tower can support CRD assemblies for N-1 and N applications

Perfusion Tower



Perfusion Tower

- Can be purchased after initial PO, configurable
- 2 optional additional pumps (e.g., cells bleed)
- SU flow sensor on perfusion medial in line
- Cell Retention components: centrifugal feed pump, feed flow sensor, CRD, 3x pressure sensors, peristaltic permeate pump and SU permeate flow sensor

Perfusion media in pump and SU flow sensor

Perfusion permeate pump and SU flow sensor

CRD retentate pressure sensor (retentate line back to bioreactor bag)

Small addition (option)

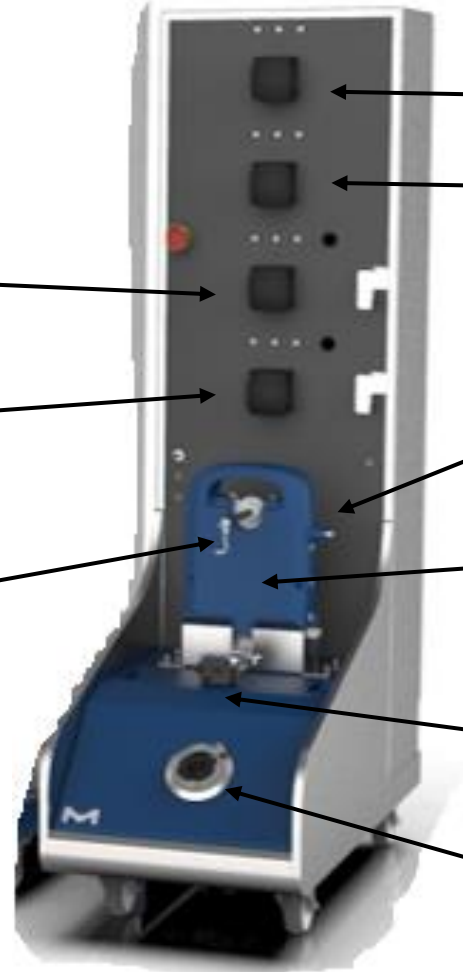
Cells bleed (option)

CRD permeate pressure sensor

Cell Retention Device (CRD)

CRD feed flow and pressure sensors

CRD feed pump (feed line from bioreactor bag)



Mobius Breez System

Hardware and Consumables



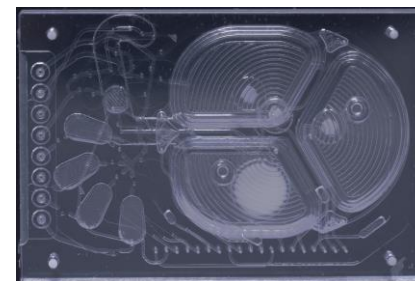
Complete System

- Basestation Hub that can hold up to 4 PODs
- CO2 Sensor Box
- PODs – environment control for bioreactor



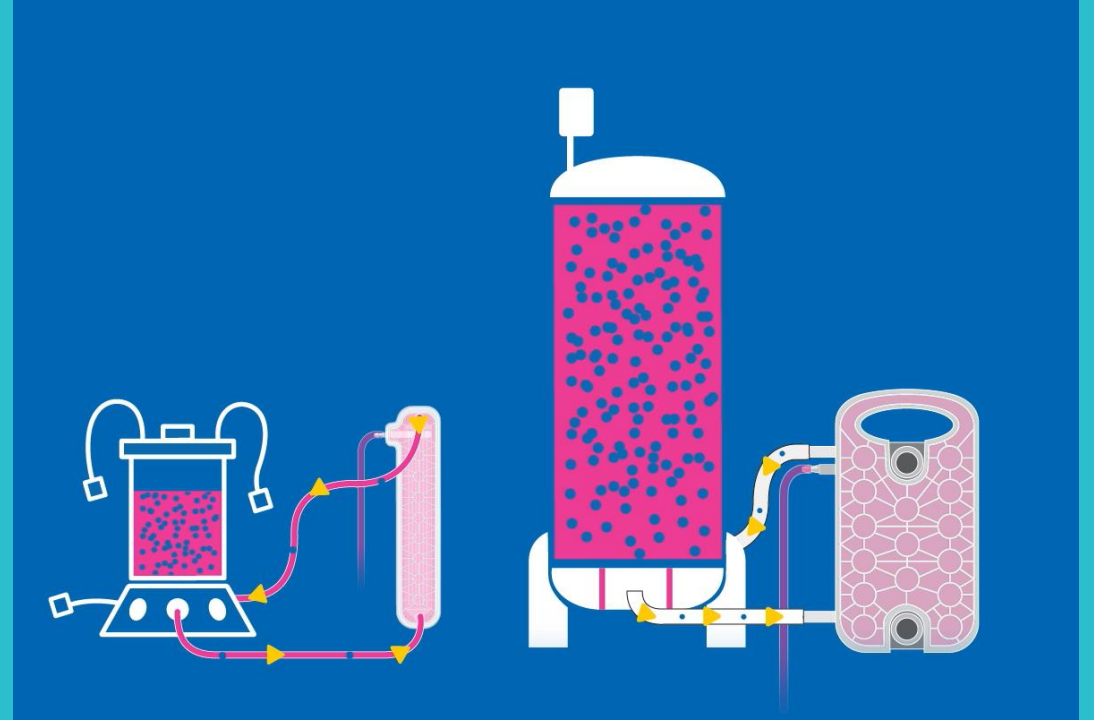
Complete Consumable

- Fully integrated –
- bottle rack / bioreactor
- Sterile
- Functionally closed



Microbioreactor Cassette

introducing the
cellicon® cell
retention solution!



MERCK

Cellicon® Cell Retention Solution

Cellicon® Filter Assembly

- Single-use, closed, gamma-irradiated assembly
- Flat-sheet tangential flow design
- Durapore® 5 µm membrane

Cellicon® Controller (lab scale)/Mobius® Cell Retention System (process scale)

- Allows for real-time process data
- Recirculation flow control, perfusate control (process scale)
- Intuitive software
- Remote connection capability

Bio4C ACE™ Software

- Complete control of process-scale Cellicon® Cell Retention Solution through interactive P&ID
- Recipe driven automation eliminates manual tasks
- Remote monitoring of process through browser-based interface

Target Applications

- Upstream process intensification
- Monoclonal antibodies and r-proteins



Lab Scale



Process Scale

Scalable Offering for Perfusion up to 2000 L

A complete solution available across the single-use bioreactor size range for perfusion applications



Bioreactor Size	3 L	50 L	200 L	500 L	1000 L	2000 L
Membrane Area (m ²)	0.01	0.2	0.8	1.9	3.8	7.6
Levitronix® PureLev® SU Pump	i30	i100-SU	i600SU	i600-SU	2000SU	2x 2000SU
Connection Feed & Retentate Lines	SW	SW/AQ	SW/AQ	SW/AQ	SW/AQ	SW/AQ
Connection Perfusate Line	SW	SW	SW	SW	SW	SW
Recommended Crossflow Rate (L/min)	0.08	1.57	5.7	14	28	2 x 28
Recommended Max Flux (LMH)	20	20	20	20	20	20
Filter Hold-Up Volume (L)	0.014	0.24	0.73	1.7	3.5	7
Scale	PD/lab	Production				

SW: sterile welding

AQ: AseptiQuik® sterile connector

Cellicon® Filter Assembly Family

Cellicon® Filter Assembly Contains:

- Flat sheet tangential flow filter designed for robust performance, easily scales across different process volumes
 - Lab scale: 1-3 L
 - Process scale: 50, 200, 500, 1000, and 2000 L (2 x 1000 L filters)
- Single-use components including:
 - Low shear levitating centrifugal feed pump
 - Pressure sensors for precise monitoring of filter performance
 - A perfusate flow sensor on process-scale assemblies for CSPR control
- Sterile connection methods to bioreactor:
 - Sterile weld (all sizes)
 - AseptiQuik® G connectors on feed and retentate (process-scale only)



Lab Scale



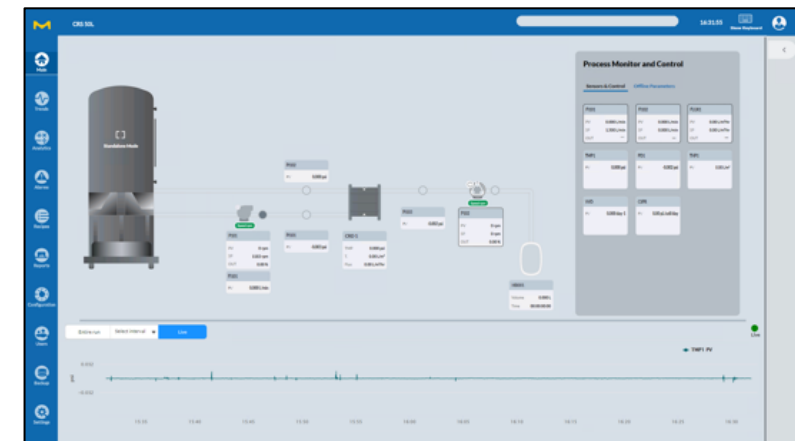
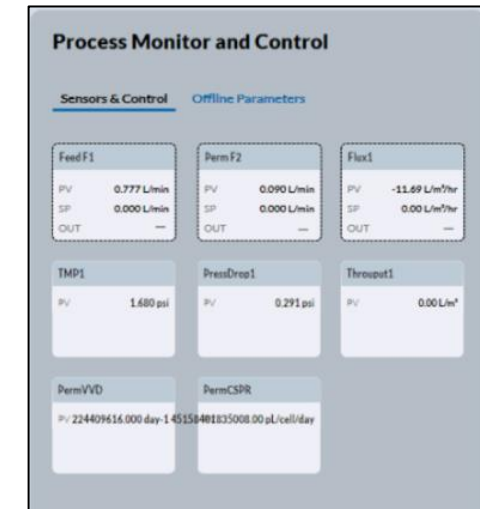
Process Scale



Mobius® Cell Retention Systems

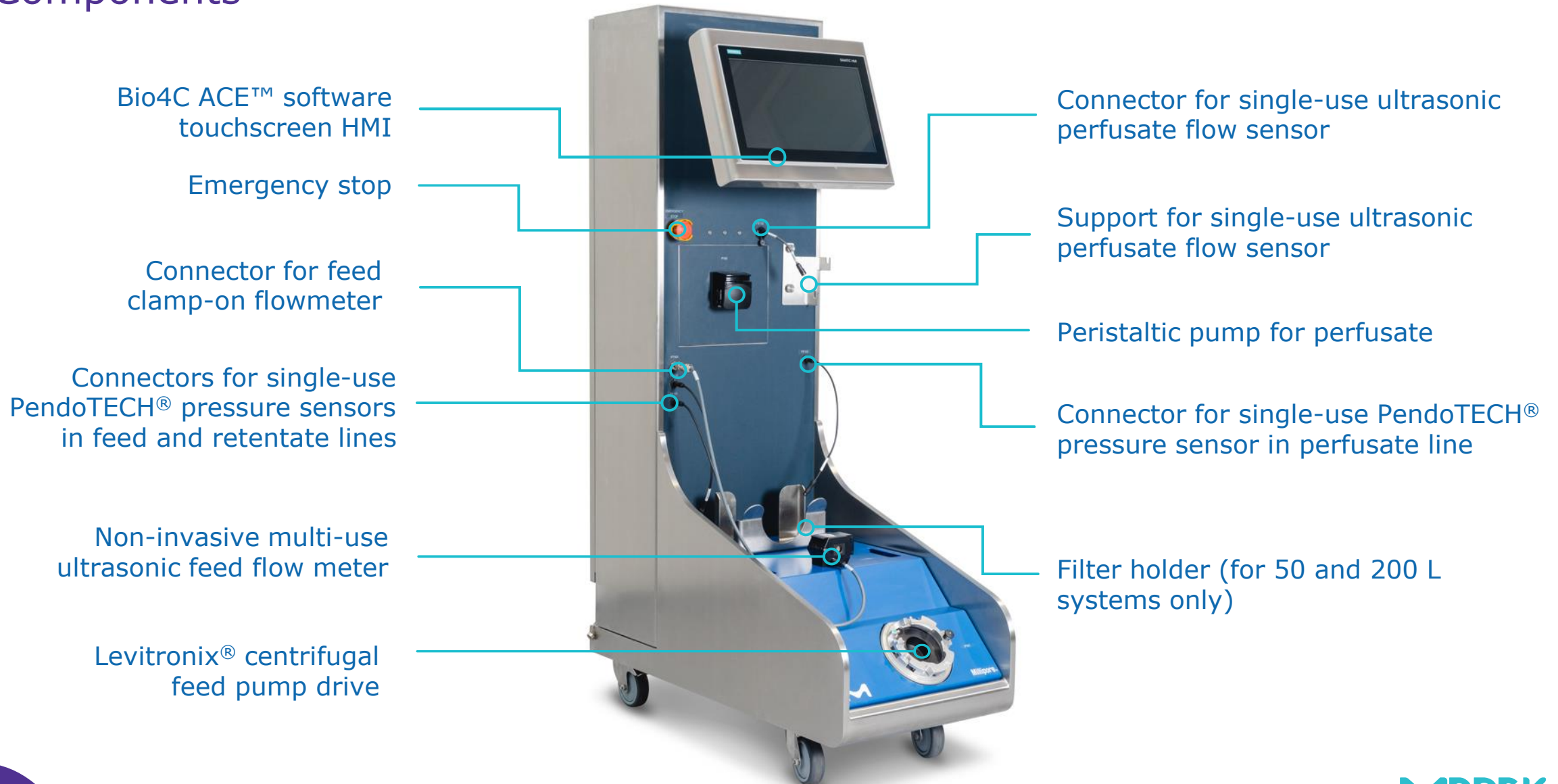
Process Scale

- System designed to operate the process-scale cell retention device, containing:
 - a Levitronix® centrifugal feed pump drive
 - a non-invasive multi-use clamp-on ultrasonic feed flow meter
 - a peristaltic pump for perfusate
 - a connector for single-use ultrasonic flow sensor for perfusate
 - connectors for single-use pressure sensors in feed, retentate, and perfusate lines
- Bio4C ACE™ control software provides monitoring of all process parameters and automated control
- Bio4C ACE™ software supports the industry standard EtherNet/IP connection which allows data exchange with other software and systems



Mobius® Cell Retention Systems

Components



Cellicon® Cell Retention Solution

Features

Constant channel height and path length

The Cellicon® filters maintain feed channel height and path length - an advantage of the flat sheet design over many of the hollow fibers currently available in the market

5 µm hydrophilic Durapore® membrane

Improved membrane efficiency

Low shear levitating pump

Lower risk of cell damage from shear stress

Intuitive Bio4C ACE™ software

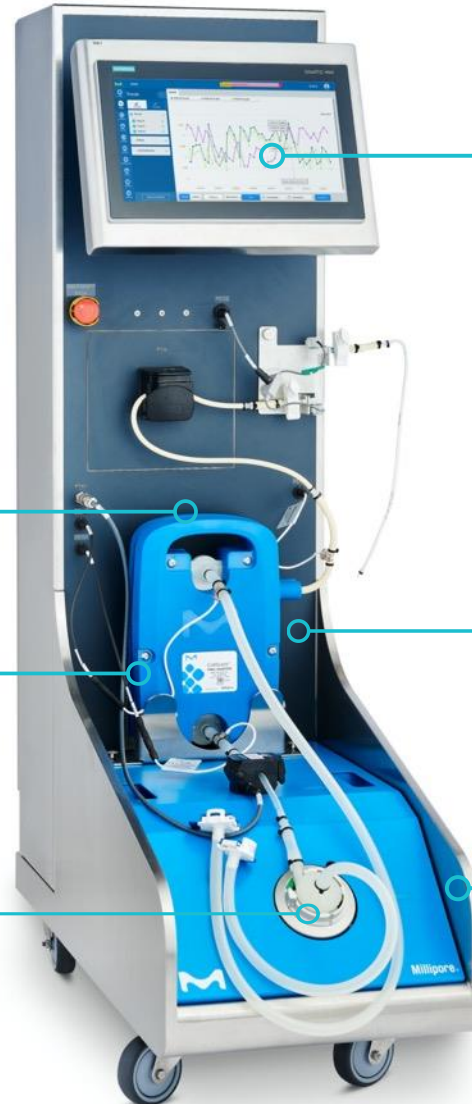
Monitor and control all process parameters in the touchscreen HMI or from anywhere through a browser-based application. Visualize trends, manage recipes and reports, and set control loops and alarms.

Single-use assembly, ready to use

Gamma-irradiated assembly, with C-Flex® tubing and AseptiQuik® connectors. Filter does not require flushing (dry).

Integrated instruments and minimum facility requirements

The system simply requires a power supply (no pressurized air/vacuum pumps are needed), and it integrates pressure and flow sensors to fully control and automate a perfusion process

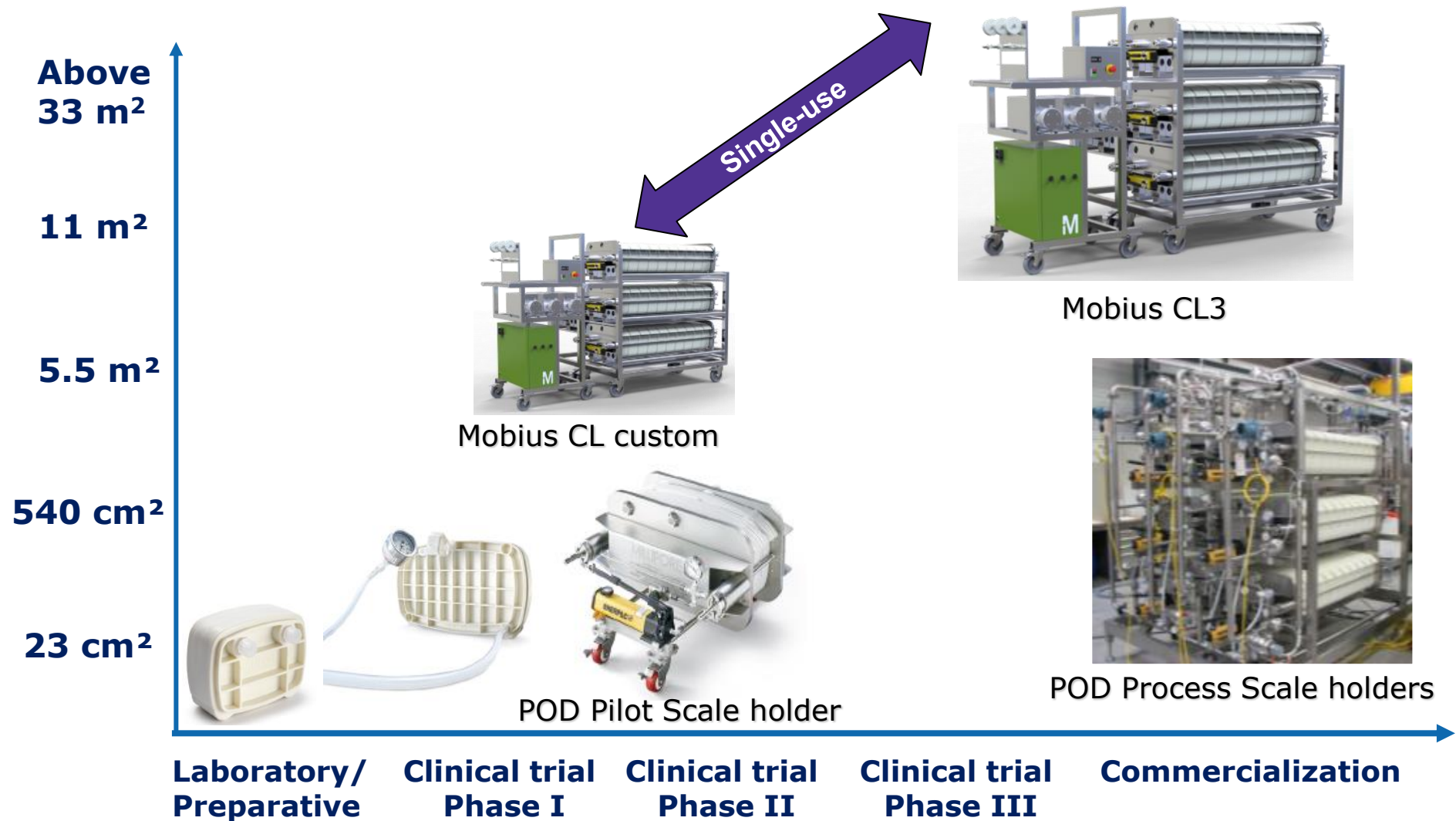




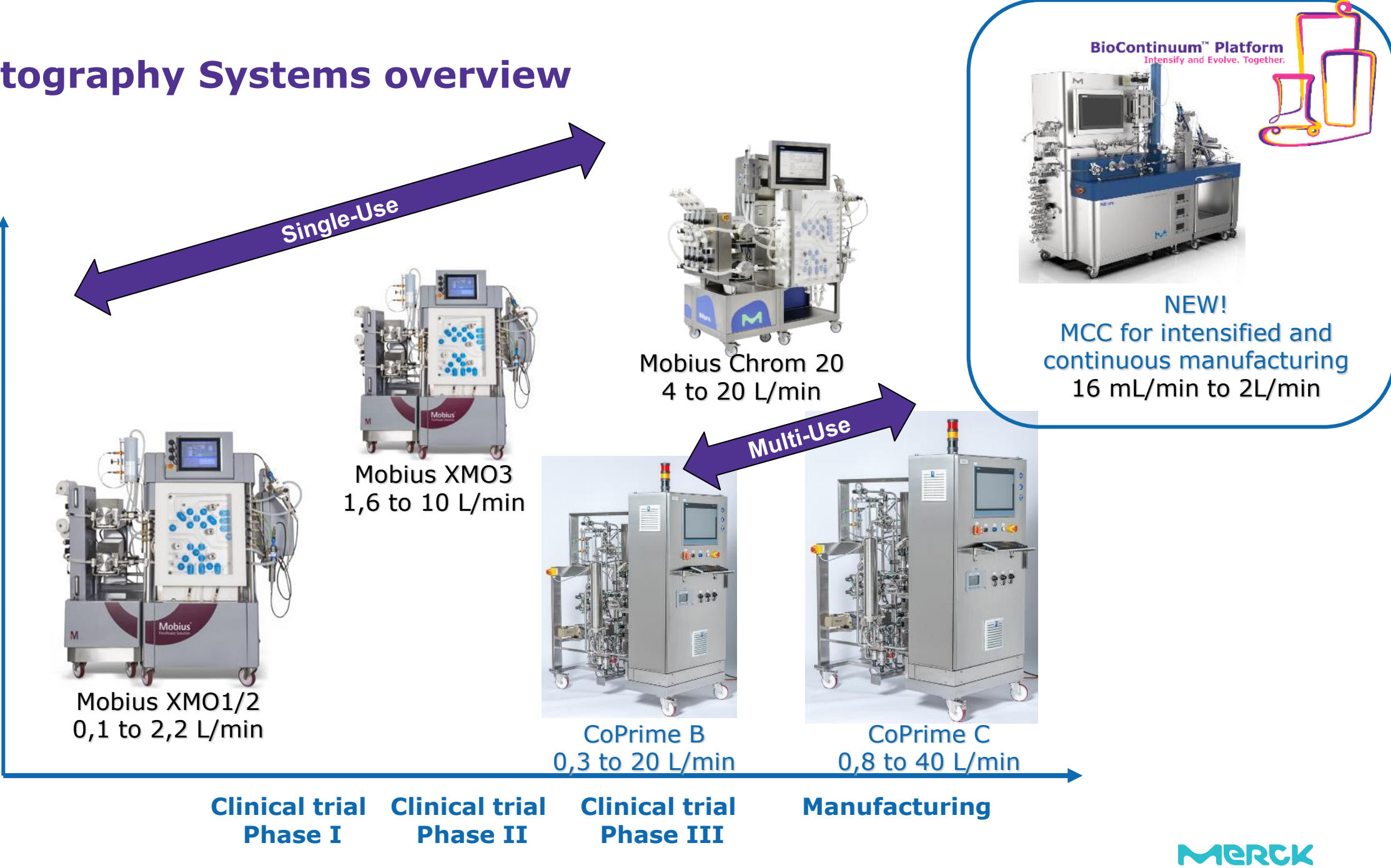
08 MERCK'S SYSTEMS portfolio - A solution for every step

DSP

Clarification systems overview



Chromatography Systems overview



Single-use chromatography systems

Mobius® FlexReady XMO family

XMO1/2



0,1-**2,2**L/min
6 – 132 L/h

XMO3



1,6 - **10**L/min
96 – 600 L/h

Chrom20



4-**20**L/min
240 – 1200L/h

NEW!

MCC for intensified and
continuous manufacturing



16 mL/min to 2000mL/min
1 to 120L/h

Single-use chromatography systems

Mobius® FlexReady Solutions Chromatography

- Dual 4-diaphragm Quattroflow 1200SU pumps
 - Individual & accurate pump control by 2x high-precision SU flowmeters
 - SU flowpath offering all functionalities: upflow, downflow, bypass,...
 - 2x 5 inlets, 3 outlets + drain
 - Instrumentation with same specification as used on MU skids:
Pre & Post pressure, conductivity, pH, and post UV 280+300 nm.
- ➔ XMO3 delivers 3% accuracy during linear & step gradient, within 10-90% range
- ➔ Your purification steps are reproducible, reliable, robust and productive !



Common control Platform® (CCP®) automation software:

- control of all pumps and valves
- recipe editing, storing and sharing
- compliant with GAMP 5 recommendations for automation software and FDA 21 CFR Part 11 requirements for electronic records and signatures.

Single-use chromatography systems

Mobius® Multi Column Capture System (MCC)



- **Fully automated for continuous bind/elute in intensified and continuous processing** (flowpaths evaluated for continuous processing for up to 20 days prior to exchange)
- Working with 3 columns in parallel
- Flow rate: 1 to 120 L/h (16 mL/min to 2000 mL/min)
- Using our CCP® software
- Flexware available in open or closed processing
- In-line buffer dilution (up to 6 buffers)

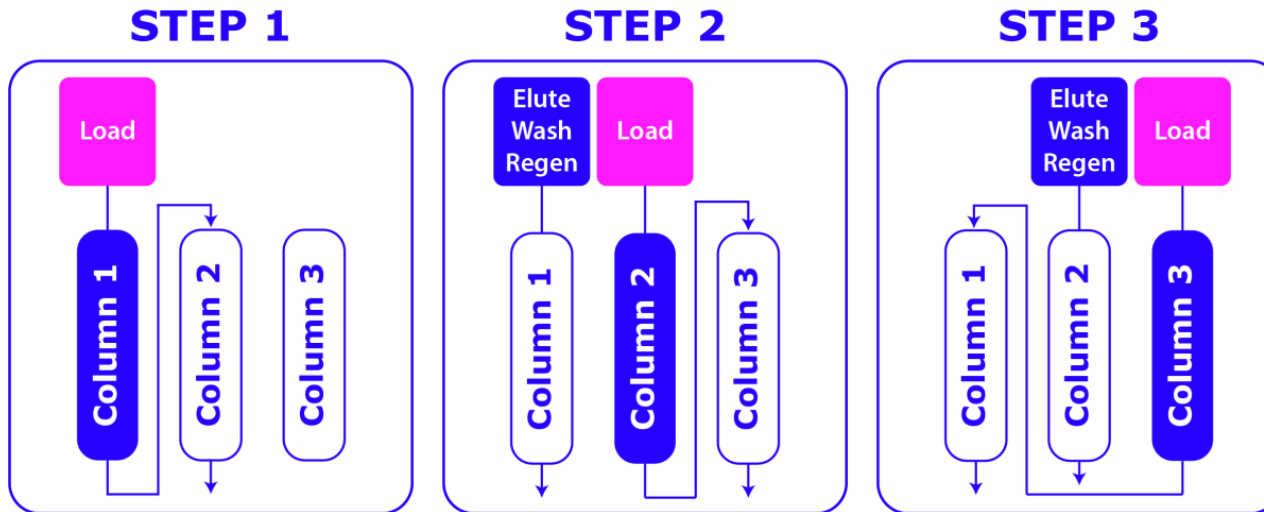
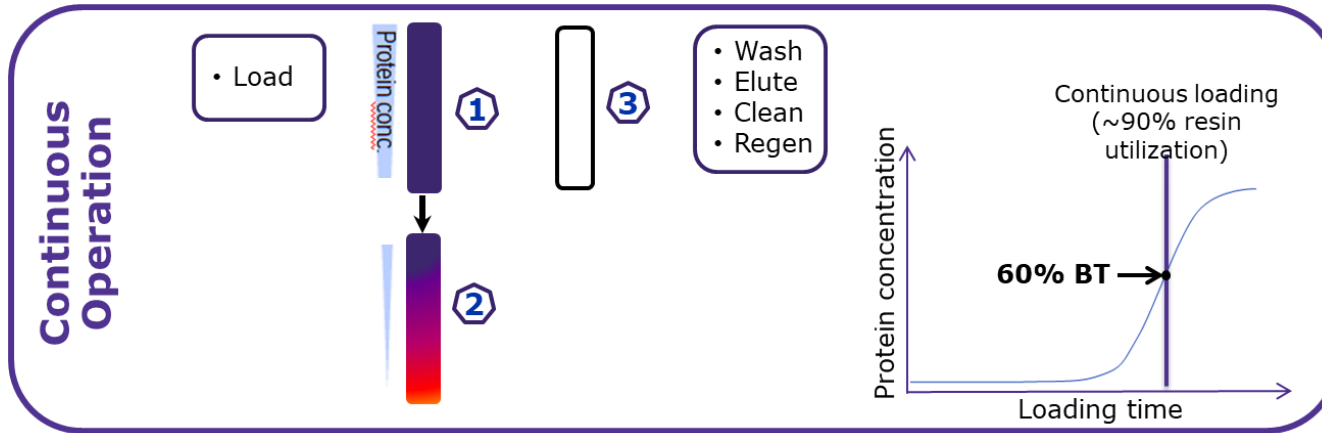
key benefits

- Reduced cost & prot A resin optimization (+ buffer consumption)
- Improved throughput & productivity
- High flexibility for intensification and continuous processes



Multi-Column Continuous (MCC) capture

Optimizes resin utilization and enhances productivity



1

High **flexibility for intensification and continuous processes.**

- 2 flexware offering (closed enabled)
- Broad range of flows pilot to production
- Inline buffer dilution capabilities

2

Prot A resin optimization and **reduced costs**

- Increased resin utilization
- Reduced buffer consumption
- Serial and parallel loading options

3

Improved **throughput & productivity**

- 200-2000 L (5g/L, 20h) or 3000 L (3g/L, perfusion)
- Intuitive software and self-adjustment to loading variations

Introducing the Mobius® Multi Column Capture System

Intuitive software

Predefined steps to ease recipe creation
Adaptation to feed variability

Inline dilution

Buffer concentrates line, WFI line
Ready to use buffer lines
Product line

Enables closed processing

Specific flowpath for closed operations

Scale-up / down

1-120 L/h on the same system

Service

Eligible to Service Reliance Plans

SU Instrumentation

All sensors / probes can be SU (including pH probe, option MU)

2 Processing modes

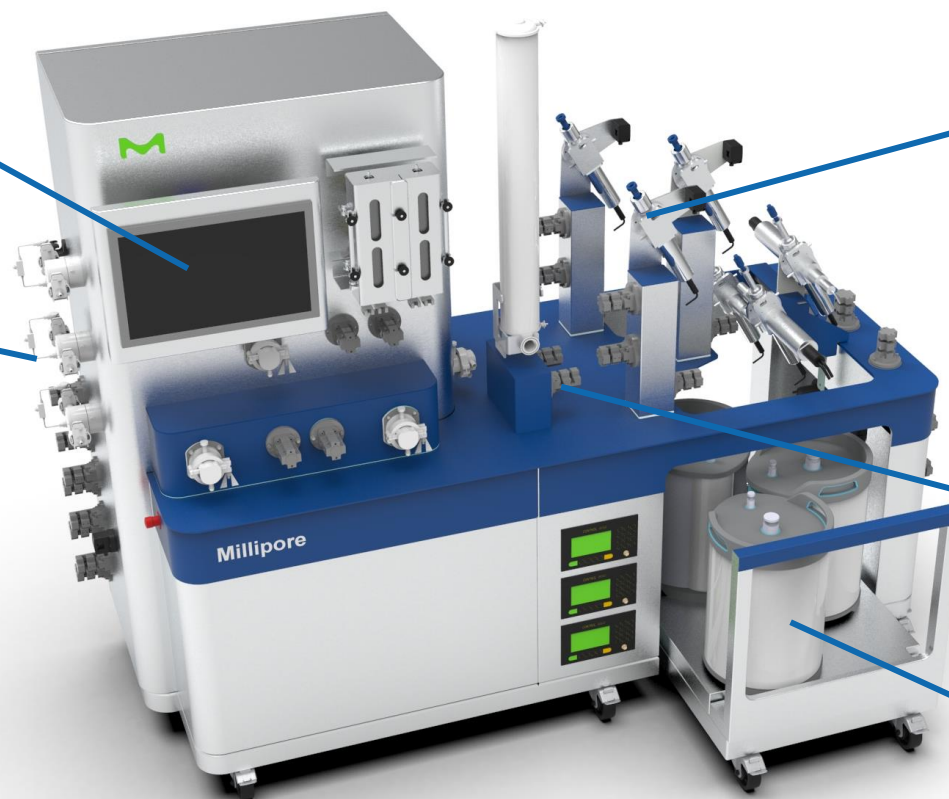
Series loading (main)
Parallel / batch (secondary)

Guided installation

Using color coding and 'signs' to ease flexware installation

Multi or single-use expandable accommodation

Using prepacked TRU columns or media in MU columns



System shown without flexware installed

Columns, media and concentrates for process intensification

Opus pre-packed column

Ideal for closed processing!

MCC can accommodate columns from 5 to 25 cm
Or: based on specific process parameters



Media and MU columns

For non-closed processing mode

Eshmuno® A resin

Packed in QuikScale® Chromatography columns



Buffer Concentrates

More for less volume and footprint

Reducing operational footprint especially for long-duration, large volume processing

3D presentation available for virtual 'demo'



Features:

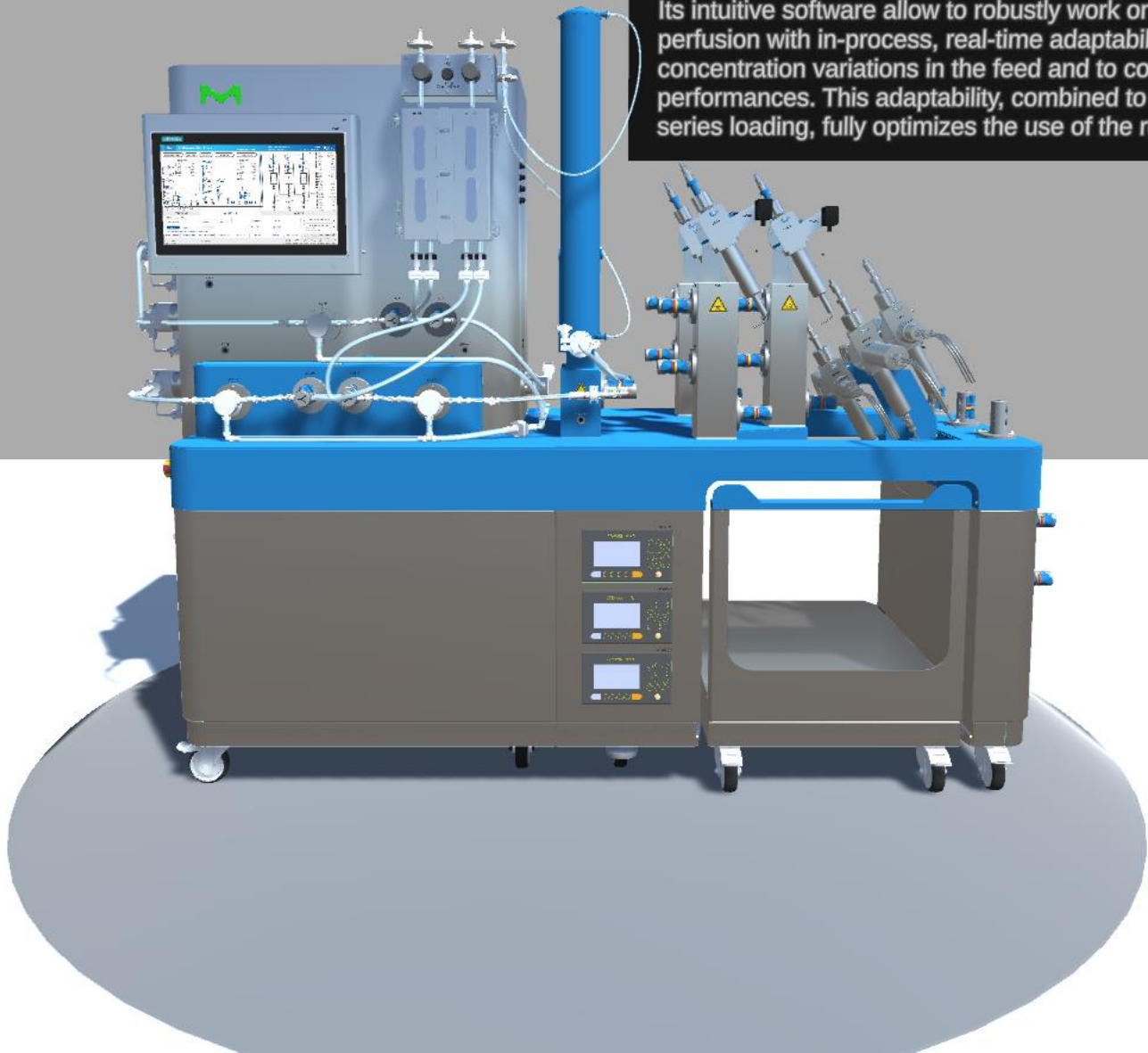
- Overview of the system with highlights
- Software highlights
- Operation modes
- Animations
 - Flexware installation
 - Bubble trap installation
 - Column


**Available for
Interphex only**


Soon Salestool!


The Mobius® Multi Column Capture System is using 3 columns with series loading for continuous chromatography.


Its intuitive software allow to robustly work on perfusion with in-process, real-time adaptability to concentration variations in the feed and to columns performances. This adaptability, combined to the series loading, fully optimizes the use of the resin.




View


Resources


Install
Uninstall


Components

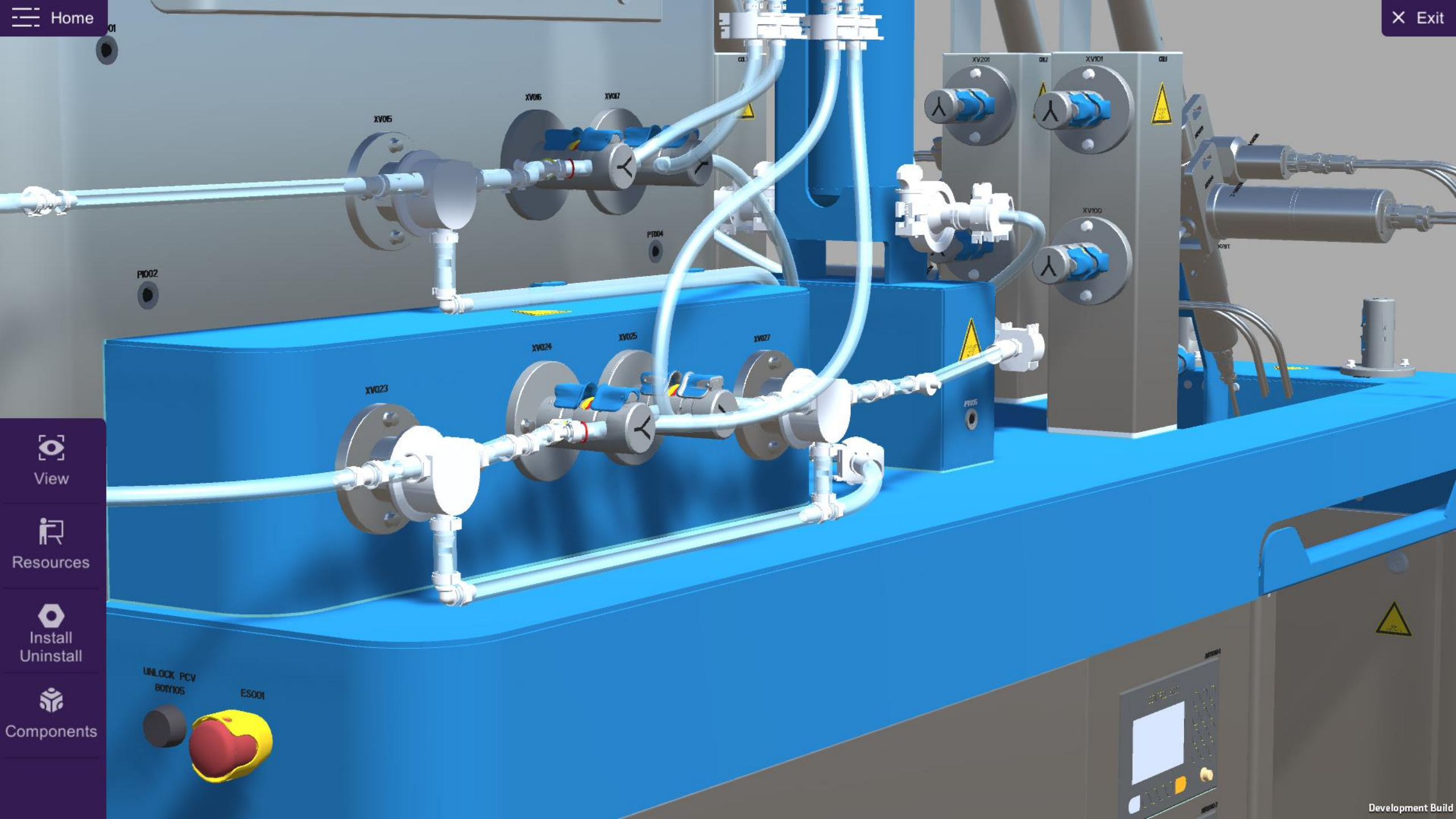
Viewpoints

Front

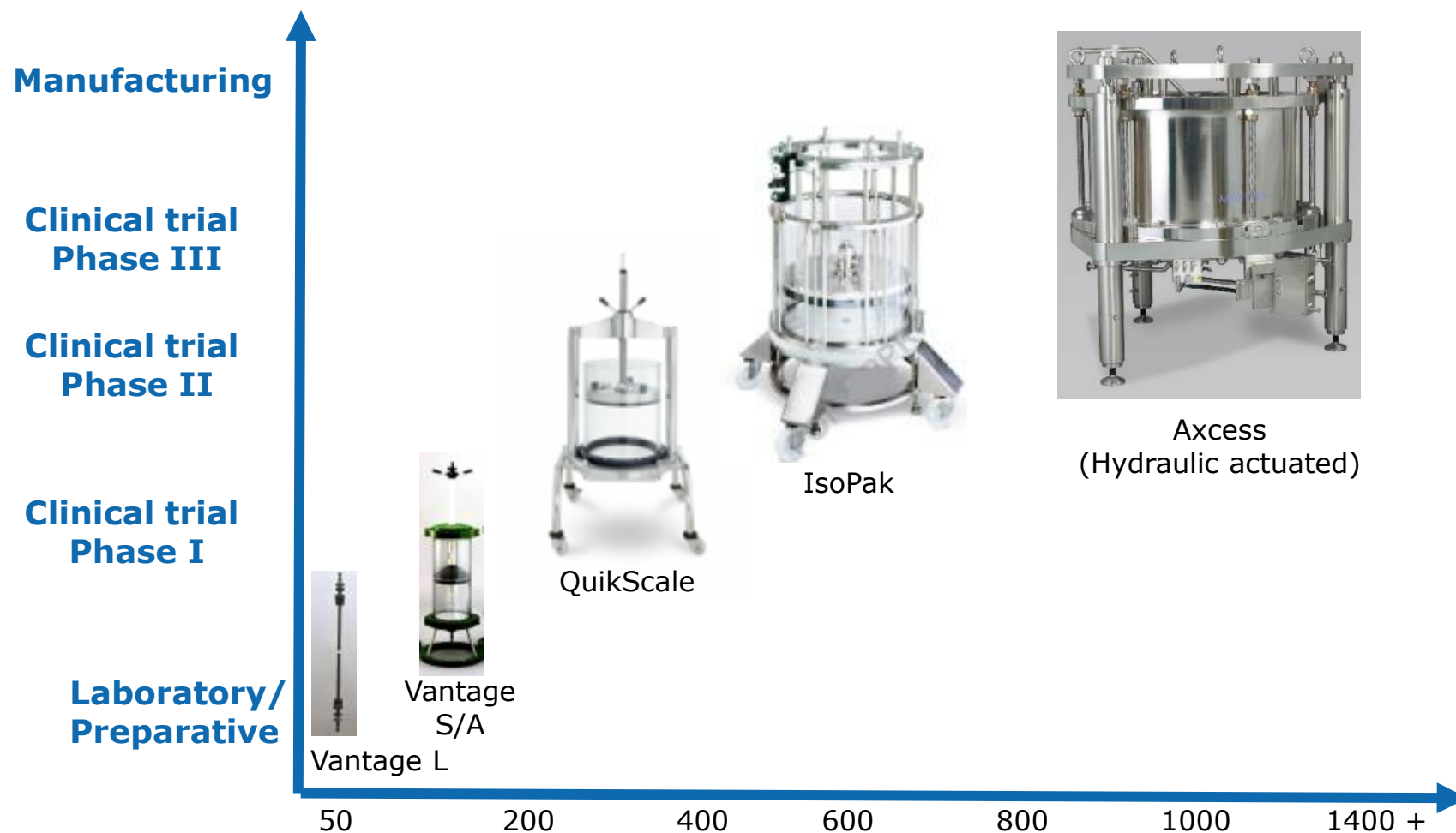
Left

Right

Software



Chromatography Columns



Chromatography columns - QuikScale

Large choice of sizes

<u>Diameter</u>	<u>Length:</u>
70 mm	550 mm
100 mm	800 mm
140 mm	1100 mm
200 mm	
250 mm	
300 mm	
350 mm	
450 mm	
630 mm	

Different frit pore size

10 , 20, 30 µm

High Pressure rating

Up to 7bar



Flange on pivot

Easy access to media
for packing / unpacking
and cleaning

Column tube

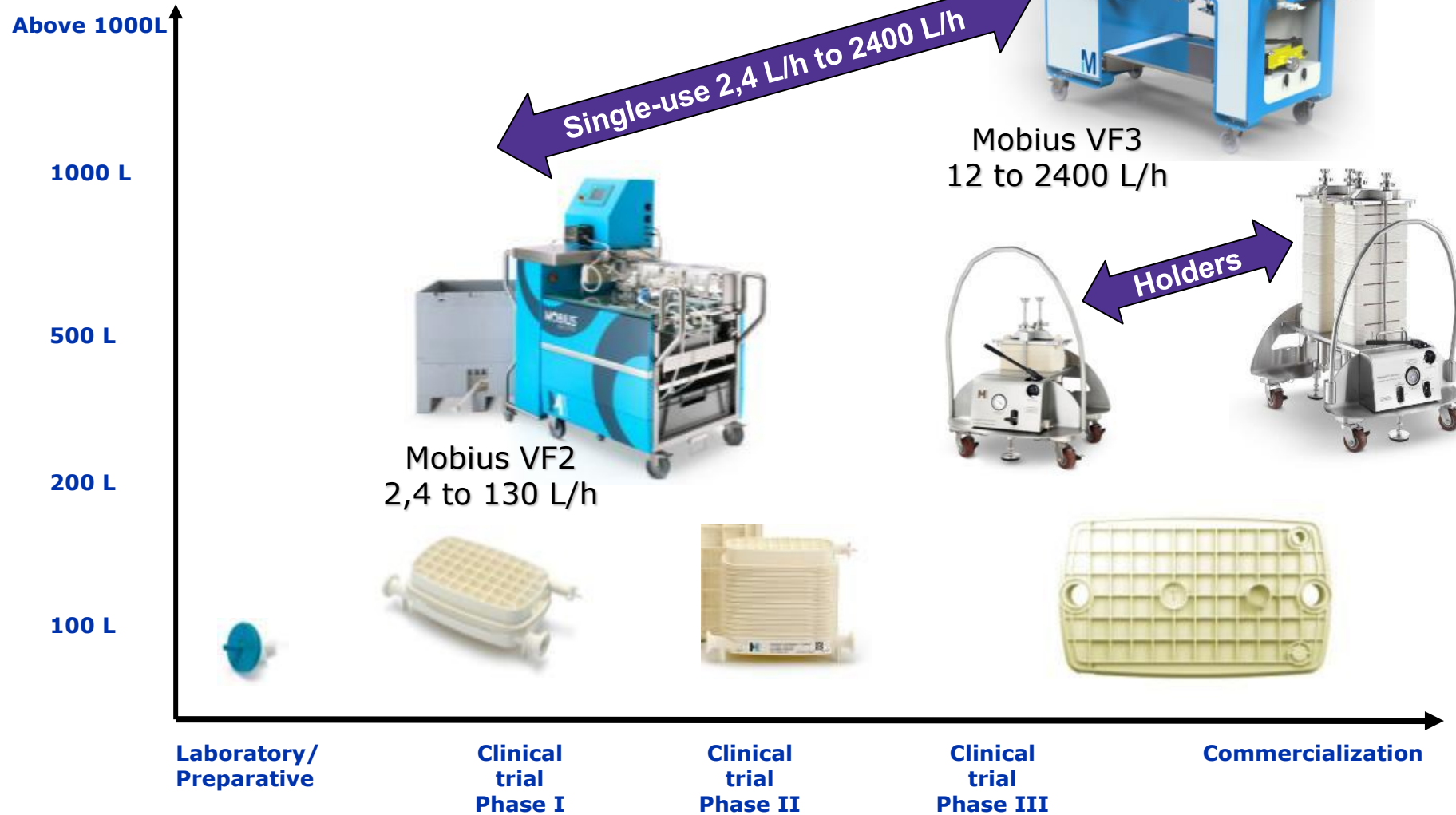
- Acrylic
- Glass
- Stainless Steel

Documentation

- User guide
- cGMP documentation
- Material certificates.

Removable end cell
or Fixed end cell

Virus Filtration systems overview



Single-use virus filtration

Mobius® FlexReady VF3



Large-scale Single-Use Virus Filtration system

- For volumes of 200 L to 2000+ L
- Magnus Viresolve® Pro holder can handle 0,51 m² to 3,06 m² of filter and pre-filter

Configurable to match your process

- Three pump configurations :
300 L/h – 1200 L/h – 2400 L/h (at 30 psi)
Single-use Quattroflow pumps
- Optional prefilter holders :
 - Viresolve® Pro Shield (Magnus holder)
 - Viresolve® VPF (POD holder cart)

HMI with data monitoring

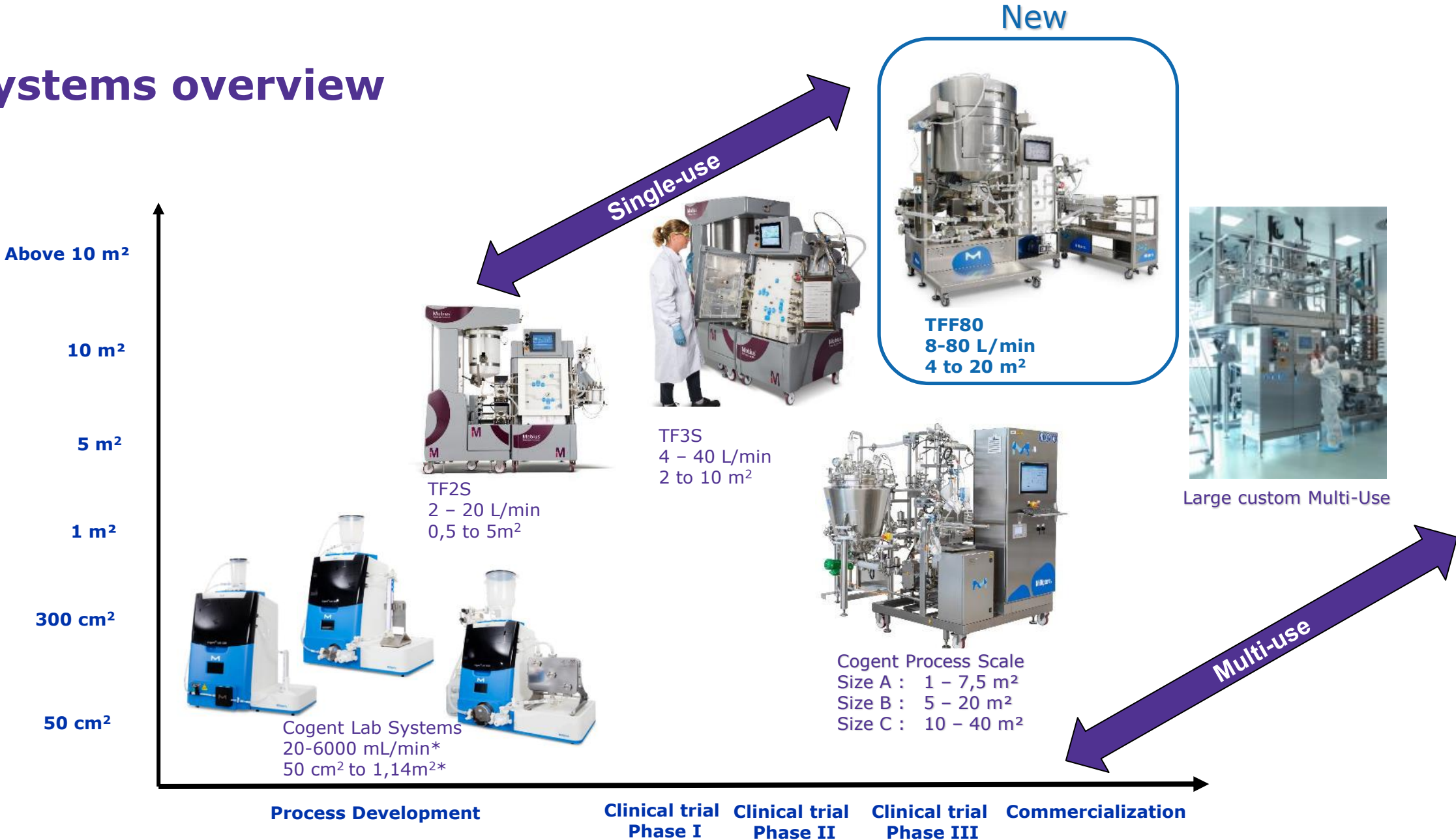
- Constant Feed or Pressure regulation to optimize duration

Options

- 21CFR Part 11 recorder (with Modbus TCP/IP & Ethernet IP)
- Ultrasonic flowmeter (e.g. for IT testing, cumulative volume)
- Conductivity, pH
- Sterilizing filter on product recovery

Possibility to customize for full automation

TFF systems overview



* 3 system sizes available : Lab 150, Lab 800, Lab 6000

A new SU TFF system designed for large scale

Mobius® TFF 80 system

Designed for large scale

- 200 – 500 L tank
- 8 to 80 L/min with matching tubes
- Holder/stand for up to 20 m²

Multiple processing modes

- From traditional to closed operation mode
- Fully SU
- Adapts to Pellicon® 2/3 cassette and Pellicon® Capsule

Designed for high yield

- Integrated tank made for TFF
- Optimized minimum working volume
- High drainability

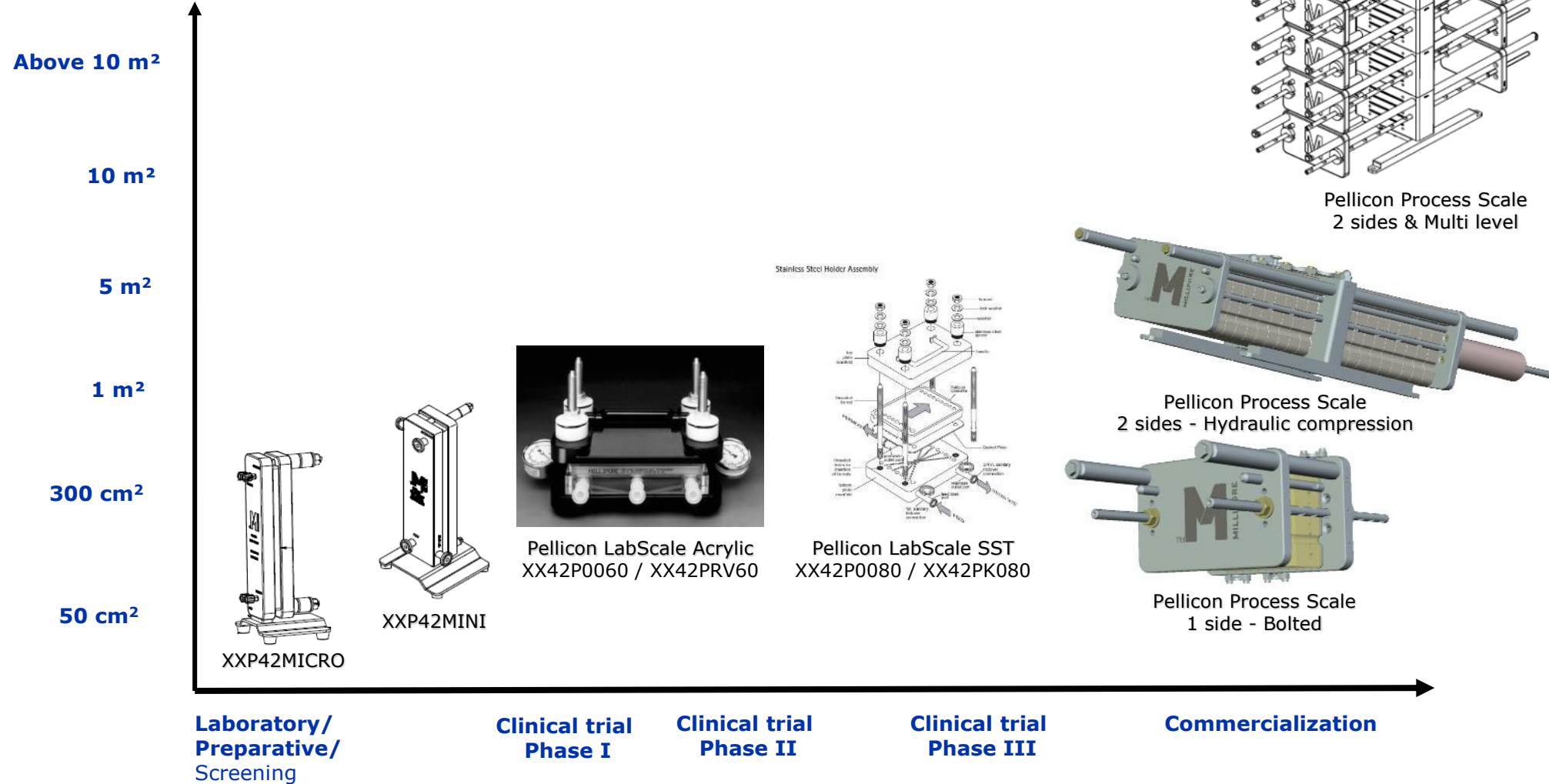


Mobius® TFF 80 system with Pellicon Cassettes



Pellicon Capsules

TFF Holders



TFF single-use system

Mobius® Family

New



TF2S
Closed/Open processing



TF3S
No closed processing offering



Mobius® TFF 80

Hardware closed processing-enabled with holder for 9 and 18 m² Pellicon® capsule
All Flexware® kits available for traditional, functionally and fully closed processing modes.

TF2S	TF3S	TFF80
2 – 18 L/min	4 – 40 L/min	8 – 80 L/min
0.5 – 5 m ²	2 – 10 m ²	4 – 20 m ²

Closed

Closed



TFF single-use system

Mobius® Family

The right feed tank with:

- 50, 100L, 200L or 500L with or w/out double jacket*
- **Levitating, bearingless impeller**
- Vortex breaker
- Retentate diverter plate

Feed pump :

- Quattroflow **diaphragm pumps** for smooth feed recirculation and diafiltration/transfer

Accurate process control:

- Temperature & pressure sensors
- Flow calculation and control
- Conductivity and UV monitoring options

*depending on the system size



Common control Platform® (CCP®) automation software:

- control of all pumps and valves
- recipe editing, storing and sharing
- compliant with GAMP 5 recommendations for automation software and FDA 21 CFR Part 11 requirements for electronic records and signatures.

Mixing solutions

Mobius® MIX and Mobius® Power MIX



Mobius® MIX for gentle mixing

- Low shear mixing due to levitating impeller.
- Perfect for mixing of protein/drug substance solutions.
- Can be used anywhere in the drug manufacturing process



Mobius® POWER MIX for mixing difficult-to-mix powders

- Vortex can quickly pull floating powders off the fluid surface.
- Turbulent mixing quickly creates a homogeneous solution even at high viscosities.

Mix with SS carrier or jacket : 10, 50, 100, 200, 500, 1000L, 2000L

Mixers with PE carrier : 10, 50, 100, 200, 500 L

Single-use mixing systems for product mixing, formulation & viral inactivation

Mobius® MIX Technology

Disposable mixing bag (10, 50, 100, 200, 500, 1000L)

- Available in PureFlex and PureFlex Plus film
- Bottom mounted levitating, magnetically driven impeller
 - No shafts, seals or bearings
 - Minimal particle generation

Electronic drive unit & motor

- “Instant on” electronics
- Portable & removable
- Common electronics for 10/50L, 100/200L, 500/1000L

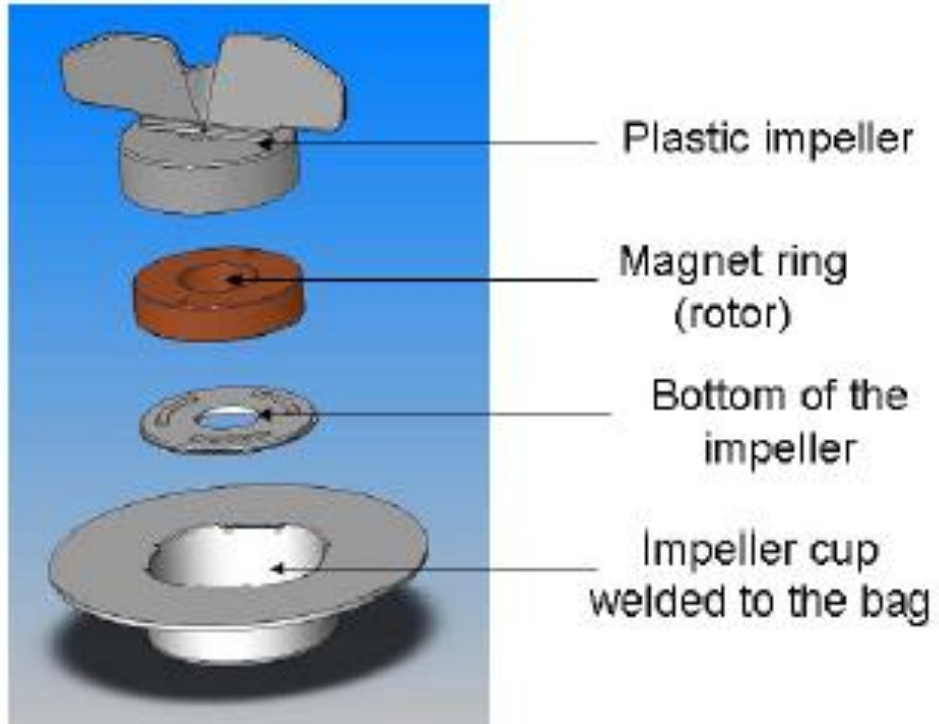
Multiple carrier options

- Plastic (10, 50, 100, 200, 500L)
- Stainless steel (10, 50, 100, 200, 500, 1000L), with load cell, jacket and temperature sensor options

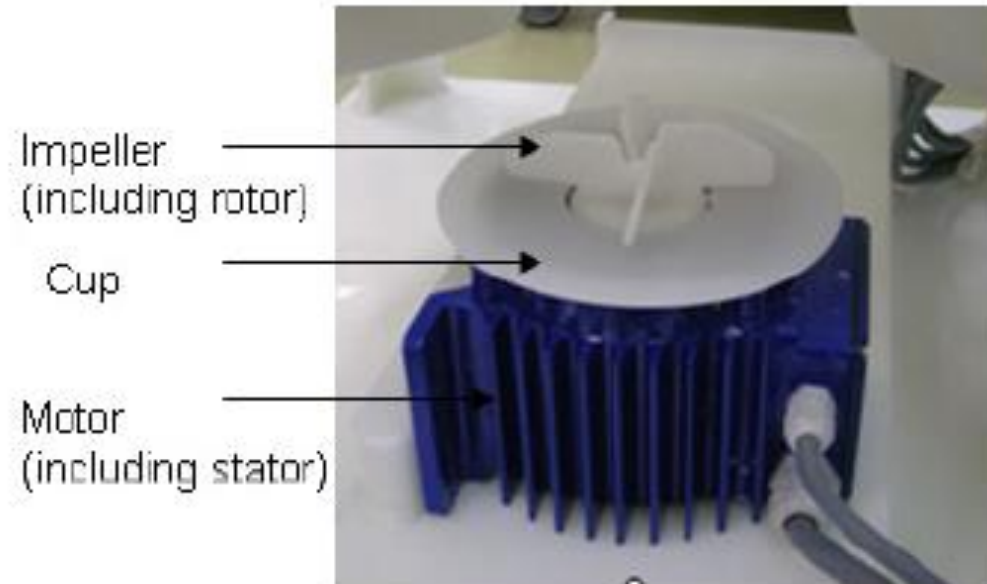


Well suited for downstream mixing - virus inactivation, intermediate pool holds, pool adjustments and formulation

Magnetically-Levitating Impeller



- Motor/Impellor Position Off Center
- Allows for both axial and radial mixing



Single-use mixing systems for buffer and media preparation

Mobius® Power MIX Technology

Electronics – shared among sizes

- Two motors (100/200/500L and 1000/2000L)
- Two control boxes (100/200/500L and 1000/2000L/2500L/3000L)

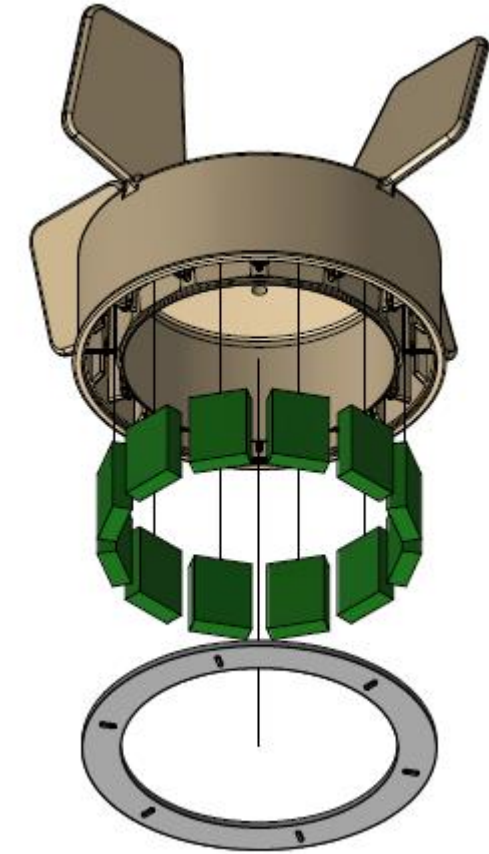
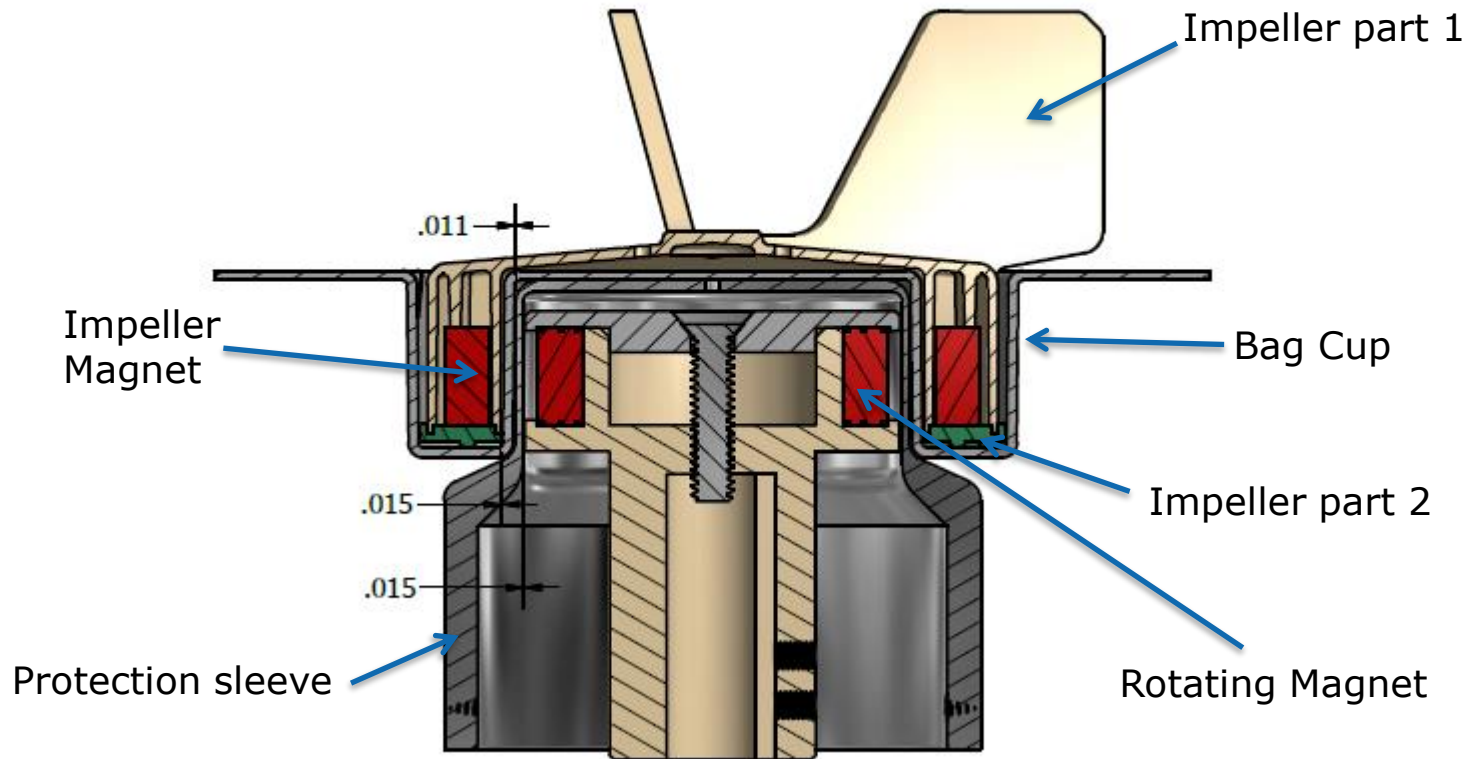
Impellers – shared among sizes

- Size 1 (100/200L)
- Size 2 (500L)
- Size 3 (1000/2000L/2500L/3000L)



Power MIX motors, control boxes, and flexware are independent of Mobius® MIX and cannot be used interchangeably

Cross-section of Impeller and Magnetic Coupling



Magnetic coupling does not utilize a bearing surface

- At low speeds, there is some contact between cup and impeller
- At higher speeds, the impeller will levitate

MIX / POWER MIX

In addition to our standard solutions, we offer highly customizable options tailored to specific client needs:

- **Mechanical Adaptability** : to fit unique operational requirements, providing increased flexibility and optimization / hygienic designs
- **Automation Architectures** : tailored automation solutions designed to integrate seamlessly with existing infrastructure.
- **Flexibility** : wide range of options to accommodate specific client preferences and technical specifications.
- **New Technologies**
Our systems support the latest advancements in technology (Raman, MAST, etc.)



Probe
insertion



Weld
on BAG



11

project execution

Speed up your project execution

Leverage our pre-engineered solutions



Application	Multi Use	Single Use
TFF	Cogent Process Scale	TF2S, TF3S, TFF80
Chromatography	Coprime size A, B & C	XMO1/2, XM03, Chrom 20, MCC
Buffer & Media prep		Mix, PowerMix
Storage		Drums, Bins

- pre-defined and ready to use URS with pre-set configurations
- ready to use validation/qualification package for proven performances
- ready to use maintenance package
 - ✓ reduce your workload
 - ✓ speed up your project execution
 - ✓ ensure proven product performances



Thank you!

