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Нижний Новгород (831)429-08-12
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Псков (8112)59-10-37
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mAb & Recombinant

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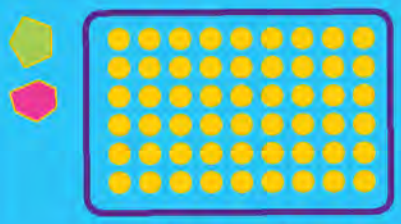


Cell Line Development

Expansion Cryopreservation

CELL LINE & PROCESS DEVELOPMENT

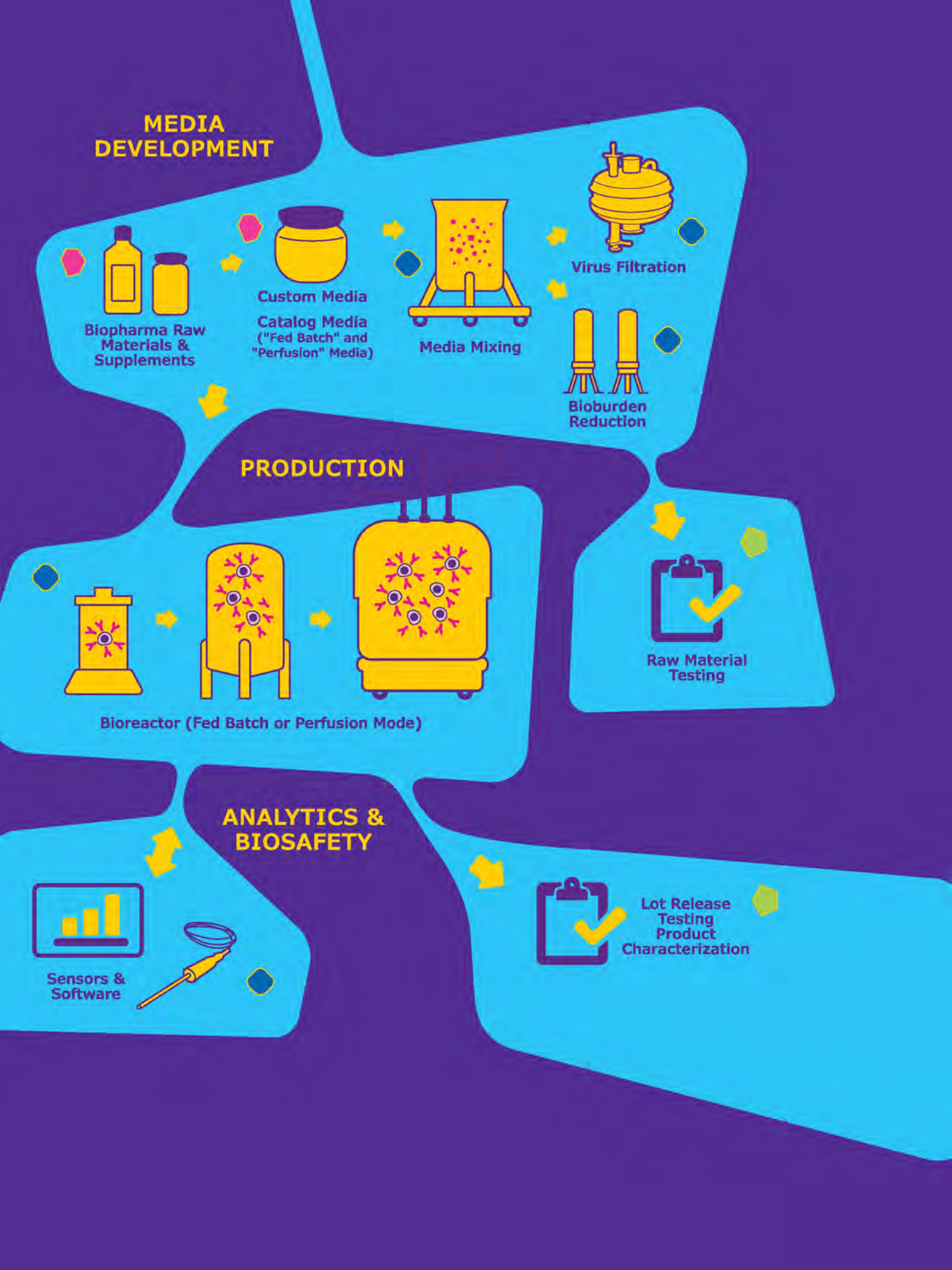
UPSTREAM DEVELOPMENT EXPERTISE

Cell Line Development, Analytical Development, Media Development, Process Development, Tech Transfer, GMP Clinical Supply

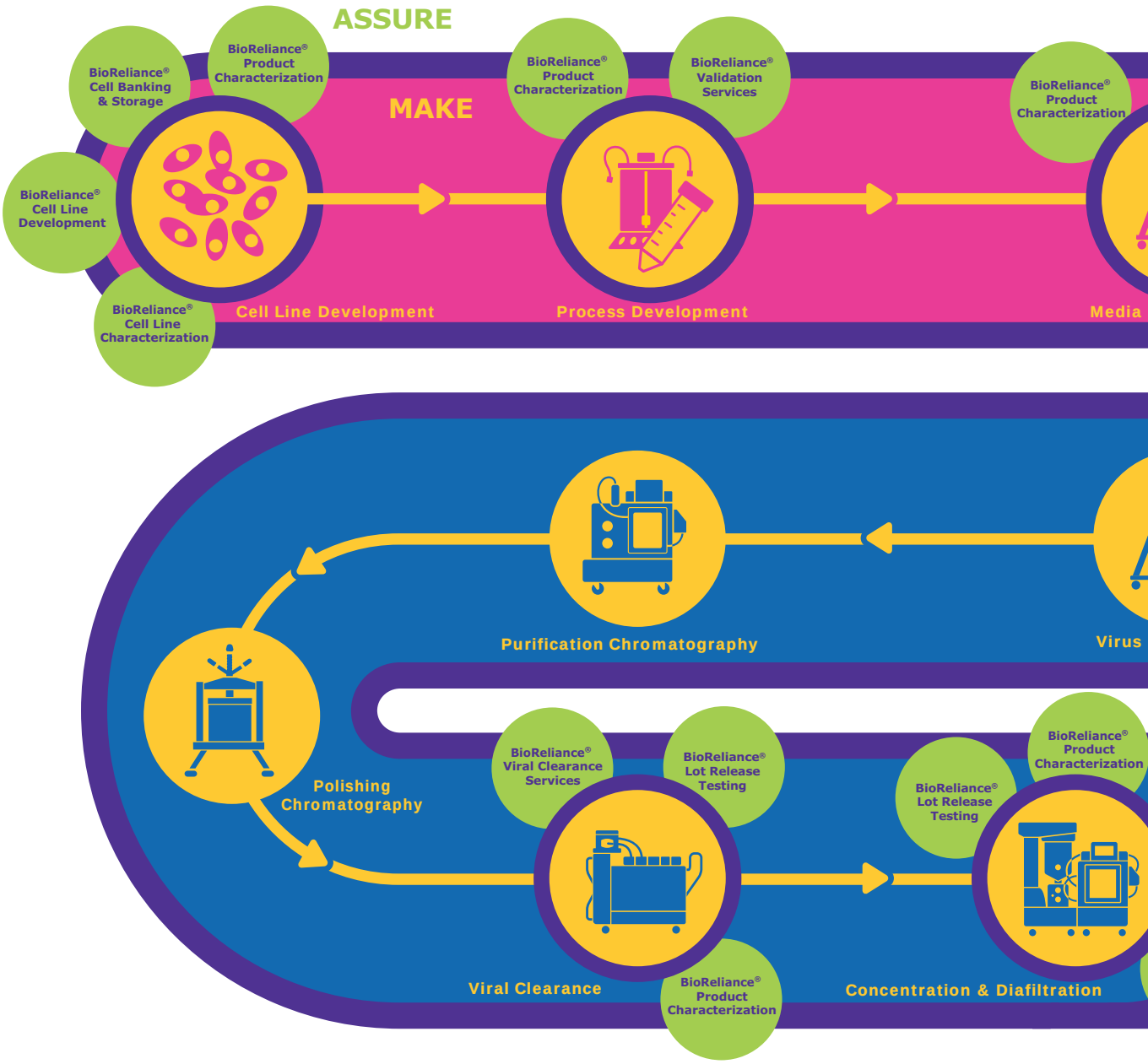
Cloning & Banking

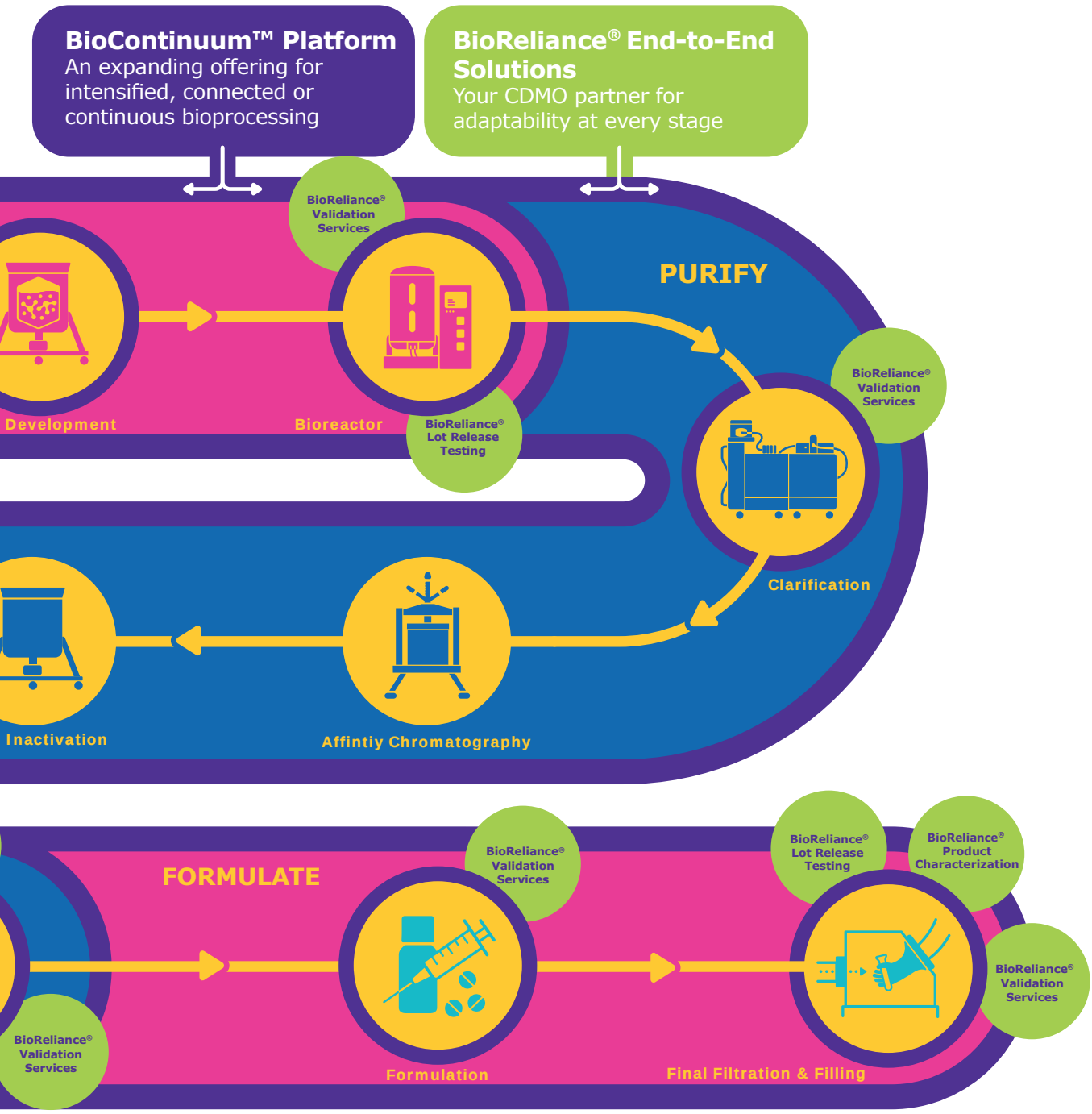
Product Characterization Cell Line Characterization

BioReliance® Services
SAFC® Products
Millipore® Products


MEDIA DEVELOPMENT
Biopharma Raw Materials & Supplements
Custom Media
Catalog Media ("Fed Batch" and "Perfusion" Media)
Media Mixing
Virus Filtration
Bioburden Reduction
PRODUCTION
Bioreactor (Fed Batch or Perfusion Mode)
Raw Material Testing
ANALYTICS & BIOSAFETY
Sensors & Software
Lot Release Testing Product Characterization

Make, purify, formulate, and assure with:




BioContinuum™ Platform
An expanding offering for intensified, connected or continuous bioprocessing
BioReliance® End-to-End Solutions
Your CDMO partner for adaptability at every stage
BioReliance® Validation Services
PURIFY
Development
Bioreactor
BioReliance® Lot Release Testing
BioReliance® Validation Services
Clarification
Inactivation
Affintiy Chromatography
FORMULATE
BioReliance® Validation Services
BioReliance® Lot Release Testing
BioReliance® Product Characterization
BioReliance® Validation Services
BioReliance® Validation Services
Formulation
Final Filtration & Filling

Cell Lines

CHOZN® Expression Platforms

The CHOZN® platform is a mammalian cell expression system based on CHO cells (Chinese Hamster Ovary) for fast and easy selection and scale up of stable clones producing high levels of recombinant protiens. CHOZN® platform is:

- High productivity
- Highly robust and stable
- Proven scalability
- cGMP cell banked

In addition, the CHOZN® platform provides complete traceability documentation.

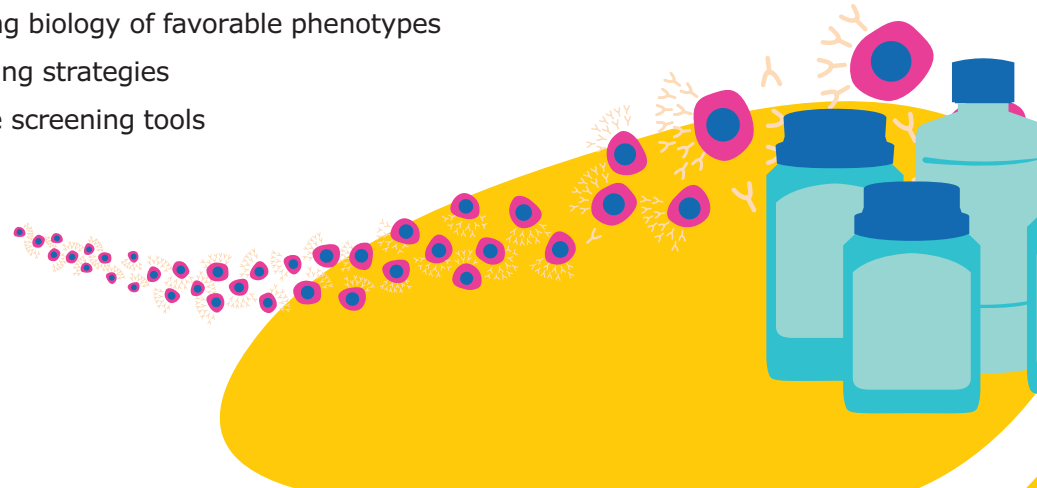
Key to the CHOZN® Platform is the development of the CHOZN® ZFN Modified GS-/- CHO cell line that eliminates the endogenous Glutamine synthetase (GS). The CHOZN® Platform also includes an optimized set of chemically defined (CD) cell culture media and feeds that have been developed to maximize the performance of the cell line.

The CHOZN® CHO K1 line is a suspension CHO K1 cell line, adapted for high viability and productivity in chemically defined (CD) cell culture media for the expression of biologics. Our chemically defined (CD) cell culture media are highly recommended for use with the CHOZN® CHO K1 cell line.

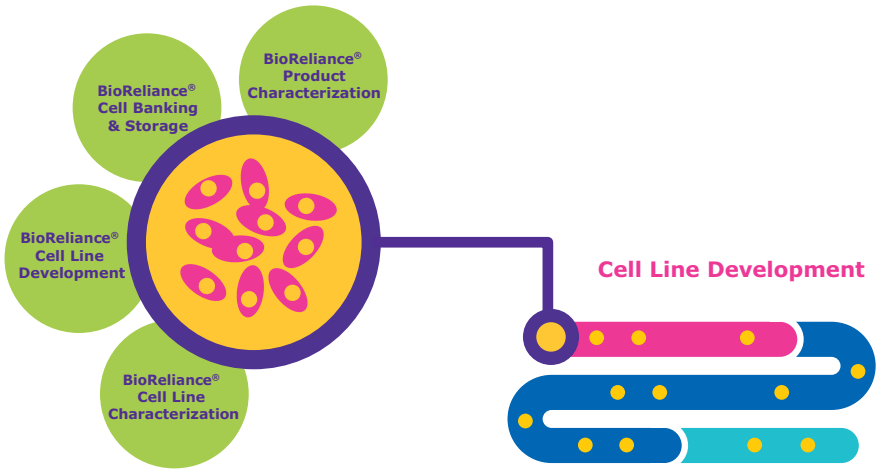
The CHOZN® Omics Explorer

The CHOZN® GS-/-, fully-annotated, genome and transcriptome is available via a user-friendly, web-based interface, the CHOZN® Omics Explorer, that provides an unprecedented ability to characterize and genetically examine the host cell line and associated manufacturing clones. The full genetic and trancriptomic transparency will maximize your efficiency to:

- Characterize transgene integration events with increased precision and confidence
- Characterize and compare the host cell line with associated manufacturing clones
- Better understand the underlying biology of favorable phenotypes
- Plan complex genome engineering strategies
- Design and utilize genome-wide screening tools



Using our proprietary CHOZN® GS-/- cell line, a de novo genome, transcriptome assembly and annotation was performed utilizing second generation (Illumina®) sequencing, third generation long-read (PacBio® Sequel) sequencing as well as ultra-long range interaction mapping via sequencing of Hi-C and CHiCAGO® libraries.



BioRepository

Safe sample storage is our priority. We have a segregated, GMP compliant, storage facility for your samples across our 3 sites which mitigates the risk of interrupting your manufacturing operations through split site storage.

Cell Banking

Our cGMP production facilities allow our experts to produce your Master Cell Bank (MCB) and Working Cell Bank (WCB). Your MCB is critical to therapeutic product development and supports not only clinical development and manufacturing but also the commercial supply phase for biologicals. A WCB is produced from a single vial of the master cell bank (MCB) that has been grown for several passages and cryopreserved for later stages of therapeutic development and manufacturing.

Lot Release Testing Services

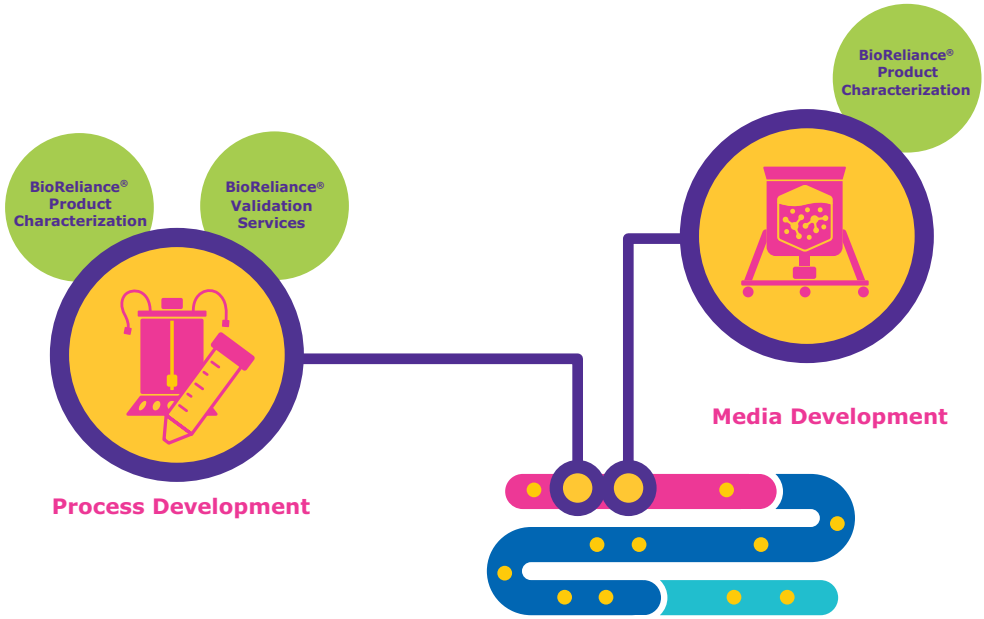
Every batch of biologic produced must undergo lot release testing to comply with comprehensive regulatory guidance on quality and safety. This includes detailed analysis of not only the raw materials, but also the bulk harvest, purified bulk (drug substance) and the final filled product (drug product).

We support lot release testing at any stage of the biomanufacturing process including adventitious agent detection, identity, purity, potency, and residuals and excipients testing.

Cell Culture Media, Feeds and Supplements

The bioproduction expression platform defines the quality and yield of your product and the efficiency of your production process.

Selecting the right expression system and cell culture media is critical for your overall cell culture process development. We offer a proven ready-to-use cell culture media portfolio for fed-batch and perfusion applications supporting your needs from expansion to production scale to ensure your process meets your targets.



Our Cellvento® CHO and EX-CELL® Advanced products are optimized for CHO cell expression. For fed-batch applications we recommend medium and companion feed, however the feeds can be flexible combined with our media and other basal media as well.

Cellvento® 4Feed is a high concentrated feed that includes our new modified amino acids and compaction technology. EX-CELL® Advanced HD Perfusion medium is specifically desinged for perfusion application and Cellvento® 4CHO-X is designed to enable seed train intensification (N-1) addressing the different nutrient demand in perfusion. All products are proven to contribute to superior cell growth and productivity and are designed to support flexibility in production and increase of capacity.

Cell Culture Supplements and Additives

We offer a comprehensive portfolio of non-animal origin cell culture supplements and additives to help you achieve consistent yields and simplify your regulatory process.

- CellPrime® portfolio including: rTrypsin, rLysozyme, rTransferrin, rAlbumin, rInsulin
- Long® R3 IGF

Media & Feeds for CHO expression or mAb manufacturing

Cellvento® 4CHO COMP Medium

Cellvento® 4Feed COMP

Cellvento® 4CHO-X COMP Expansion Medium

EX-CELL® Advanced CHO Fed Batch Medium

EX-CELL® Advanced CHO Feed

EX-CELL® Advanced HD Perfusion Medium

Buffers, Raw Materials & Process Chemicals

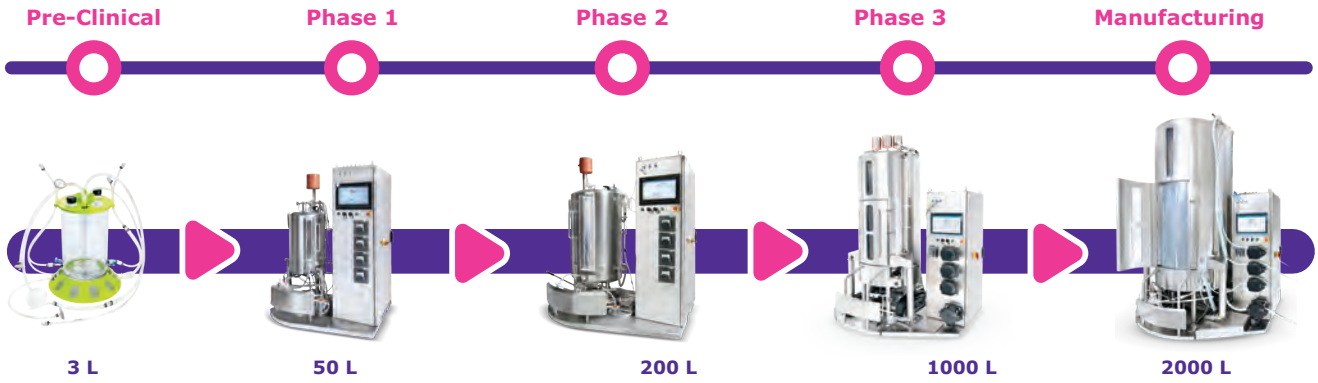
We offer a broad range of high-quality raw materials, buffers and process chemicals for your upstream, purification and formulation steps with traceability of our sourced raw materials to ensure the quality and consistency of your product. We can provide a comprehensive, regulatory documentation package for our Emprove® products to support your regulatory filing. These include:

- Amino Acids
- Carbohydrates
- Vitamins
- Mineral Salts
- Buffers
- Cleaning in Place
- Process Chemicals for Purification
- Upstream Components and Supplements

Liquid Manufacture Capability and Capacity

We continue to progress our cGMP liquid manufacturing facilities and capabilities to meet or exceed current industry standards. We routinely provide a wide range of customized sterile filtered bulk liquids with lot sizes ranging 50L – 10,000L down-filled in single use bags suitable for use in clinical and commercial manufacturing processes.

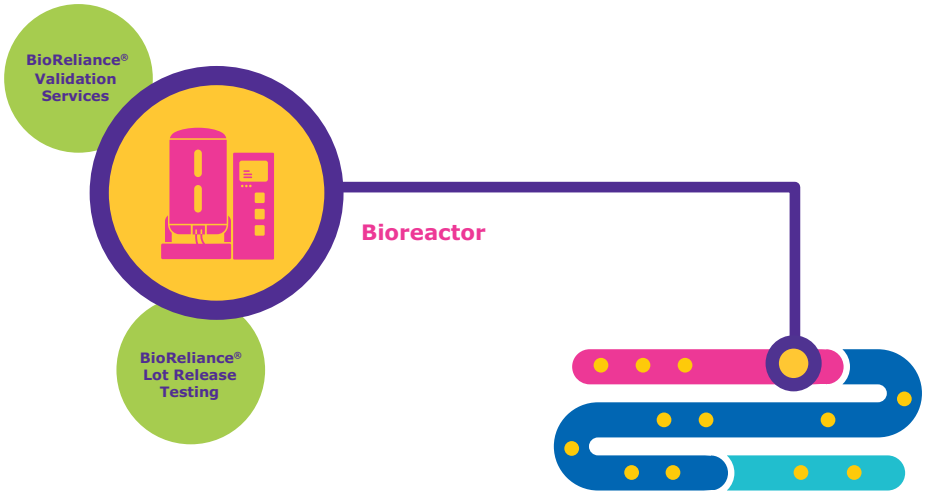
- Cell Culture Media
- Upstream Buffers and Additives
- Downstream Purification Buffers
- Cleaning in Place Solutions
- Bulk Water (WFI – grade source)



Bioreactors, Mixers & Clarification Tools

Mobius® bioreactors are a scalable portfolio of single-use stirred tank bioreactors that provide flexibility through configurable software, hardware and single-use assemblies for use in suspension and adherent cell culture applications.

Our bioreactor platform has been designed to ensure that ease-of-use and operational flexibility at small scale can be translated to full-scale production.



Mobius® Power MIX

The Mobius® Power MIX single-use mixing systems combine high performance mixing technology with design features that make them easy-to-use and are available in capacities from 50 L to 3000 L. The impeller design and motor are based on our magnetically coupled NovAseptic® mixing technology, a proven mixing technology in stainless steel tanks. These systems efficiently mix the most challenging buffers, media and biopharmaceutical ingredients.

Mobius® Single-Use Mixing Systems

The Mobius® single-use mixing solution delivers advanced technology for mixing pharmaceutical ingredients from intermediate to final drug products and for the preparation of process solutions, such as buffers and media.

This single-use integrated mixing solution offers economic and operational efficiency, saving valuable processing and validation time. The Mobius mixing solution includes mixer sizes ranging from 10 L to 3000 L (above 1000 L only Mobius® Power MIX), as well as an easy and safe powder delivery system.

Clarification

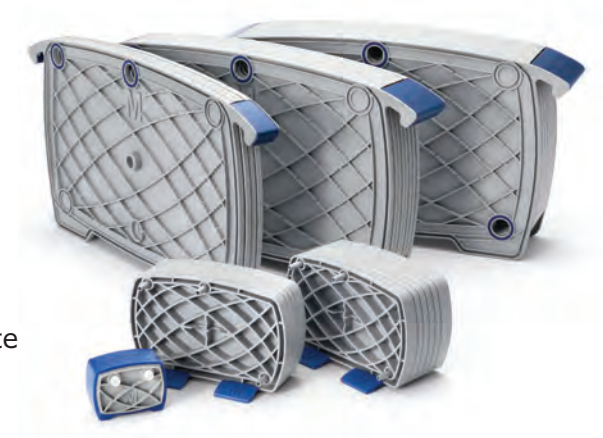
With more than 40 years of clarification experience, we are committed to introducing innovative, easy-to-use technologies, like Millistak+® Pod and Clarisolve® disposable depth filters, to help improve your productivity and process efficiency.

Millistak+® Pod Disposable Depth Filters

Millistak+® CE, DE, and HC Pod ideally is suited for primary and secondary clarification. These disposable depth filters offer flexibility and ease of use through their unique modular design.

- Compact design maximizes product yield and minimizes facility footprint
- Scalable from 5 L up to 20,000 L
- Disposable pod device protects operators from exposure to biohazards and eliminates the cost of housings, Cleaning in Place (CIP) and cleaning validation

Millistak+® HC Pro Synthetic Depth Filters



Millistak+® HC Pro fully synthetic depth filters provide a cleaner and more consistent depth filtration media as compared to current diatomaceous earth (DE) and cellulose (CE) based filter media.

- Reduced TOC extractables and a 50% reduction in the recommended pre-use flush volumes
- No beta-glucans to interfere with Limulus amebocyte lysate (LAL) testing for bacterial endotoxins
- Improved lot to lot consistency
- Provides as much as two times the filtration capacity with equivalent filter retention over commercial DE-based benchmarks for primary clarification
- Improved HCP impurity clearance

Unparalleled Scalability

The Pod holder system's modular design makes it easy to configure a system for a specific application and conveniently reconfigure it as process capacity requirements scale-up or down. The flexible, modular format offers scalability from 5 up to 20,000 liters or more.

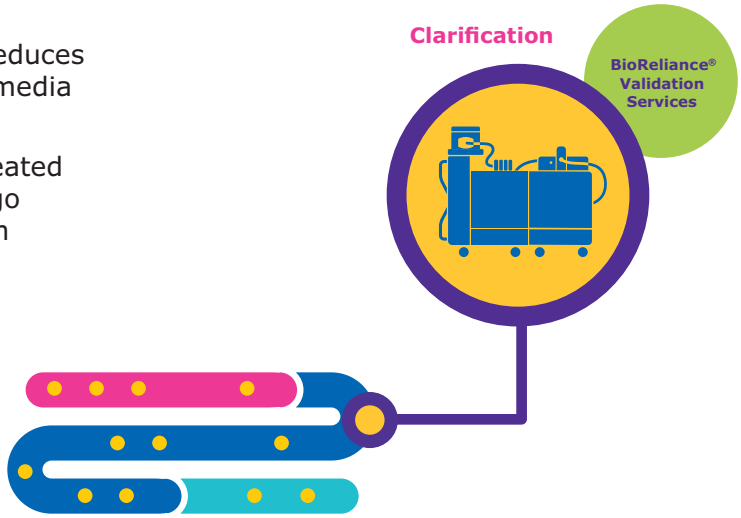
Small Scale | Lab Scale | Pilot Scale | Process Scale

Clarisolve® Disposable Depth Filter

The innovative Clarisolve® depth filter is a fast and efficient way to clarify challenging, high density cell culture feed streams that require pre-treatment. The innovative Clarisove depth filter can be used with pretreatment solutions to improve the consistency and efficiency of clarification operations by reducing the levels of soluble process impurities such as host cell proteins (HCP) and DNA.

When used with flocculation or precipitation:

- Eliminates the need for a centrifuge and reduces pre-use flush volumes, depending on the media grade, versus traditional depth filters
- Enables single stage clarification for pretreated and high solids-containing feed streams; go directly from the bioreactor to downstream sterile filtration



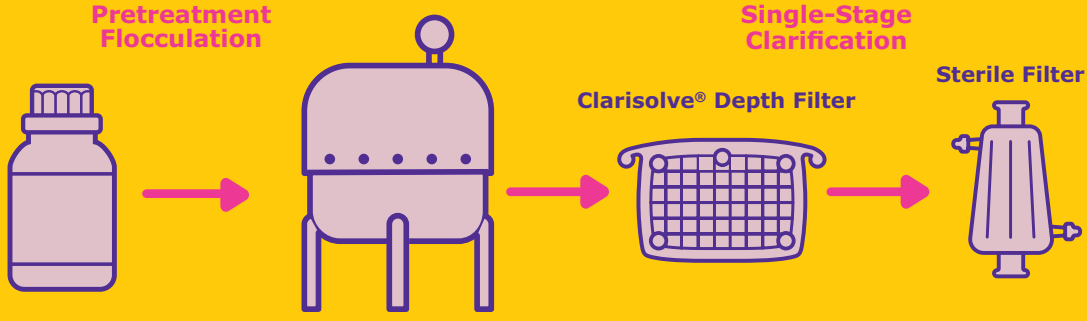
Flocculants

To meet the technical challenges of high titer mammalian cell culture processes, our novel chemical flocculant can be used to pretreat high density cell harvests before clarification over Clarisolve® depth filters.

pDADMAC (poly diallyldimethyl-ammonium chloride) is a GMP-compliant cationic flocculation reagent targeted for biopharmaceutical applications.

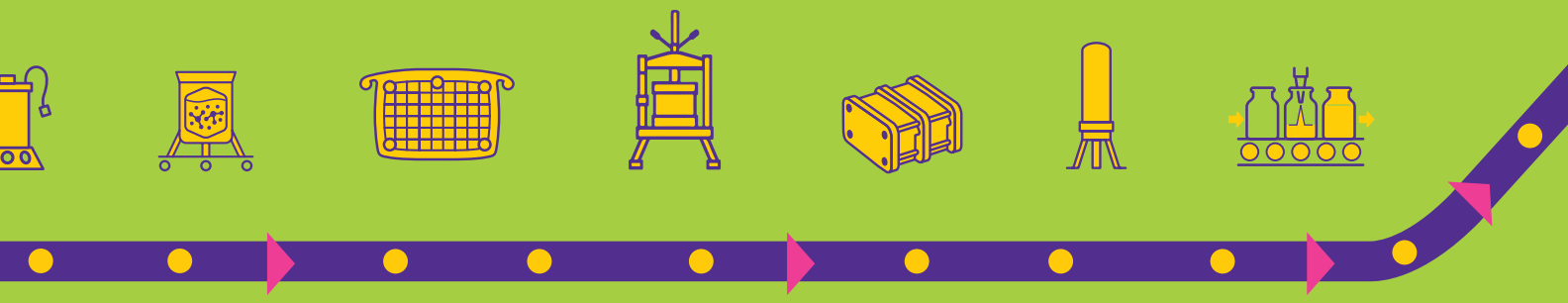
- Rapidly flocculates negatively charged cells and cellular debris into larger particles via via ionic interactions
- Minimal to no pH adjustments required to be effective
- Clarisolve® 40MS depth filters support the clarification of feed streams treated with the pDADMAC polymer flocculant

Next Generation Clarification using the Clarisolve® Pretreatment Portfolio



Pathways for Pioneers

EMERGING BIOTALK



Get insights from your peers and experts

Emerging BioTalk is the forum for professionals in emerging biotechnology to discuss and exchange ideas **across all modalities.** Connect with other experts and entrepreneurs in your field to help solve challenges, big and small, and discover new opportunities.

You will learn about regulatory issues, manufacturing, scalability, collaboration, development, partnering, and more.

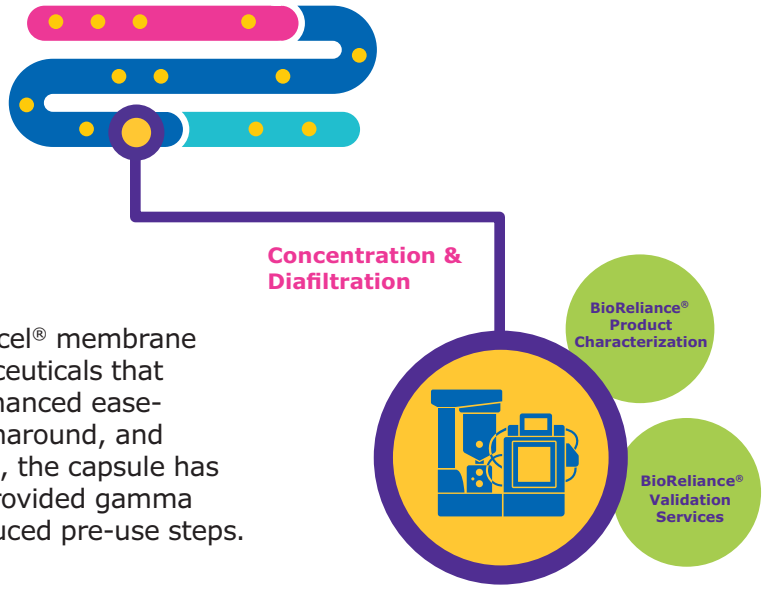
Visit, subscribe, or contribute now!

Ultrafiltration and Diafiltration

Our Pellicon® family of ultrafiltration products are the ideal solution for a range of high value applications. Pellicon® filters consistently deliver purity assurance at every stage and scale throughout the lifecycle of your drug products.

Pellicon® 3 Cassettes

Our advanced, high performance Pellicon® 3 cassettes, available with Ultracel® and Biomax® membranes, deliver high yield and consistent product purity and quality at every scale for the purification of mAbs, IgG, insulin, plasma, and vaccines. Pellicon® 3 cassettes offer the caustic resistance required for proper membrane regeneration with no product carryover after multiple reuse cycles. To overcome high viscosity challenges under normal processing limits and conditions, we offer the novel D screen, optimized to achieve higher protein concentrations.



Pellicon® Capsules

Our innovative Pellicon® capsules with Ultracel® membrane are ideal TFF devices to process biopharmaceuticals that require single-use capabilities, including enhanced ease-of-use, process flexibility, rapid product turnaround, and reduced operator exposure. First-of-its-kind, the capsule has a holderless, self-contained design and is provided gamma sterilized, offering easy installation and reduced pre-use steps.

Pellicon® Single-Pass TFF

Single-pass TFF with Pellicon® 3 cassettes is a powerful purification approach to concentrate product without recirculation, allowing for higher final concentrations and improved product recovery compared to traditional TFF batch processes. It can easily run connected with other steps to reduce in-process volumes and intensify operations in the purification of therapeutics.

Viral Safety

Viral safety is a critical aspect of biopharmaceutical/biologics production and relies on the well-established principles of “prevent, detect and remove” to assure drug safety for patients. These principles are the foundation of every viral safety strategy and depend on the approaches outlined below.

Viral safety is a critical aspect of biopharmaceutical production and relies on:

- Careful selection and pretreatment of raw materials to prevent adventitious viruses from entering processes
- Robust testing strategies to detect the presence of viruses in cell banks, raw materials, and process intermediates
- Implementation of technologies to remove or inactivate viruses in downstream purification

Upstream Viral Safety

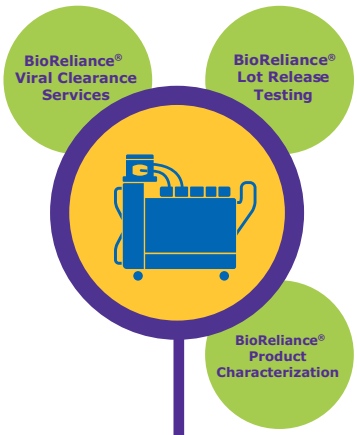
Bioreactors are at particular risk of contamination from adventitious agents. High profile viral contamination events have led manufacturers to re-examine risk assessments around viral safety and implement additional steps upstream of the bioreactor to reduce the risk of viral contamination. Such steps might include

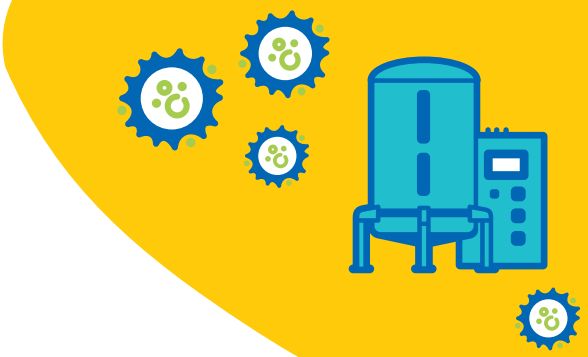
— Viresolve® Barrier filters specifically designed for processing cell culture media

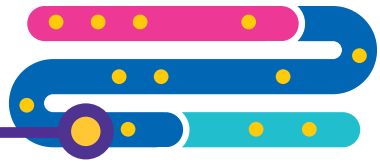
— HTST (High Temperature Short Time) pasteurized glucose

— Non-animal origin and chemically-defined raw materials

— Genetically modified virus resistant CHO cell line







Viral Clearance

Downstream purification operations improve viral safety by either removing or inactivating viral contaminants.

Chromatography operations reduce levels of virus by affinity binding or binding based on charge or hydrophobicity.

Many downstream processes include dedicated steps to reduce levels of viral contaminants through inactivation or size-based removal. Our portfolio of high-quality chemicals can be used to inactivate viral contaminants using low pH, solvents or detergents.

Virus filtration is a key component of viral safety in most downstream processes. The Viresolve® Pro Solution is comprised of the innovative, high-performing Viresolve® Pro Device in conjunction with the Viresolve® Pro Shield or the Viresolve® Pro Shield H prefilters. The Viresolve® Pro Solution works across a broad range of operating conditions delivering high levels of virus retention, high capacity and flux.

BioReliance® viral clearance studies are designed and executed by experts in regulatory, downstream processing, and virology at our facilities in Singapore, the US, and the UK. Our global experts can support you with your IND and BLA studies in accordance to regulatory guidelines for monoclonal antibodies, recombinant proteins, and plasma derivatives. Our dedicated project management support and local teams of experienced technical experts accelerate your time to results and minimizes risk as you bring your product to market.

Sterile Filtration

Liquid filtration is performed at different steps in upstream and downstream processing. We provide a range of membranes that offer different levels of microbial retention performance in both single-use capsules as well as cartridge filter formats, to meet your specific process needs.

You need filters to efficiently process buffers, cell culture media, process intermediates and purified drug product under your specific process conditions. Our comprehensive portfolio of products includes prefilters to reduce particulates and sterilizing-grade filters containing our trusted Millipore Express® or Durapore® membranes to deliver the highest levels of sterility assurance.

OptiScale® capsules are ideal for quickly evaluating performance of different filters while our Opticap® capsules and cartridge filters are designed for pilot and production-scale processing. All filters are available with different connection options offering maximum flexibility.

Milligard® PES Filters

Milligard® PES filters are designed for effective bioburden control and reliable removal of particles from a broad range of fluid streams. These filters reduce bioburden in non-critical applications and can be used as prefilters to improve the performance of sterilizing-grade filters and other unit operations.

Millipak® Final Fill Filters

Millipak® Final Fill capsule filters are designed for reliable final sterilizing filtration of small volume, high value solutions. These filters:

- Maximize product recovery in final and high value filtration steps
- Simplify operation and reduce the risk of microbial and particulate contamination
- Contain trusted Durapore® membrane for high flow rates, low binding and extractables, and broad chemical compatibility

Protein Purification Chromatography

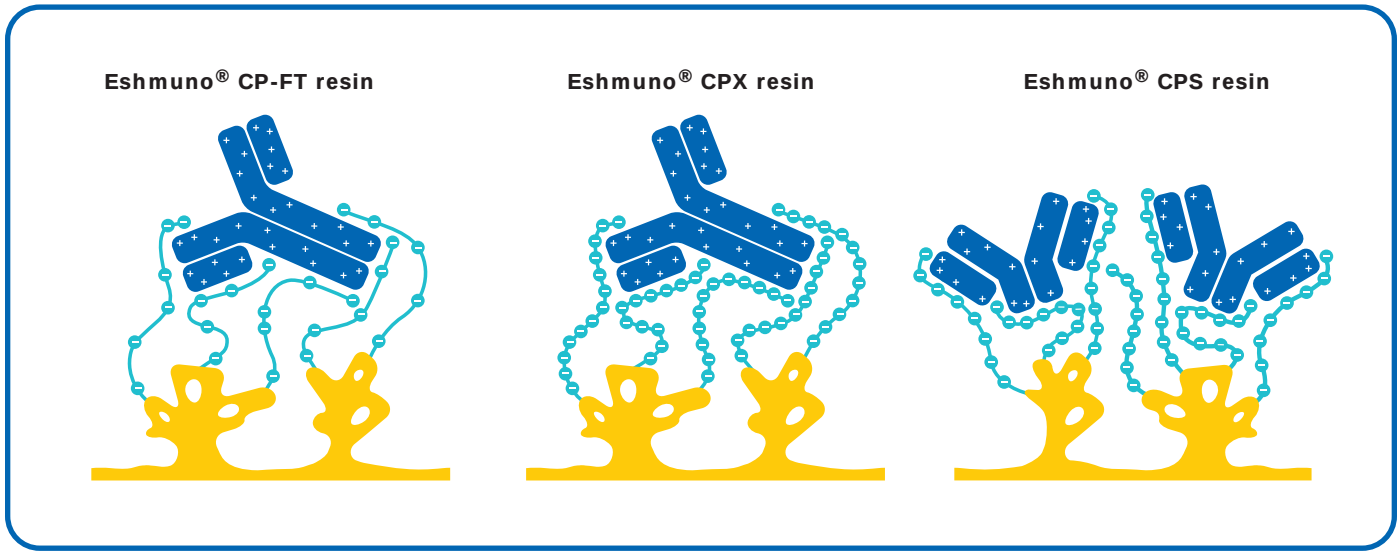
You have a diverse set of molecules that need to be purified. We have a full suite of industry-trusted and proven chromatography resins and membranes to help you tackle them all from lab to process scale.

- Membrane Chromatography
- Affinity Chromatography
- Ion Exchange Chromatography
- Prepacked Columns
- Process Chemicals
- Multi-use Systems
- Single-use Systems

Chromatography Resins

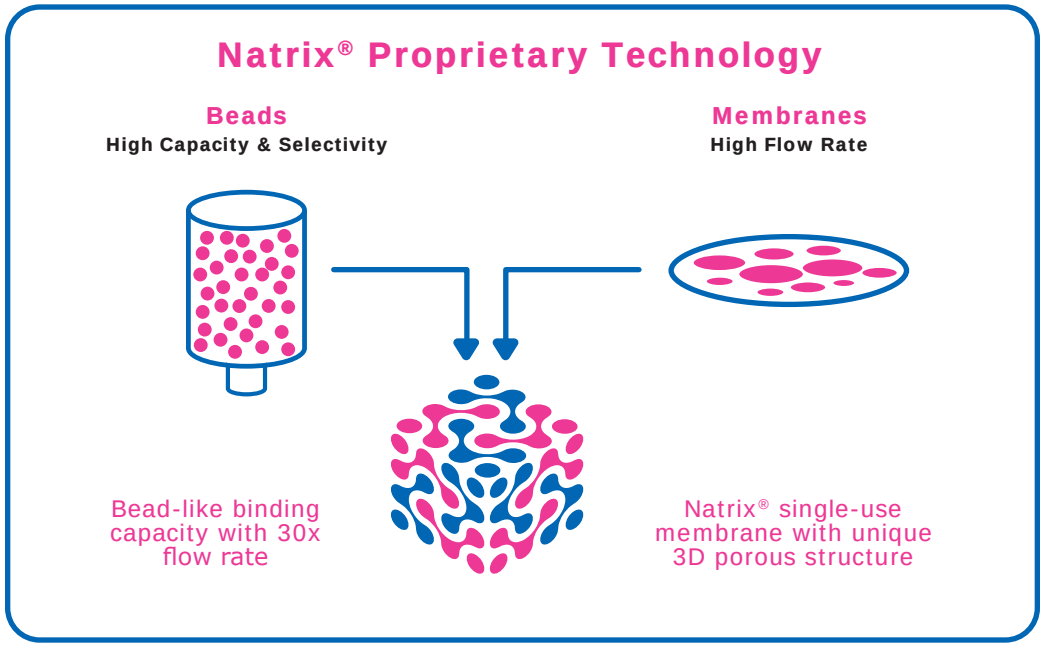
Our portfolio of reliable, trusted chromatography solutions has been optimized for your molecule across its entire life cycle, from early-phase development through commercial manufacturing.

Our proven tentacle technology offers a number of advantages compared to conventional resins due to increased accessibility of functional groups and binding of target molecules. This allows reliable purification and efficiency for your process with high selectivity, excellent yield and purity. We optimized the tentacular surface chemistry of our resins for different applications.



Chromatography Membrane

By combining the functionality of resin-based columns, the flow rates of membranes, and single-use format, Natrix® membrane technology enables a new level of downstream productivity and versatility. Natrix® single-use chromatography membrane technology can be utilized for primary capture steps through intermediate and final polishing, and is adaptable to common functional groups and ligands.



Chromatography Buffers

For even the most complex purification challenges, we offer a comprehensive portfolio of buffers (organic and inorganic), deep bioprocessing expertise, and unrivalled regulatory support to meet your process challenges.

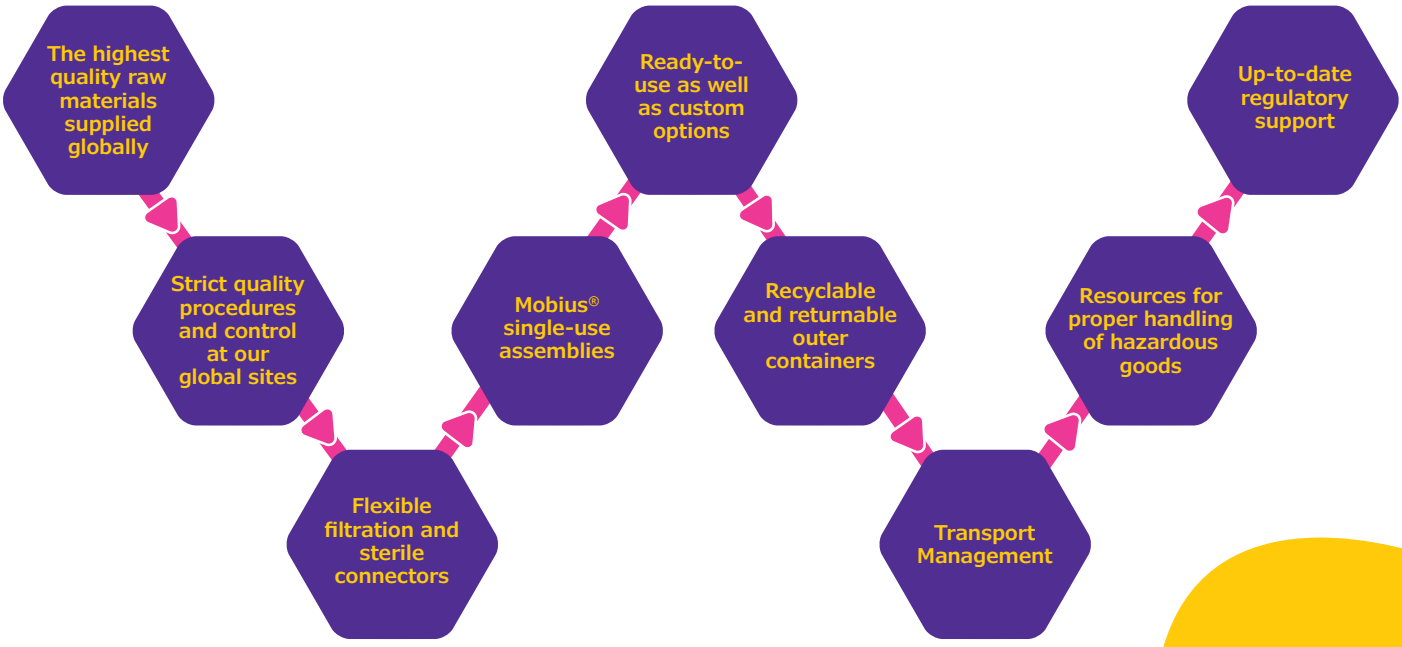
Look to us for reliable, trusted chromatography products and buffers, optimized for your use in bioprocessing across its entire life cycle of your product, from early-phase development through commercial manufacturing.

Cleaning In Place Solutions

Our tailor-made, top quality clean in place solutions save you time, money and effort. You can order the exact solution, in the volume you require, from our extensive clean-in-place (CIP) portfolio produced at our GMP facility. We also provide technical support regarding packaging and full regulatory documentation to simplify approval and validation procedures.

1L → 17.000L

Quality is the key every step of the way...



Fluid Handling

From media preparation through final fill, our broad portfolio of Mobius® single-use manufacturing products, Lynx® connectors, and NovaSeptum® GO sterile sampling systems can help you work faster and more efficiently in your fluid handling processes. Mobius® 2D and 3D Assemblies and Storage Systems include a range of different options for product storage, transfer, tubing, handling and transport. Mobius® Mixers deliver advanced technology for mixing and offer operational flexibility as they can be up and running in a short time. Mobius® Bioreactors are a scalable portfolio of stirred tank bioreactors that provide flexibility by configuring software, hardware and single-use assemblies.

The Mobius® MyWay portfolio is a design and delivery offering to help biopharmaceutical manufacturers implement flexible manufacturing with greater speed and enhanced supply security.

Mobius® SELECT Component Library

For fast and easy process set up, configure-to-order assemblies from an optimized component library.

- The perfect balance of off-the-shelf speed and custom flexibility
- Monitored component supply levels for reliable delivery
- Comprehensive documentation for fast and easy implementation

Formulation

Biomolecule Formulation with the Process in Mind

Chemicals play an important role in the stabilization of a biologic drug during its manufacturing and formulation – for instance, by preventing aggregation. We offer a wide range of high-quality stabilizers, buffers and salts to successfully formulate your biomolecules.

Specifically developed for high-risk applications, our buffers, salts and stabilizer are low in bioburden and endotoxins. They are supported by our Emprove® Program and come with extensive documentation, helping you minimize regulatory and quality-associated risks in your biopharmaceutical manufacturing.

Benefit from:

- Reliable product quality
- Low endotoxin and microbial limits
- Emprove® Program supporting risk assessment
- Elemental Impurity Information according to ICH Q3D

ADC Express™ Services

Pre-clinical Conjugation Services for the Best Candidate Selection

Speeding your path to the clinic — with ADC Express™ Services

As an industry leading contract manufacturing organization (CMO) in the Antibody-Drug Conjugate (ADC) space, we are offering a rapid approach for developing your ADC constructs. By using our extensive bioconjugation expertise we can reduce your time to produce development grade constructs for target molecule identification. To efficiently turn your and our antibody, linker and payload into an ADC we will leverage our established platform technology.

Why choose ADC Express™ Services?

Speed to selection:

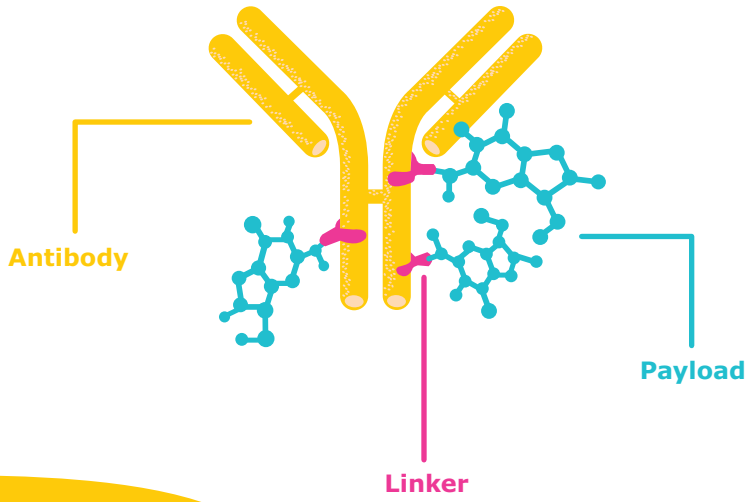
- Rapid production of multiple ADC constructs for screening
- Leverages our platform technology with key analytics

Speed to clinic:

- Our expertise for reliable scale up of your target molecule
- Benefit from a reliable partner offering comprehensive services for GLP and GMP production
- Supply chain consolidation gives you comprehensive ADC services within one organization

ADC Express™ Features

- Mini-prep scale: 10–20 mg ADC construct ± column purification
- Medium-prep scale: up to 100 mg ADC ± column purification
- Certificate of testing with key quality attributes
  - — ADC concentration
  - — Payload density/DAR (drug antibody ratio)
  - — Monomer/aggregate content
  - — Endotoxin



The Advanced Emprove® Program

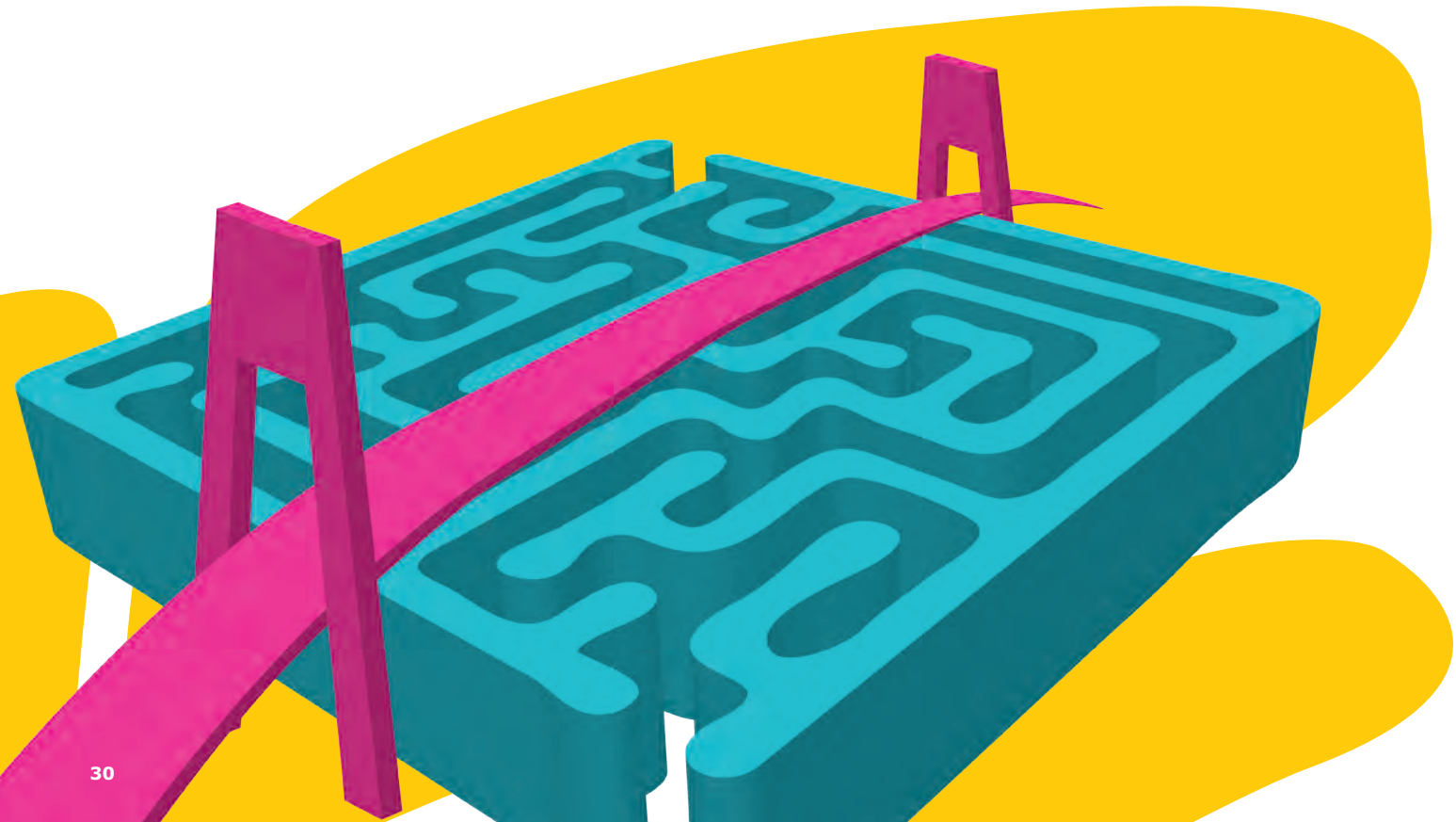
The Emprove® Program. Your fast track through regulatory challenges.

Ensuring the compliance of your pharma and biopharma products involves the compilation of a vast amount of data, which can be time- and resource-intensive. In order to facilitate and accelerate this process we developed our Emprove® Program. It includes more than 400 pharma raw and starting materials and a selection of filtration and single-use products. Each product in the portfolio is complemented with three different types of dossiers supporting you throughout the different stages of your operations: qualification, risk assessment, and process optimization, speeding your way through the regulatory maze.

The Emprove® Program simplifies your processes by:

- Accelerating approval preparation
- Facilitating qualification processes
- Supporting risk assessment, management and mitigation
- Increasing supply chain transparency
- Saving time and money

When using raw and starting materials including excipients, risk levels vary depending on the product manufactured and its application. The different categories provide exactly the information for the products used as per the end user's needs.



EMPROVE® EVOLVE
product line provides fit-for-purpose high quality raw materials designed for the earlier stages of regulated manufacturing processes along with detailed and transparent supply chain information and documentation to support risk assessments.

EMPROVE® ESSENTIAL
product line is designed for moderate risk levels. Best-in-class regulatory support is combined with our high quality standards.

EMPROVE® EXPERT
product line addresses higher risk applications, where the lowest microbiological and endotoxin levels are of utmost importance. These products are documented as being manufactured with low microbio logical and endotoxin levels.

EMPROVE® API
product line provides the right quality and regulatory documentation required for active pharmaceutical ingredients. All the products in this line are manufactured in Europe and comply with ICH Q7 requirements.

Emprove® Program for Filtration and Single-Use

Due to the need of high transparency and standardization across the whole supply chain, the Emprove® Program also includes filtration and single use technologies ranging from sterile, clarification and virus filters to single-use components used in the major steps of the biopharmaceutical process. Extractables data summarized as per BioPhorum's (BPOG) standard testing protocol and USP <665> form a part of the dossiers to support safety risk assessment seamlessly.

The three different types of dossiers support you throughout the different stages of your operations:

Material Qualification Dossier – Information to start material qualification.

Quality Management Dossier – Answers questions during risk assessment.

Operational Excellence Dossier – Supports process optimization

Comprehensive regulatory information at your fingertips

The Emprove® Suite is your online gateway to conveniently access all our Emprove® dossiers on demand. The Emprove® Suite is always up-to-date and optimized for any targeted search. While the material qualification dossier is available free of charge on our website, the full access to all dossiers anytime in the Emprove® library is available through a one-time subscription for 1, 2 or 5 years.

Why Visit an M Lab™ Collaboration Center?

At the M Lab™ Collaboration Centers, no challenge is too great. Our technical expertise spans all aspects of the process train. Areas of support we offer include, but are not limited to:

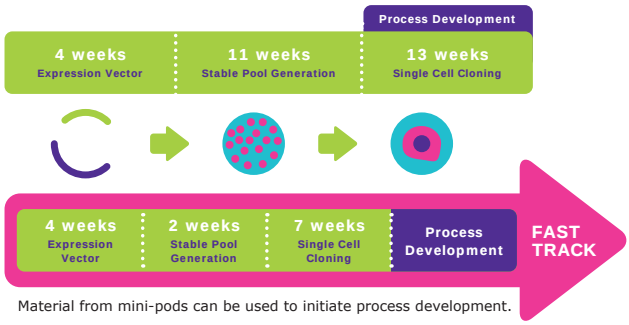
- Overcome barriers to single-use implementation
- Receive guidance for process development and scale up
- Troubleshoot existing processes
- Gain technical knowledge required prior to new product adoption
- Acquire new skills and expertise in bioprocessing and formulation development
- Discover best practices and techniques for adopting next generation bioprocessing
- Develop and test new procedures prior to implementation

Plug & Play Upstream Development Service

Get Easy Access to a Tailored Suite of Services

- A plug & play service tailored exactly to your needs — Cell Line Development CHOZN® License
- Leverage our expertise in cell line development — Standard Analytics Early Material from Stable Pools
- Enjoy freedom from royalty fees — Stability Study Clone Selection

Take advantage of our mini-pool approach to speed up development by up to 13 weeks



Material from mini-pods can be used to initiate process development.

Add-on services give you options to choose the path that's right for you:

- Off-the-shelf Media & Feed Screening
- Analytical Method Development
- Complete Analytics
- GMP Master Cell Bank & Cell Bank Characterization
- MCB Storage

Support for all phases of drug development

Service	Preclinical	Phase I	Phase II	Phase III	Commercial
Cell banking & testing	•	•	•	•	•
Raw materials testing	•	•	•	•	•
Lot release testing	•	•	•	•	•
Clearance validation		•		•	
Virus manufacturing	•	•	•	•	•

BioReliance® cell banking services provide cGMP manufacturing of mammalian master and working cell banks.

Cell Line Characterization services:

Cell line characterization is the process of evaluating the identity, purity and genetic stability of the cell line. Recognized as a global leader in biosafety testing, we have proven expertise in every aspect of cell line characterization. Operating from global, world-class facilities — staffed by highly trained personnel and equipped with the very latest technologies — we offer a full range of identity, purity and genetic stability testing services.

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Белгород (4722)40-23-64
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