

GE Healthcare
Life Sciences

Plug & Play

ReadyToProcess™. Ready-to-use technologies
for greater speed and agility in bioprocessing.



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Imagine & Lead

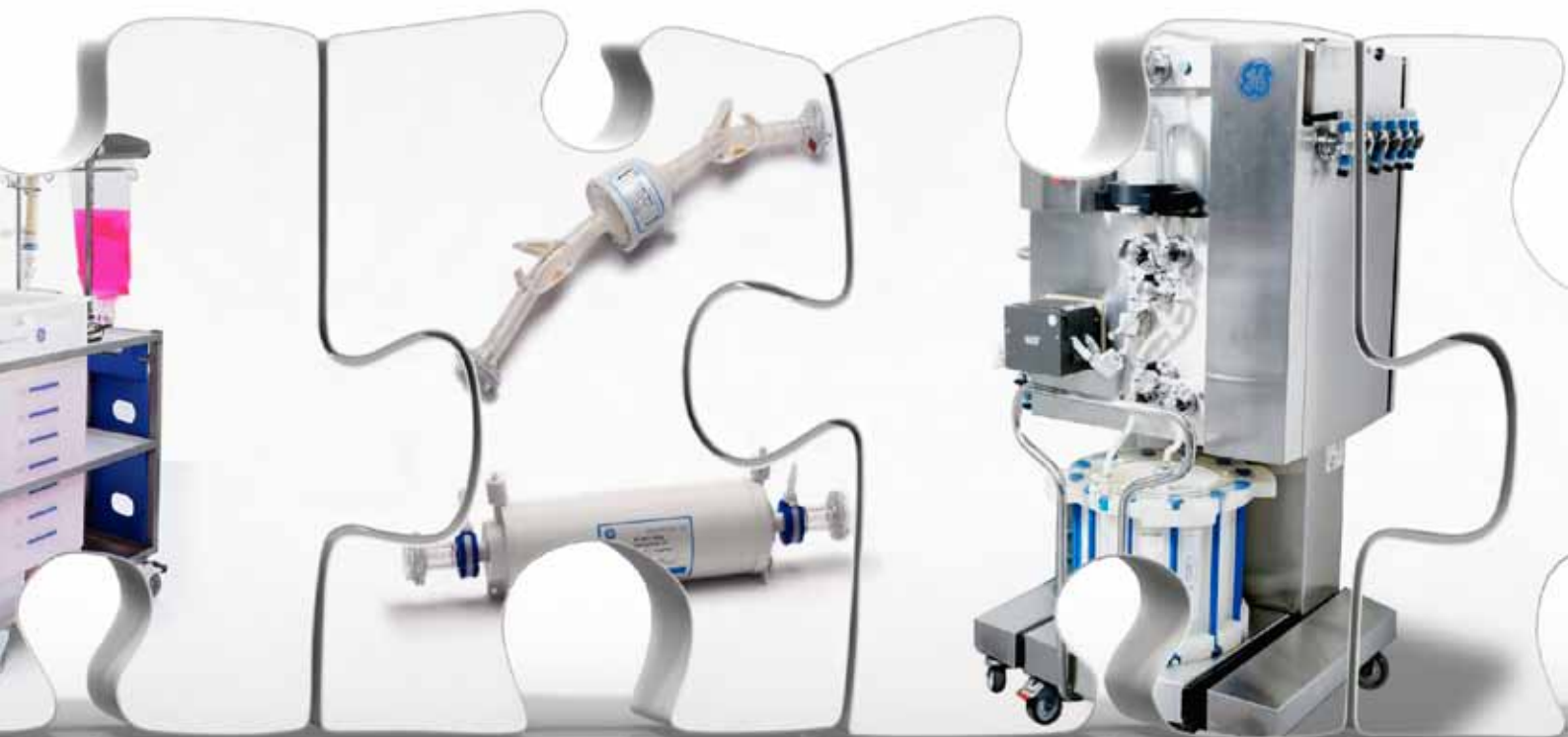
Biopharmaceutical development and manufacturing demands scalable processes that can be quickly developed, easily implemented, and smoothly transferred to production. Ready-to-use technologies play a crucial role in providing the flexibility to support multiproduct facilities. They deliver process time savings by removing steps such as cleaning and cleaning validation, and thus allow for faster changeover between products.



Plug in and you are ready to go

A complete suite of systems and accessories for cell culture and fermentation, separation and purification, fluid management, and connectivity, GE Healthcare's ReadyToProcess platform is designed to help you plug right into today's challenges—simplifying and accelerating biopharmaceutical manufacturing, reducing time-consuming routines, and ultimately increasing your manufacturing agility.

ReadyToProcess brings seamless, scalable implementation to your biopharmaceutical operations both upstream and downstream. Flexibility, rapid response, and product safety are possible from start to finish. And of course our systems are manufactured to the high quality and regulatory standards you have come to expect from GE Healthcare.



Our ready-to-use technologies bring plug-and-play options to biopharmaceutical manufacturing. Many of these are designed for single-use and disposable, others can be re-used. The key, however, is that they are preconditioned and prepared for immediate use.

Grow & Move

Pivotal to production agility

WAVE Bioreactor™ is an effective, cost-efficient system for cell culture. Cells and culture medium reside within the presterilized Cellbag™ bioreactor. A rocking motion generates waves in the culture fluid, providing optimum mixing and gas transfer, resulting in an excellent environment for cell growth. The disposable bioreactor bag eliminates the need for cleaning, sterilization, and validation. Multiple instrument configurations are available for suspension, microcarrier, batch, fed-batch or perfusion culture.

WAVE Mixer™ has been optimized for extremely efficient mixing and dispersion. Large volumes can be handled quickly, with no dead zones. Mixing operations can be monitored and controlled to suit the application.



Easier setup and changeover, no need for cleaning and validation procedures, ReadyToProcess helps to turn downtime into uptime while also maintaining the integrity of your operations.

Flex & Flow

Fit together for seamless routines

Available in a wide range of capacities and pore selections, ReadyToProcess filters include single-use cartridges for both cross flow filtration (CFF) and normal flow filtration (NFF) operations. Preconditioned, sterile, and ready for immediate use, they cut unnecessary downtime as they minimize preparation steps as well as eliminate associated cleaning protocols and cleaning validation.

ReadyToProcess connectors include ReadyMate™, Tube Fuser, and Tube Sealer, and are key to secure fluid transfer in processes requiring multiple connection and disconnection cycles. We offer a selection of integrated devices that provide aseptic and disposable connections between unit operations as well as leak proof seals of thermoplastic tubing to ensure sterile integrity and smooth workflows.



Ease & Assist

Secure in simplicity

ReadyCircuit assemblies comprise bags, tubing, and connectors. Together with CFF and NFF filters, ReadyCircuit assemblies form self-contained purification modules that maintain an aseptic path and remove time-consuming process steps associated with conventional systems.

All bags, tube sets, filters, and related equipment can be secured in appropriate orientations for efficient operation using the flexible mobile processing station, ReadyKart. With an array of features, and optional accessories, ReadyKart supports a variety of process-specific, fluid handling needs in a simple way.

Our on-line tool, ReadyKonfigurator, lets you design your fluid management circuits. Just enter the parameters, and the configurator will generate the design you need. Fast and convenient output includes Piping and Instrumentation Diagram drawings and Bill of Materials for prompt product order.



Synchronize & Run

Readier than ever

ÄKTA™ ready is a fully automated chromatography system for process scale-up and production of materials for clinical trials. The system operates with ready-to-use, disposable flow paths that are available in High and Low Flow Kits. The need for cleaning between products/batches is eliminated and no development or validation of cleaning procedures is required. The ÄKTA ready system is controlled with UNICORN™ software, with a setup wizard that automatically checks the installation of new flow kits. All systems come with traceability documentation.

Prepacked, prequalified, and presanitized, ReadyToProcess chromatography columns ensure quick and cross-contamination free project changeover between applications. The columns are sized for development work and clinical-scale manufacturing, and are packed with BioProcess™ media, including MabSelect™ and Capto™.



Significant time savings can be achieved in the downstream processing when column packing, qualification and sanitization are made redundant and ready-to-use, disposable flow paths are used.



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GE Healthcare

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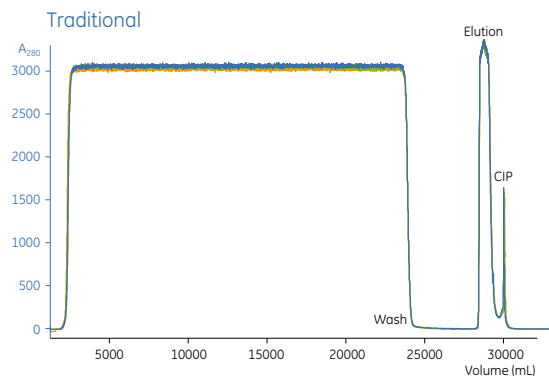
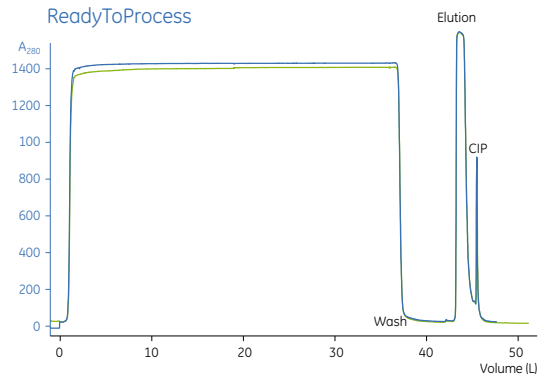
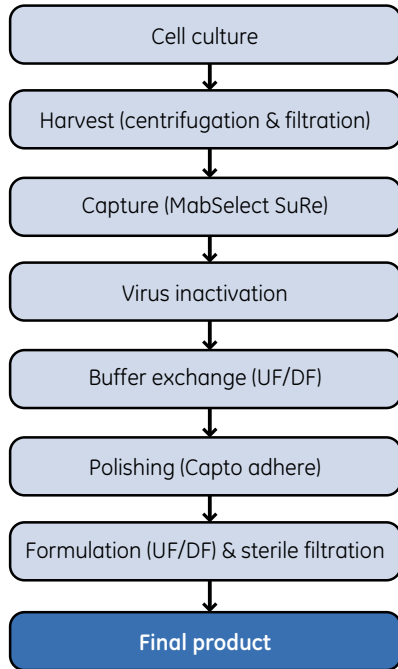
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Act & Accelerate

To compare the time-savings and performance of the ReadyToProcess approach with a more traditional approach, a mAb purification process was run identically on the two platform formats. The chromatograms show that the performance of MabSelect SuRe™ in the different formats was identical. However, the whole process was almost 50% faster using the ReadyToProcess approach. For details of the study, see GE Healthcare application note code number 28-9403-48.



Process step	ReadyToProcess	Traditional
Harvest	2 h	2 h
Capture, MabSelect SuRe*	8 h	17 h
Buffer exchange	3.5 h	6 h
Polishing, Capto adhere**	5 h	14 h
Formulation	4.5 h	6.5 h
Total time	23 h	45.5 h

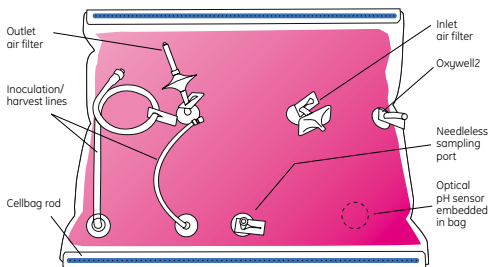
* Two cycles including preparations

** One cycle including preparations



WAVE Bioreactor Systems

WAVE Bioreactor is a cell culture instrument for the production of recombinant proteins in mammalian and insect cell lines in batch, fed-batch, and perfusion culture. The system is scalable over a wide volume range from 50 ml up to 500 l, and suitable for seed train and cGMP commercial production. Multiple configurations include use with Cytodex™ microcarriers. Depending on the specific system, features include temperature control, aeration controller, integral airpump, and integrated loadcell.



Cellbag Bioreactor

Cellbag bioreactor is a presterilized plastic bag that forms a disposable cell cultivation chamber. It is available in different sizes, for both standard and customized configurations. Cellbag components meet USP Class VI specifications for plastics. Validation data and Cellbag Drug Master File are available to demonstrate biocompatibility.



WAVEPOD™ II and UNICORN DAQ

The WAVEPOD II integrated controller enables accurate and quick regulation of the cell culture parameters of importance for cell culture success. Reliable and accurate control of pH is ensured by the “in-the-bag” integrated optical pH sensor. Data logging and analysis is made easy with UNICORN DAQ software. WAVEPOD II is designed for WAVE Bioreactor 20/50 system, whereas UNICORN DAQ is also available for larger systems.



WAVE Mixer

WAVE Mixer has been optimized for efficient mixing and dispersion of up to 35 l of liquid, in a choice of 20 or 50 l M Bags. Functions include thawing, pooling, mixing, media and buffer preparation. A screw cap port allows powders or other solids to be easily poured into the bag, and a probe (to measure pH) to be inserted.



Tube Fuser

Tube Fuser is a fully automated device for welding together a wide range of dry thermoplastic tubing in a sterile operation without the need for a laminar flow cabinet or similar environmental control device. Operated via a single push-button operator interface, it connects tubing between sterile containers, Cellbag bioreactors, and process equipment for the aseptic transfer of large volumes of fluids such as inoculum, media, buffers, and process intermediates.



Tube Sealer

Tube Sealer is a portable device that can heatseal a wide range of thermoplastic tubing types without the need for tubing adaptors. The seal forms a tamperproof and leakproof closure. The instrument is self-calibrating and ensures repeatable performance.



ReadyMate Disposable Aseptic Connector (DAC)

The genderless design and cross-size connectivity of ReadyMate aseptic connectors reduces complexity of inventory and creates flexibility in the assembly of single-use flow paths. Connectors come in standard hose barb, mini TC, and TC sizes. A large inner diameter provides for high throughput.



ReadyToProcess Hollow Fiber Cartridge

Hollow Fiber cartridges are preconditioned and ready-to-use cartridges for cross flow filtration, minimizing preparation steps and eliminating cleaning and cleaning validation. Hollow Fiber cartridges are available in a wide variety of ultrafiltration molecular weight cut-offs and microfiltration pore sizes, from laboratory to pilot-scale.



ReadyToProcess Normal Flow Capsule Filter

Normal Flow Capsule filters are preconditioned single-use filters designed for laboratory through process-scale applications. The filters provide sterilizing grade filtration for a wide range of biopharmaceutical solutions.



ReadyKart Mobile Processing Stations

ReadyKart processing stations have a flexible design with removable and re-positionable holders, trays, bins, and shelves for organizing any bags and associated tubing, ReadyCircuit assemblies that include CFF and NFF filters, pumps, and monitors. The carts are manufactured with industrial 360° swivel casters for smooth mobility. ReadyKart supports a variety of process-specific fluid-handling needs.



ReadyCircuit Assemblies

ReadyCircuit assemblies comprise bags, tubing, filters, sensors, and connectors for upstream and downstream applications. This easily configurable, aseptic, and disposable solution reduces time consuming process steps. The assemblies are provided as both complete off-the-shelf or custom-designed modules.



ReadyToProcess Konfigurator Tool

ReadyKonfigurator is a web-based tool that helps expedite the design of ReadyCircuit assemblies. Select your application, configure your assembly, select accessories, and then print the recommendations for a fast and convenient product order.



ÄKTA ready System

ÄKTA ready is biocompatible and hygienic, and meets all GLP and cGMP demands for Phase I-III in drug development and full-scale production. UNICORN software includes a complete guide and documentation for installation of flow kits and columns. After the completion of a purification task, columns and flow kits can either be disposed or exchanged for reuse. Replacing flow paths between projects is simple, with a downtime of less than 1 h.



ReadyToProcess Columns

ReadyToProcess chromatography columns are currently available with a range of BioProcess media in four different sizes: 1 l, 2.5 l, 10 l and 20 l. The columns offer the possibility to work in a fully flexible mode in early clinical phases while keeping a conventional reuse option for large-scale manufacturing open. Robust column construction and performance ensures process security and product safety.

