G&G TECHNOLOGIES, INC.

6 Grandview St.
Coventry, RI 02816
401-295-4000
www.ggtechnologies.com

WholeStream Bioreactors

Redefine Upstream& Downstream Processing

SmartFlow Technologies and G & G Technologies have combined their experience to bring biopharmaceutical companies a state of the art single use processing breakthrough in bioreactor and cell harvesting technologies. Removing the traditional upstream and downstream barriers, customers can breakthrough into a WholeStream manufacturing suite.

The WholeStream system, an industry first designed and built by SmartFlow Technologies and G & G Technologies, combines a bioreactor unit working in conjunction with a fully-integrated, automated cell harvest/clarification/concentration operated from a single control and HMI on a single skid. The WholeStream system includes the option to install additional microfiltration, ultrafiltration, and/or chromatography capabilities in a "plug and play" fashion. The first WholeStream system introduction, the WholeStream BioProcessor Model 50 3000, is a fully integrated, single-use disposable system comprised of a 50L G&G Technologies Omni Bioreactor system with automated controls and process monitoring. The cell harvesting utilizes the SmartFlow Technologies disposable OptiOne 3000 module technology assembled singly or in series within a SmartFlow Technologies Phoenix-class system. Each unit's operation is controlled via a single HMI screen with any additional unit operations (microfiltration, ultrafiltration, or chromatography) being automatically integrated as needed.

The WholeStream BioProcessor can function as a single-use disposable bioreactor and cell harvest/ clarification/ concentration system with a single-use pump design, sterile tubing, and sanitary connections or provide multiple usage capability with low volume 316L stainless steel piping. For true expandable operation, WholeStream users have the option to integrate additional SmartFlow Technologies microfiltration and/or ultrafiltration systems utilizing reusable OptiSep or single use OptiOne modules and/or a SmartFlow Technologies Chromapure chromatography system with customer-defined column and media components. Each unit's operation is fully automated and can be integrated into a facility's existing SCADA system or function as a stand-alone system. The use of a single integrated HMI control screen across the entire WholeStream system reduces queue times between processing steps, reduces the risk of spoilage or cross contamination when switching unit operations, and provides a uniform look, feel, and function, for the entire whole stream of processes.

For optimal cell growth potential, the WholeStream unit also introduces the new G&G Technologies Omni Bioreactor system, the only single use bioreactor employing the rapid and thorough blending capability of the PoGo mixing technology, adapted for high performance bioreactor operation. The Omni Bioreactor provides all control functionality needed for bioreactor operation in a sleek, integrated, and portable system design. Control of agitation, pH, dissolved oxygen, temperature, gas flow rates to sparge and overlay, and bag pressure are integrated into a simple user interface. Control is provided by open architecture PLC and software. A stainless steel holder has been tailored to hold the single use bioreactor bag, maximizing heat transfer and probe support, while providing viewing windows into the culture.

The single use bioreactor bag provides agitation without use of shaft seals or magnet and bearing assemblies that can leak and corrode. The unique shaft drive action of the PoGo Mixer provides direct and precise control of mixing, providing highly efficient blending. Mass transfer occurs by a unique delivery of air, oxygen and/or nitrogen to an integrated sparge connection. Delivery of carbon dioxide to a separate entry from the sparge entry point ensures precise control of pH without accumulation of carbon dioxide in the culture. Physical features that permit optimization for specific cultures include sparge orifice size, mass flow controller range, blend port diameters in agitator plates, and mixing stroke depth and speed. The bag is fully customizable with specific ports, tubing, and filter connections. In combination, these parameters provide an unparalleled range of capability. Scalability is easily achieved and characterized on a geometric scale.

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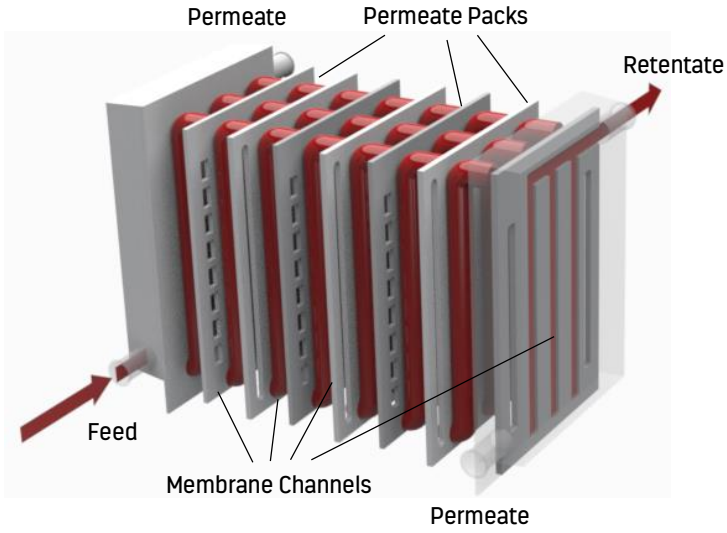
The ultra-low hold up design of the filtration system is based on the standard SmartFlow Technologies PuroSep Phoenix design, and users are ensured of consistent flow, monitoring, and operation with top of the line disposable or re-usable components.

The WholeStream system utilizes SmartFlow Technolgies' patented OptiSep technology. The OptiOne 3000 disposable module contains an open channel and rib design to ensure that retentate flow is dispersed over the entire membrane. Surface area resulting in higher yields, higher flux rates, and less fouling than traditional filtration techniques. The WholeStream 50-3000 has been optimized specifically for cell harvest applications, which require low shear and ultralow hold up volumes for maximized product yield.

The WholeStream system utilizes SmartFlow Technologies' proprietary StepWise software platform for easy to use control and automation of the bioreactor, filtration, and optional chromatography operations The integrated software provides easy-to-use HMI screens incorporating all unit operations, password protection, and full recipe management. Users have up to 20 configurable recipes to enable the optimization of any cell lines. Additionally, the StepWise platform allows for
easy integration into all plant wide networks.

Built in trending and Ethernet capability allows for historical tracking of production lots either at station or from remote log-in in a 21 CFR Part 11 compliant manner.

To discuss the full potential of WholeStream in your own facility, contact Feed SmartFlow Technologies (info@smartflow-tech.com) or G&G Technologies (info@ggtechnologies.com).



BIOREACTOR	
Max Working Volume (L)	50
Min Working Volume (L)	10
Tank ID (in)	12
H/D	2.5:1
Vessel Material of construction	304 Stainless Steel
Bioreactor Bag Material of Construction	Gamma Irradiated, USP Class VI LDPE
Agitation	
Motor	DC / AC
Impeller	Top-mounted, single use integrated with bag assembly
Impeller Type	Reciprocating / rotating discs
Number of Blades	3
Impeller Diameter (in)	6-8
Number of Baffles	0
Impeller Location	Centered
Sparger	Stainless steel sintered
	Optional: UHMW
Process Instrumentation	
pH Probes	1-2
DO Probes	1-2
Rotometer	1
MFCs	3-5
Pumps	1-4
Temperature Control Unit	Heater and Cooler available
Load Cell	1
Utility Requirements	110-240V, 1 phase, 50-60 Hz, Process gases
E-Stop	Available
FILTRATION SYSTEM	
Filter Holder	Disposable OptiOne 3000 or resusale OptiSep 3000
Retentate Loop Size	3/4"
Filter Orientation	Verticale, Horizontal, or Side
Pump Flow Rate	Min: 6L/hr; Max: 1200 L/hr
Max Pressure	4 bar (60 psi) at 20 deg C
Feed, Permeate, and Retentate Connections	Tri-Clamp and / or other sanitary fittings optional
Level Control Type	Load Cell (see Bioreactor)
Pump Type/ Model	QuattroFlow 1200 Single Use
Pump HP/ Max RPM	1 HP / 1750 RPM
Contact Material of Construction	Pre Sanitized Single use Grade Materials
Process Instrumentation	
Temperature	Retentate and Permeate
Conductivity	Permeate
pH Probes	Permeate
Pressure	Inlet and Outlet
Flow Rate	Retentate and Permeate