

atf SYSTEM

IMPROVE YOUR BIOPROCESS



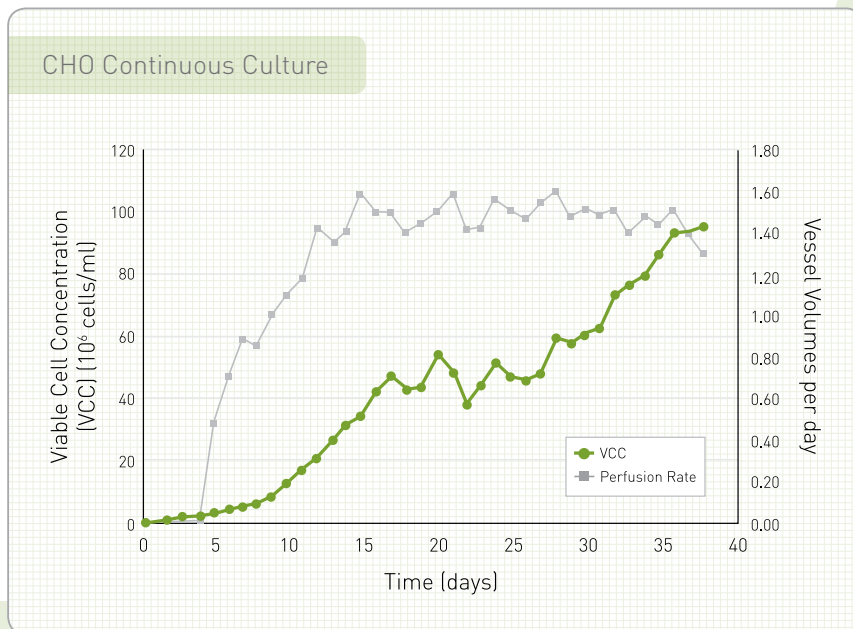
Significantly Increased Cell Density
Simpler Cell Separation
Higher Productivity

Designed to increase productivity of cell derived biopharmaceuticals, the ATF™ System provides a more reliable and efficient process of cell separation with the inherent ability to support cell growth to extreme concentrations. The ATF System allows increased volumetric productivity and reduced bioreactor size. The ATF System scales on a linear basis from 1 liter to greater than 1000 liters and can be used with traditional or disposable bioreactors and with all cell types including anchorage dependent lines.

Benefits of the ATF System include

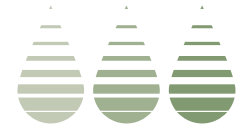
- Cell concentrations in the range 40-150m/ml with suspension cells such as CHO and PER.C6®
- Continuous protein production of 1g/L/day and higher
- Cells are maintained in a healthy state providing a more consistent product quality
- Rapid media removal or exchange at over 1w/hr
- A filtered product stream ready for purification
- No osmolarity increase, constant removal of waste / toxic molecules
- Faster, simpler virus production with a reduced cost of goods

High volumetric productivity in continuous culture using an ATF System



Data from CMC Biologics, published October 2007, Genetic Engineering News



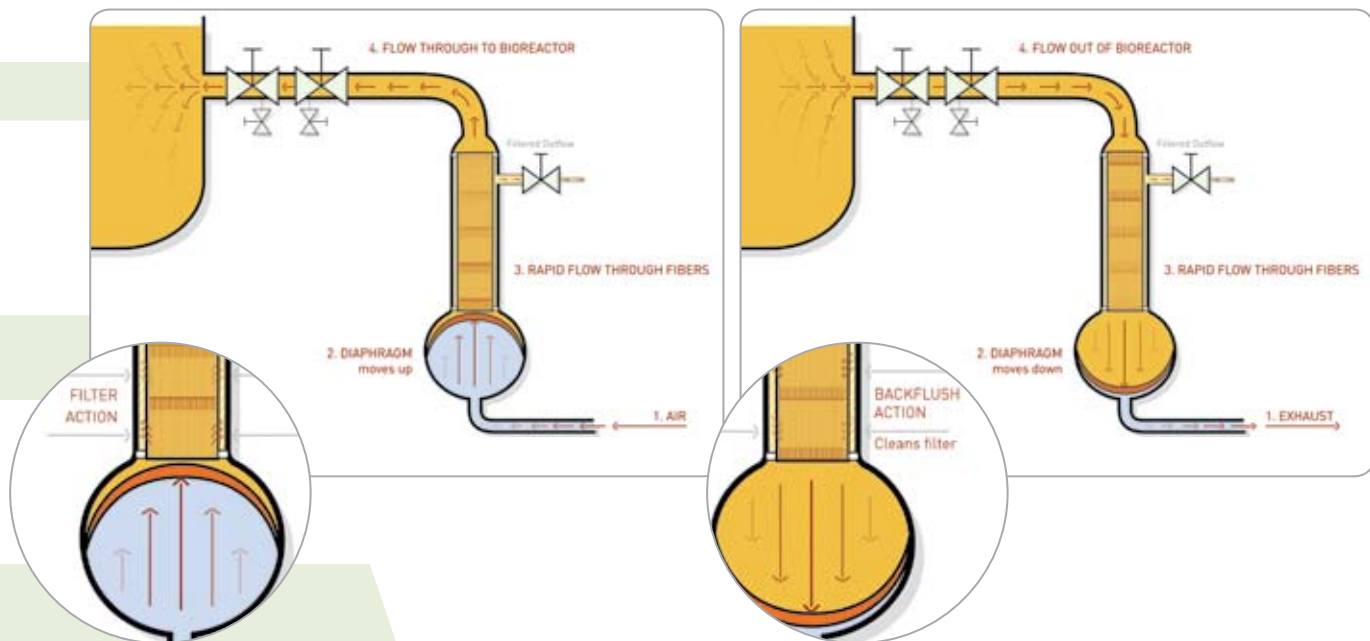


THE UNIQUE SYSTEM

The unique way the ATF System works is why it works

The heart of the system is a diaphragm pump which is powered by controlled flow of filtered air. The alternating flow of air into the base of the pump causes liquid above the diaphragm to flow through the ATF System and a filter to and from the bioreactor with each cycle. With each short 10 to 15 second cycle a small backflush occurs at each end of the filter. This backflush prevents filter clogging despite cell concentrations of over 100 million cells per ml.

To see this process in action visit www.refinotech.com

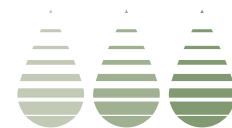


PROVEN APPLICATIONS

- Concentrated Fed-Batch
- High Productivity Continuous Culture
- Virus Production and Filtration
- XD™ Process
- Rapid Media Removal and Exchange
- Clarification and Harvest
- Cell and Product Concentration
- HD Cell Banking & RAPIDstart Manufacturing
- HD Seed Transfers & Reduction of Seed Train Steps
- Microcarrier Wash, Perfusion, Diafiltration, Medium Exchange and Cell Separation



Photograph courtesy of Avid Bioservices



Materials and Controller

The ATF System product contact parts are 316L stainless steel finished to 15 microinches Ra and electropolished. Sanitary fittings and valves are industry standard FDA approved and 'O' rings, gaskets, the diaphragm membranes and filters are USP Class VI certified.

The ATF System controller measures and controls pressures, flows and other operating parameters with appropriate alarming functionality. Two controllers are available: the C24 for R&D operations and the C410 for pilot and production scale which is designed to GAMP5 standards.

Each ATF System provided for use in a cGMP environment is offered with a complete documentation and validation package.

Connection to Bioreactor

With a range of standard port adapters the ATF System can be connected to any bioreactor. At small scale a diptube is used and at large scale a sanitary diaphragm valve tree is used. For disposable reactors, single-use solutions are available.

Sterilization and Cleaning

All ATF Systems are sterilizable by autoclaving either together with the autoclavable bioreactor or separately followed by connection with single use connector or a re-sterilizable valve tree.

All ATF System parts are machine washable.

Services

Services required are compressed air at 30-90psi (2-6 bar) and electricity at 100-240VAC.

Guideline Bioreactor Sizes and Scale-Up

	ATF2	ATF4	ATF6	ATF8	ATF10
Continuous Culture, XD™ Process or Concentrated Fed-Batch	0-4L	4-25L	25-150L	150-400L	400-1000L
Microcarrier Processes	0-10L	10-50L	50-250L	250-1000L	Up to ~5000L

The ATF System is used in both clinical and commercial manufacturing. Linear scale up of the ATF System is achieved by maintaining filter fiber length constant while increasing the number of fibers per module. With a proportional scale up in the ATF System pump, a relatively constant flow per fiber and ATF System cycle time is achieved at all scales thus allowing vessel scale-up from a 1L to 1000L with confidence.

Media Exchanges, Clarifications, Virus Filtrations and other processes are subject to large variation in the starting conditions and therefore are not included in this table.

Please call us to discuss your application.