



# THE QUANTASEP<sup>®</sup> FAMILY

## FULLY AUTOMATED CHROMATOGRAPHY "SCALE UP" SYSTEMS

### Scale Up Challenge

Advances in the genomic sciences and biotechnology have led to an unprecedented need to rapidly isolate novel biotherapeutics for preclinical and clinical testing and then bring them to the market.

Sepragen Corporation specializes in providing advanced liquid chromatography devices to separate and purify biomolecules from the development stage to commercial production of biological drugs.

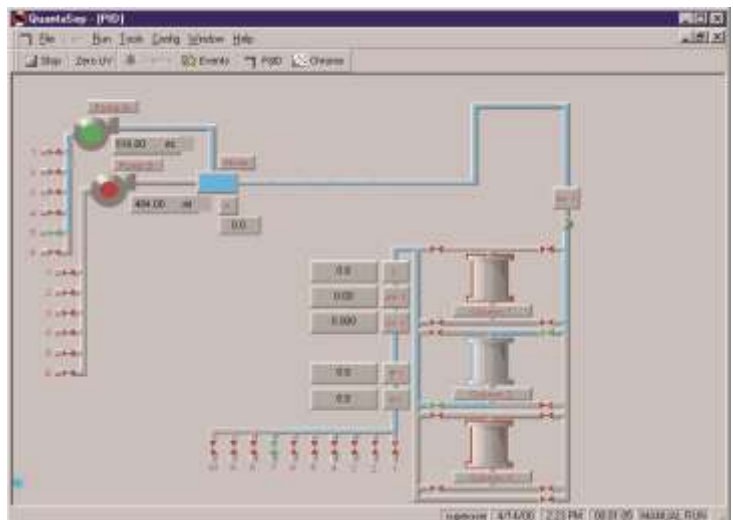
### Speed and Capacity

To meet the growing need for cGMP compatible sanitary purifications, Sepragen has developed a family of 5 systems designed to provide purification capability at different scales. All systems are scalable, and use the same design philosophy and software. They all automate many routine tasks so that mission critical project deadlines can be met. Clinical production capacity can be scaled up quickly within existing space and headcount limitations.

All QuantaSep<sup>®</sup>'s consists of dual metering pumps, buffer and fraction selection valves, UV, conductivity and pH sensor. Alarms for overpressure, leaks and air safeguard the system. An intuitive, powerful and graphical user interface allows manual operation and status display by the click of a mouse. Automatic operation of all steps including load, equilibrate, wash, elute, and regenerate are easily affected. Buffer and fractions can be enabled to switch on preset process parameters. Gradients can be performed. All events and alarms are logged. The QuantaSep<sup>®</sup> automatically produces batch history reports consisting of chromatograms, methods, calibration information, data analysis, security access control and alarm/event logs in GMP compatible format.



*QuantaSep<sup>®</sup> systems in use for contract manufacturing*



*The "P&ID Dashboard" allows easy operation by clicking on devices in the flow path.*



## About Sepragen

Sepragen Corporation, founded in 1985, has 14 patents underlying its core technology, including the invention of radial flow liquid chromatography and the advent of the fully automated chromatography system.

Sepragen chromatography equipment and systems are used in North America, Europe, Australia and Asia. Its customers include Alpha Therapeutics, Amgen, Asahi Glass, Aventis, Bayer, Baxter, Berlex, Cambrex, Chiron, Chugai, Cohesion Technology, CSL, Dade Behring, Dow, Dupont, Eli Lilly, Glaxo Wellcome, Genencor, Hoffman La Roche, Human Genome Sciences, IDEC, Lonza, Merck, Schering Plough, Roche Molecular Systems, Serono, Smithkline Beecham, Roche Diagnostics, Yoshitomi.

Sepragen's products are already used to manufacture over 20 FDA approved drugs including Kogenate (a registered trademark of Bayer), Alphanate (a registered trademark of Alpha Therapeutics), Neupogen, (a registered trademark of Amgen, and GammaGuard, (a registered trademark of Baxter).

Vinit Saxena, noted inventor and entrepreneur is founder and CEO of Sepragen Corp. Saxena states, "Our technologies enable our biotech and gene therapy customers to produce large quantities of product quickly, for clinical testing, which accelerates their time to market. The QuantaSep® Chromatography Systems will facilitate of biotech companies of all sizes to accelerate and complete pilot studies and FDA trials, and secure approval to manufacture and market life saving drugs."



**QuantaSep® 100**

Flow range 1-100 ml/min



**QuantaSep® 1000**

Flow range 10-1000 ml/min



**QuantaSep® 1000LX**

Dual range: 1-100 & 10-1000 ml/min



**QuantaSep® 1800**

Flow range 20-1800 ml/min

## The QuantaSep® Advantage

- ✓ **Scalable:** Select the QuantaSep® workstation you need, with distinct systems delivering between 100 to 5000 ml/min. When you require a higher flow rate, it is easy to scale up to the next level of QuantaSep® workstation, using the same system capabilities and software.
- ✓ **Automated Chromatography:** All separation steps are carried out via intuitive Windows NT Control Software. Multiple studies can be run automatically.
- ✓ **Exceptional Consistency:** even at the highest flow rates, the QuantaSep® system maintains low pressure and yields the highest standards of biological separations for a wide range of applications.
- ✓ **Automatically Generates GMP Reports:** You can now generate FDA-compliant reports without the time-consuming process of individually documenting each step, including variances.
- ✓ **Space Efficient:** The QuantaSep® system requires 70% less laboratory space than other models, thereby freeing valuable lab space for other applications.
- ✓ **Highly Reliable:** Our automated chromatography systems enable you to get the highest flow rate needed for your project, using a propriety technology. In the unlikely event of error, an early warning system is available.
- ✓ **Increases Productivity by 70%:** one operator can perform the work of two or three full time individuals by performing multiple chromatography studies.
- ✓ **Reduces Cost:** By enabling an operator to perform other activities and by providing automatic GMP reports, overall labor costs can be reduced by 50%. Payback is less than six months!
- ✓ **Outstanding Technical Support:** Sepragen is highly regarded for providing person-to-person interfaces to insure effective customer support.



**QuantaSep® 5000**

Flow range: 50-5000

#	Pgm	Label	A	B	A+B Flow ml/min	Col	Dir	Ch Meth	Ch Thresh	Ch Time	Slope	Grad	Event
1	-	equil1	6	0	70	1	Fwd	Col Volume	0.5	0.0 m	Pos	0	Zero the UV1 Baseline, Turn fil
2	BEG[E	Load	0	1	70	1	Fwd	Air 1	0	0.0 m	Pos	0	No Events
3	END	Wash	6	0	70	1	Fwd	Col Volume	2	0.0 m	Pos	0	No Events
4	-	Elute 1	0	6	50	1	Fwd	Col Volume	2	0.0 m	Pos	0	No Events
5	-	regen	1	0	70	1	Fwd	Col Volume	2.5	0.0 m	Pos	0	No Events
6	SUB	Purge											

QuantaSep®'s simple step-by-step, tabulated programming format makes it easy to replicate batch runs for laboratory process development and trouble shooting work, as well as pilot scale purifications.

## Customer Recommendations

"The efficiency of these products, in our hands, provides a significant advantage over other purification equipment we have evaluated for the following reasons.

- 1) The QuantaSep® software is easy to use and train.
- 2) The QuantaSep® allows us to reduce our standard direct hours, thus reduce our projected costs, by allowing a production chemist to perform multiple purification tasks simultaneously. This system eliminates the need to "baby-sit" all the individual purification steps. With reduced labor costs, the return on investment is easily less than two years for the QuantaSep®.
- 3) This programmable system insures lot-to-lot consistency, resulting in consistent elution profiles vs. the built in variability with more manual operations. A critical advantage for a GMP production process.
- 4) And finally, one unique advantage of this system is its versatility. We can run both our small and large volume production (5 liter to 200 liter) runs with the change over feature. No other systems we have investigated have that volume flexibility."

Dennis Gould, Manager,  
Antibody Manufacturing, Dade Behring

"The QuantaSep® are workhorses in our facility and are used routinely in development and production. They have enabled us to get work done with greater consistency in less time. We are satisfied with the performance of the QuantaSep® and - I might add - with the high level of care and responsiveness that Sepragen has demonstrated towards addressing our needs over the years. Their product technology and service are unmatched."

Guang Qu, Associate Director, Avigen

"We have purchased several QuantaSep® Systems and use them routinely in development and manufacturing. They have provided us with the capability to scale-up quickly and reliably. The robust design and compact size has enabled us to add productive capacity without waiting for additional construction.

The QuantaSep® software is easy to learn and use. Automated processing and report generation have enabled us to get more done with the same resources. Our quality and consistency have improved, as well. I would highly recommend the QuantaSep® family of products to anyone."

Mark Oelkuct, Purification Manager,  
Human Genome Sciences, Inc.



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## QuantaSep® Highlights

- Dual positive displacement pumps with 100:1 turn down ratio
- 8-12 user selectable buffers
- 1-3 user selectable columns forward/reverse/bypass mode
- 6-10 user selectable fractions with fraction collect capability
- Sanitary design
- Low hold up volume
- Small component footprint 21"x26"x15", 22"x27"x46"
- 5%-95% gradient capability
- UV, conductivity and pH sensors
- Buffer/fraction changes on UV, conductivity, pH or air
- Active P&ID for operation
- Auto air ejection system
- Leak alarm
- High-pressure alarm
- Security/controlled access
- cGMP reports
- Event log for traceability
- Data analysis
- Event annotated chromatograms
- Calibration history

## Wetted Materials of Construction

Silicone, polyethylene and polypropylene tubing; polypropylene valves and fittings; PTFE diaphragms; glass/quartz/316L stainless steel sensor components.

## Components Specifications

280 nm UV 0-2 Au  
254 nm UV 0-2 Au (Optional)  
Conductivity Sensor 0-200 ms, ± 5% pH  
Sensor 1-14 pH, ± 0.2 Air Bubble > 0.20"  
Pressure Sensor 0-100 psi ± 1 psi Leak  
Sensor 5 ml leak volume

## Warranty, Installation & Support

All QuantaSep®'s are backed by Sepragen's one year limited warranty. Installation and training, along with IQ/OQ are performed by Sepragen Service Group. Preventative maintenance and Total maintenance service is provided at added cost. Validation support packages are also available.

To learn more call:

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