

## **Bioproduction Process** Upstream, Downstream, Quality Control



# Making science real in your bioprocess

## From producing organism to final product





YOUR PARTNER IN PURCHASING AND MAINTAINING BEST-IN-CLASS LAB SOLUTIONS EVERY STEP OF THE WAY. Dual expressor HEK293T cells for cell line development









# Gentle sorting for healthy cells

#### The WOLF® is a compact and robust cell sorter

- Low sorting pressure: high post-sort cell viability and genomic integrity
- Sterile and disposable microfluidics: a faster process and no cross contamination
- 2 lasers and up to 9 optical parameters
- N1 Single Cell Dispenser: single cell sorting into 96- or 384-well plates
- Suitable tool for sample preparation, cell line development and cloning applications
- CS1 Chiller Stirrer: a module to provide cooling of sample and sheath fluid, as well as stirring of sample



Roche CustomBiotech Cedex® HiRes



## Cell Counter

An automated cell counter with high resolution, scannerbased imaging that provides deep insights into changes in your cell culture.

- Measured values: cell concentration and viability, morphological parameters, growth curves, growth rates and doubling time
- Easy to integrate into fully automated process systems
- Used in GMP-validated biopharmaceutical production processes and complies with GMP regulations such as 21 CFR Part 11

ABER Instruments **FUTURA** 



## On-line biomass probe

ABER Instruments FUTURA system allows you to measure the live biomass in your bioreactor on-line and thus close the data gaps of off-line analysis. ABER's technology already has been the benchmark in this field for several years and is used by customers throughout the entire world from R&D to GMP production.

- Real-time measurement of biomass
- Plug-and-play

Sodium Sucrose

- Possibility to automte feed strategies
- Validated according to CFR21 part 11



Roche CustomBiotech Cedex<sup>®</sup> Bio/ Cedex<sup>®</sup> Bio HT

## Automated Bioprocess Analyzer

Designed for monitoring as well as developing and optimizing the growth conditions for mammalian, bacterial and yeast culture systems.

- Available for both low and high sample throughput
- A total capacity of up to 126 samples and 32 measurable parameters
- Easy to integrate into automated sampling processes (Cedex<sup>®</sup> Bio HT) and GMP validated biopharmaceutical production processes (Cedex<sup>®</sup> Bio meets GMP regulations such as 21 CFR Part 11)

yeast & insect cells	

Substrates	Metabolites	Products
Ala-Gln (GlutaMAX) Arabinose Asparagine Aspartate Calcium Cholesterol Ethanol Galactose Glucose Glucose Glutamate Glutamate Glutamine Glycerol Iron Magnesium Nitrate Phosphate Potassium Pyruvate	Acetate Ammonia Formate Lactate LDH Osmolality calc.	lg Fab (human) IgG (human) Mouse IgG Optical Density (bio mass) Total Protein

Gator Bio Inc. **Gator Systems** 



## Label-Free Analysis Systems

Based on biolayer interferometry (BLI) technology, the Gator Systems enable real-time measurements to support the analysis of biological molecules : quantitations, kinetics and regeneration in one run. The integrated software combines acquisition and analysis to enable setup from start to finish.

	GatorPrime	GatorPlus
Detection technology		Biolayer Interferometry
Analysis types	Quantitation, Yes/N	o Binding, Kinetics, Affi
Sample types	Proteins, Antiboo	dies, Peptides, Nucleid A Small Molecules, AAV
Number of Channels	ξ	3
Data Aquisition rate		2, 5, 10 Hz
Plate format	1 x 96-well plate & 1 x 96-well max plate	1 x 96- or 384-well & 1 x 96-well max plate
Max samples per run	168	456
Quantitation throug- hput	96 samples in less than 30 minutes	384 samples in less than 2 hours
Kinetics per run	72	192
Epitope binning	12 x 12	16 x 16
Minimum sample volume	180 µl	40 µl
Baseline noise		≤4 pm(RMS)
Baseline drift		≤ 0.1 nm/hour
Association rate k <sub>on</sub>		10 <sup>1</sup> - 10 <sup>7</sup> M <sup>-1</sup> s <sup>-1</sup>
Dissociation rate $\boldsymbol{k}_{\text{\tiny off}}$		10 <sup>-6</sup> - 10 <sup>-1</sup> s <sup>-1</sup>
Affinity constant $K_{D}$		10 pm - 1 mM
Dimensions	46 x 67 x 32 cm	63 x 73 x 44 cm
GMP software		Optional
Temperature		Ambient - 40°C
Automation compatible	n	0

## Gator<sup>™</sup> Probe

ProA	• Ni-NTA
SA	• APS
MFC	• AR
HFC	• ProG
SMAP	• ProL
AAVX	• Anti-Rabbit
Flex SA	<ul> <li>Anti-FLAG</li> </ul>
FAB	• SARS-RBD
HIS	<ul> <li>Anti-GST</li> </ul>

• IgG Fc Gen II

• IgG Fc • AAV9







Acids, Liposomes,

32



• High sensitivity AAV • High sensitivity AAV9 • AAV empty/full (ratio kit)

### Assays

#### **BIOTHERAPEUTICS**

Antibody titer measurements **Kinetics analysis** Epitope binning **Process development** Manufacturing QC Pharmacokinetics

### **GENE THERAPY**

AAV quantitation & kinetics **Receptor interaction** Gene expression

#### **DRUG DISCOVERY &** DEVELOPMENT

Protein - small molecule interaction Peptide binding analysis

#### LIFE SCIENCE RESEARCH

**Protein interaction** 

Receptor - ligand binding

Assay development and optimization



**Connect the SegFlow S3** with a FISP Separation Probe to your bioreactor for cell free samples.

"The introduction of a Protein Maker

instrument has made it possible to

simultaneously affinity capture 24

samples at 20 - 200 mL culture volume

192 purifications

per dav





## Automated sampling and analysis 24/7

The SegFlow S3 is the new generation of automated sampling and measurement data management. The user interface is graphically very catchy, contains new functions and more information about a current sampling process. The cleaning and disinfection of the flow path are arranged centrally, the sampling is automatically optimized and adapted to the sample.

- Up to 8 vessels or process stream connections
- Real time transfer of measured values
- Easly connected to analyzers: FLEX2<sup>®</sup>, CEDEX Bio HT<sup>®</sup>, Vi-CELL<sup>®</sup>, CEDEX HiRes<sup>®</sup>, YSI<sup>®</sup> Analyzers, HPLC, Kaiser RamanRxn2<sup>®</sup> and the Flow Fraction sample collector





## Radial Flow Chromatography

Sepragen Columns help increase separation efficiency while maintaining quality and cGMP demands in the production. Due to the special architecture, the system ensures running on high flow rates while maintaining a low back pressure. Perfectly fit for a linear scale up (50 mL up to 500 L) and can be integrated in an automated control systems (Quantasep® range).

Protein Biosolutions, Inc Protein Maker™

## High throughput protein purification chromatography

Accelerate your research on protein function with parallel purification. Run 24 columns (1 - 5 mL) in parallel, and process 96 samples unattended to achieve a variety of tasks:

- **PRODUCE** purified proteins and antibodies
- **EVALUATE** gene expression levels
- ANALYZE functions of different isotypes or clones
- **DETERMINE** the best proteine or enzyme purification method for scaling up
- SCREEN constructs for protein
- 24 different protein samples, one type of chromatographic resin
- Automated, multi-column chromatography
- 24 different chromatic resins, one protein sample
- Compatible with common commercial columns
- Optional 24-channel LIVE UV Monitoring

#### Linear scale up from 400 mL to 12L



QuantaSep® 1000
20 mLs Bovine serum
95 mL/min
DEAE
7.1 grams/100mL diluted serum
0.05 M Tris-HCl, pH 7.1
0.25 M NaCl in Tris Buffer

within 1 - 4 hours"

Yang et al. Mabs. 2021



## Simplicity and Power in Separation

The Quantasep® simplifies separation processes while maintaining critical quality attributes and keeping a small lab footprint. The software is fully 21 CFR part 11 compliant and designed to fulfill end user's requirements. The graphical user interface enables efficient programming of complex time and different methods. A variety of models allows effort scale up, while maintaining consistency even at the highest flow rates.





System:	QuantaSep® 5L
Sample:	600 mls Bovine serum
Flow Rate:	2850 mL/min
Media:	DEAE
Protein Content:	7.1 grams/100mL diluted serum
Buffer:	0.05 M Tris-HCl, pH 7.1
Gradient:	0.25 M NaCl in Tris Buffer



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