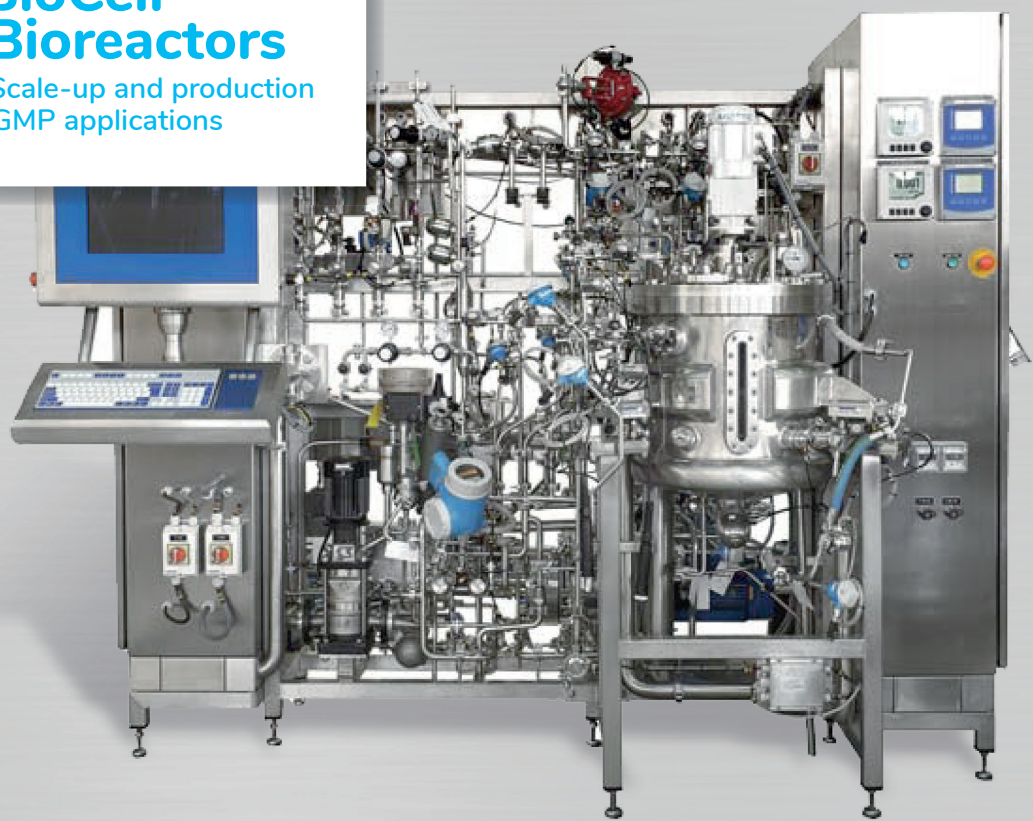




# BIOCELL™ Lab & Pilot Series STEAM IN PLACE BIOREACTORS 10L to 300L W/V

Innovative solutions and support

**BioCell  
Bioreactors**  
Scale-up and production  
GMP applications



PG's fermentation solution: Affordable modularity

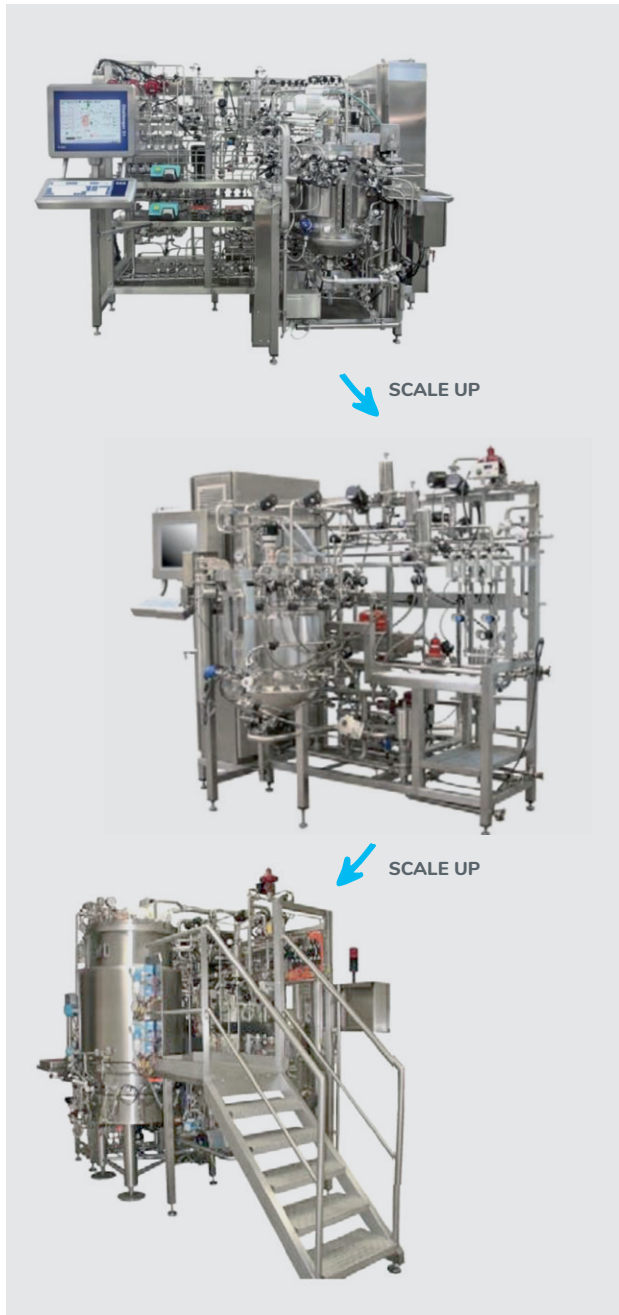


# BIOCELL™ BIOREACTORS FOR BIOPROCESS SCALE UP AND PRODUCTION RUNS

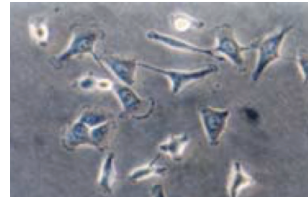


## Experience & innovation

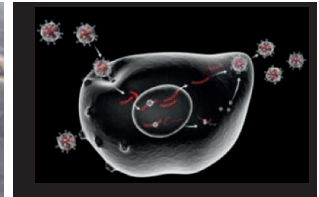
Utilizing its expertise in industrial bioprocesses and automated systems, **PIERRE GUERIN - BIOLAFITTE offers its BIOCELL™** series, a new generation of Lab & Pilot Steam In Place bioreactors designed for optimization studies scale-up and production runs in GLP or GMP environments.



These systems represent the best pre-engineered cell culture devices and are suitable for the cultivation of either suspended or attached cells in batch, fed-batch or perfusion mode (with appropriate accessories).



MAMMALIAN CELL CULTURE



VIRUS AMPLIFICATION

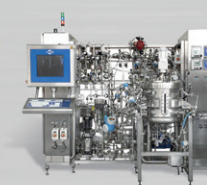
## Benefits

- > Ergonomic, modular and compact systems allowing easy installation and maintenance
- > Fully customizable pre-engineered systems designed for R&D, scale-up and productions in GLP or GMP environments
- > High thermal transfer performance and minimum shear force via the use of the patented HTPG4™ impeller
- > **NEPTUNE™** Control system with user friendly / intuitive interface and multiple options
- > Micro PLC / PLC – PC based control technology and industrial components ensuring robustness and reliability to the system
- > Software developed from non-proprietary platforms complying with GMP requirements (21CFR PART11 and GAMP 5)
- > Remote supervision and maintenance of multiple bioreactors via **ETHERNET™** network

## Quality program and qualification

- > Full system testing and comprehensive FAT
- > Rigorous quality program including 100% endoscopic control of process welds with numeric records, full material traceability for product-contact parts and comprehensive tests for problem-free start-up
- > Extended test program and documentation package (FS, HDS, SDS, FAT / SAT protocols) designed to support and ease qualification

# BIOCELL™ BIOREACTORS TECHNICAL SPECIFICATIONS



## Vessel, agitation & accessories

### Vessel

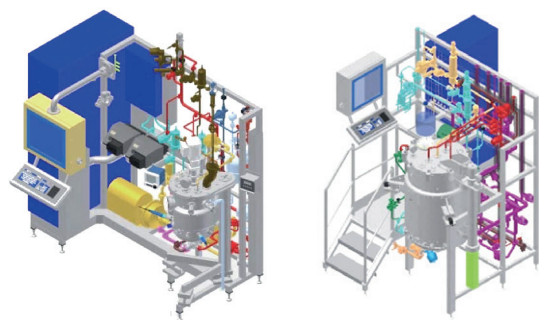
- > Jacketed vessel fitted with removable head plate
- > Available sizes : 10, 20, 30, 60, 100, 150, 200, 300 w/v - working aspect ratio of 1:1
- > Material (product-contact parts): stainless steel grade 1.4404 (316L)
- > Finish (product-contact parts):  $R_a \leq 0.5 \mu\text{m}$  for vessel (with electro-polishing) and piping
- > Maximum operating pressure: 3 bar g for vessel and jacket

### Agitation

- > Bottom or top mounted agitation equipped with one HTPG4™ impeller or equivalent like pitched blade or marine impeller - tip speed : 2 m/s
- > Agitation with magnetic coupling

### Accessories

- > Round sight glass and illumination lamp
- > Sanitary pressure relief valve and pressure gauge
- > 3 x resterilizable product lines for inoculation, media loading and sterile additions & disposable connections on request
- > 5 x DN25 Ports for standard probes and sensors
- > Combined resterilizable harvest and sampling line with flush-mounted diaphragm valve
- > Up to four peristaltic pumps including one with adjustable speed for fed-batch or perfusion culture
- > Two independent gas supply lines to the overlay (Air and CO<sub>2</sub>) and to the sparger (O<sub>2</sub>)
- > O<sub>2</sub> flow-rate controlled via mass flow controller



Additional equipment (peristaltic pumps, reagent flasks, autoclavable or SIP vessels, scales, CIP units, ...) and customized design for specific applications and biological containment are also available on request.

Code	Vessel Volume (Working/Total)	Selection
B01	10L / 20L	
B02	20L / 35L	
B03	30L / 50L	
B04	60L / 90L	
B05	100L / 150L	
B06	150L / 200L	
B07	200L / 280L	
B08	300L / 420L	

Code	Version	Selection
M	Semi-automatic	
A	Full automatic	

Code	Vessel, agitation and accessories options	Selection
00	Oval sight glass in replacement of the round sight glass	
01	Vessel insulation	
03	Independent Spin Filter with magnetic coupling for perfusion	
20	Resterilizable gas filters	
24	Additional resterilizable product addition line	Qty :
25	Resterilizable product transfer line	Qty :
26	CIP devices	
27	Independent resterilizable sampling valve	
30	Nitrogen line with rotameter	
31	Exhaust gas condenser	
32	Double filtration on gas exhaust line	
34	Exhaust gas heater	

0.2  $\mu\text{m}$  absolute filters on gas inlet and outlet

## Temperature control

- > Cultivation temperature automatically controlled by injection of plant hot or cold water into jacket
- > Steam sterilization of empty vessel

Code	Temperature control options	Selection
21	Jacket circulating pump	
22A	Cooling via chilled water circulation in jacket	
22B	Cooling via glycol water heat exchanger <sup>(1)</sup>	
23A	Heating via steam heat exchanger <sup>(1)</sup>	
23B	Heating via electric heater <sup>(1)</sup>	

(1) To be combined with option 21

# BIOCELL™ BIOREACTORS TECHNICAL SPECIFICATIONS



## Instrumentation

Automatic control of temperature, speed of agitator, pH and pO<sub>2</sub> O<sub>2</sub> flow rate to the sparger automatically controlled by mass flow meter and air / CO<sub>2</sub> flow rate to the head space controlled via rotameters and automatic valves

Code	Instrumentation	Selection
40	Air mass flow controller in replacement of the rotameter	
41	Automatic control of the head space pressure	
43	Foam level control	
44	Vessel low level switch	
45A	Vessel weight measurement (Load Cells)	
45B	Continuous level measurement	
46	Temperature measurement on drain lines Qty :	
47	Feed back control of valve position Qty :	
48	Feed back control of speed	
49	Printer	
50	Control of nutrient flow rate	
51	Optical density measurement	
52	O <sub>2</sub> / CO <sub>2</sub> exhaust gas analyzer	

## Neptune control system

- > Micro-PLC / PC based control with a wide choice of Human Machine Interfaces: laptop or desktop PC as standard or optional Industrial Touch Screen Panel
- > Up to 32 configurable control loops for a wide range of process parameters including temperature, pH, Redox, speed control, pO<sub>2</sub>, foam, gas flow rates, weight or level, OD, pO<sub>2</sub> / pCO<sub>2</sub> on gas exhaust
- > Control types include : PID, digital on/off and others – cascade mode for advanced control strategies

## NEPTUNE™ InTouch software includes the following modules

- > Customized **User Access** module complying with 21CFR PART11
- > **Synoptic overview** presenting all on-line measured values, actuator status, phase running, alarms
- > **Parameter editing** module allowing operator for adjusting set points, PID settings,...
- > **Audit Trail** module capturing all actions made with the software and providing a query SQL database record for a batch with customized report generation
- > **Trend** module allowing data display in the form of trends or historic graphs
- > **Maintenance** module allowing by-pass



**Neptune**  
PIERRE GUERIN

## NEPTUNE InTouch Advanced version

(additional modules to the standard software version)

- > **Strategy** module enabling process to be defined stepwise for process customization and repeatability typically used for feed control, complex gassing addition, set-points ramps or event based actions

## NEPTUNE InTouch Expert version

(additional modules to the advanced software version)

- > **Calculation** module providing a means to take automatic calculations (RQ, OTR,...) in real-time. Calculated values can then be logged or implemented as a new process control variable.
- > **Profile** module for controlling set-points via imported or plotted data
- > **Data Offline** module allows definition of offline variables with their specific time stamps and values for a selected batch
- > **Advanced Maintenance** module providing the total function time of each actuated system
- > **Flex Control** module allowing for editing or modifying a controller



## Software configuration

Code	Software configuration	Selection
60TA	NEPTUNE SCADA InTouch in <i>Advanced version</i>	
60TE	NEPTUNE SCADA InTouch in <i>Expert version</i>	
-	Remote supervision via Team Viewer	

## Available sizes & dimensions (without control cabinet)

Nominal working	Minimal working	Total volume	Depth (mm)	Width (mm)	Height (mm)	Weight
10L	5L	17L	950	950	1950	175 kg
20L	8L	30L	950	1000	2200	185 kg
30L	12L	40L	950	1050	2300	200 kg
60L	24L	90L	1300	1500	2550	350 kg
100L	40L	150L	1350	1550	2750	480 kg
150L	60L	200L	1350	1550	3000	520 kg
200L	80L	275L	1400	1600	3350	550 kg
300L	120L	400L	1450	1750	3900	650 kg