

BIOCELL™ PILOT SERIES

GMP BIOREACTOR 60 Up To 300L WV

EXPERIENCE AND INNOVATION

Utilizing its expertise in process vessel manufacturing, cell culture and automated systems, **DCI-BIOLAFITTE** introduces its **BIOCELL™ PILOT SERIES**, a new generation of SIP / CIP pilot bioreactor. These systems represent the best tool for optimization of your batch, fed-batch or continuous cell culture processes using suspended cells or micro-carriers.

BENEFITS

- ❑ Open frame units are pre-mounted and pre-wired, allowing easy installation and maintenance
- ❑ High thermal transfer performance and minimum shear force via use of patented HTPG4™ impellers
- ❑ User friendly control interface utilizing Windows™ operating system
- ❑ Software packages for cell culture research/process optimization or production
- ❑ Designed to meet all needs for cGMP validated applications:
 - Material and component traceability - Endoscopic control of welds
 - Comprehensive testing and documentation package to support validation
 - Software compliant with cGAMP revision 4, 21 CFR Part 11 and S88 standards (batch module)

TECHNICAL SPECIFICATIONS

REACTOR

- ❑ Bottom and wall jacketed vessel with flat cover - aspect ratio of 1 : 1 - available sizes: 60/90 L, 100/150 L, 200/280 L, 300/420 L
- ❑ Material and finish: stainless steel grade 1.4404 (316L) Ra ≤ 0.4 µm; all parts in contact with the culture are electro-polished
- ❑ Design pressure: 3 bar g (43 PSI) for vessel and jacket
- ❑ Standard features: round sight glass, illumination lamp, sanitary relief valve, pressure gauge, product inlets, DN25 ports for probes independent resterilizable sample valve

Options: Oval sight glass, clean in place devices, independent spin filter with magnetic drive for continuous culture, vessel insulation (bottom and wall)

AGITATION

- ❑ Top-mounted agitation system equipped with one HTPG4™ impellers - tip speed of 2 m/s
- ❑ Magnetic coupling

AERATION

- ❑ Via sparger (O₂) and overlay in headspace (air and CO₂)
 - ❑ 0.2 µm absolute filters on gas inlet and outlet
 - ❑ O₂ flow-rate controlled via mass flow controller
- Options: Additional gas supplies (N₂), automatic pressure control, exhaust gas condenser, exhaust gas heater, double filtration of exhaust gas, mass flow controller on air inlet, resterilizable filters*

PRODUCT ADDITION LINES

- ❑ 3 resterilizable lines for addition or transfer of product
- ❑ Combined resterilizable harvest and sampling line with flush-mounted diaphragm valve
- ❑ Connections for 4 peristaltic pumps, including one with adjustable speed for fed-batch cultures

Option: Additional resterilizable product lines, independent resterilizable sampling line



TEMPERATURE CONTROL

- ❑ Cultivation temperature controlled by injection of hot or cold water into jacket
 - ❑ Sterilization via direct / indirect steam injection
- Options: Glycol water heat exchanger, steam heat exchanger, electrical heater*

INSTRUMENTATION AND AUTOMATION

- ❑ PLC or DCU and PC workstation - Pentium 4 microprocessor, 1 GHz minimum
 - ❑ Operator interface with touch screen
 - ❑ Highly flexible control loops - Control types include PID, digital on/off, and others - Cascade mode for advanced control strategies
- Options: Color printer, measurement and/or control of all cell culture parameters: air flow / pressure / anti-foam / weight / additional temperature monitoring on drain lines / low level / positive feedback of valve positions / nutrient flow / optical density / gas analyzer*

CONTROL SOFTWARE

WINPROGRESS™ SCADA/PLC combination or NEPTUNE™ SCADA/DCU combination

Basic version:

- ❑ Graphical representation of system, updated in real time
- ❑ Data logging and archiving with trends and graphs - Data can be exported via standard file format for use in reports or for further analysis
- ❑ Archive management
- ❑ Color printing of graphs, events and alarms
- ❑ Audit trail
- ❑ Alarm monitoring
- ❑ Access by password

Option: Advanced version

- ❑ Calculation module allowing users to define additional calculations and apply control based on those calculations - Also adds set point profile feature - Cultivation file management
- Option: Expert version*
- ❑ Batch module compliant with ISA S88 guideline or Sequence module for process strategy optimization

QUALIFICATION AND VALIDATION

- ❑ Full material traceability - All manufacturer certifications supplied
- ❑ 100% endoscopic control of process welds + 10% with CD record
- ❑ Comprehensive test and documentation program designed to ease and support validation

BIOCELL™ PILOT SERIES - SELECTION GUIDE

Indicate your selection here →

Code	Vessel Capacity (Working/total)
B11	60 / 90 L
B12	100 / 150 L
B13	200 / 280 L
B14	300 / 420 L

Code	Version
M	Semi-automatic
A	Automatic

Code	Control System
N	NEPTUNE
W	WINPROGRESS

Code	Construction code
C	CODAP 2000
B	BRITISH STANDARD 5500
A	ASME

- (1) To replace round sight glass
- (2) All requires option 21, jacket circulator
- (3) Basic version already fitted with 3 lines

Additional equipment (peristaltic pumps, reagent flasks, autoclavable or SIP vessels, scales, CIP units, gas analyzers...) and customized designs for specific applications and biological containment and perfusion are also available.

Indicate your selection here →

Code	Available Options
00	Oval sight glass ⁽¹⁾
01	Vessel insulation
03	Independent spin filter fitted with magnetic drive for continuous cell culture
20	Resterilizable gas filters Qty:
21	Jacket circulator
22A	Cooling via chilled water circulation in jacket
22B	Cooling via glycol water heat exchanger ⁽²⁾
23A	Heating via steam heat exchanger ⁽²⁾
23B	Heating via electrical heater ⁽²⁾
24	Resterilizable product addition line ⁽³⁾ Qty:
26	Cleaning in place device
27	Resterilizable sampling valve
30	Nitrogen line with rotameter
31	Exhaust gas condenser
32	Double filtration of gas inlet and exhaust gas lines Qty:
33	Exhaust gas heater
40	Air flow rate measurement and control
41	Vessel pressure measurement and control
43	Anti-foam control
44	Vessel low level switch
45A	Vessel weight measurement
45B	Continuous level measurement
46	Temperature measurement on drain lines Qty:
47	Feedback control of valve position
48	Feed back measurement of agitation speed
49	Color printer
50	Nutrient flow rate control
51	Optical density measurement
52	Gas analyzer
60B	Advanced version supervision software
60C	Expert version supervision software

AVAILABLE SKID SIZES

Nominal working volume	Minimum working volume	Length	Width	Height	Weight Empty
60 L	20 L	1850 mm (73 in)	1050 mm (41 in)	2200 mm (87 in)	250 kg (550 lbs)
100 L	30 L	1850 mm (73 in)	1050 mm (41 in)	2200 mm (87 in)	280 kg (620 lbs)
200 L	65 L	2500 mm (98 in)	1500 mm (59 in)	2500 mm (98 in)	300 kg (660 lbs)
300 L	90 L	2500 mm (98 in)	1500 mm (59 in)	2500 mm (98 in)	330 kg (730 lbs)

Other sizes available upon request

