

## AbioPilot Stainless Steel Bioreactor

Applitech Biological Technology Co., Ltd., as a high-tech enterprise integrating design, R & D, production, sales and service, we are committed to providing professional production and analysis equipments, single-use consumables and comprehensive solutions for the biopharmaceutical field. Since our establishment, we have always been customer-centered and taken "Quality First, Service Foremost" as our business principle. Based on the optimization, scale-up and production of bioprocess, we have been continuously improving the product lines in the biopharmaceutical field, providing users with all-round professional solutions for biotechnology and helping them to continuously make new breakthroughs in the biopharmaceutical field.

With nearly two decades of expertise in the bioreactor field, Applitech is dedicated to developing premium, self-branded bioreactors. Our product range spans from R&D to pilot-scale and cGMP production, with applications in antibody, vaccine, cell therapy, gene therapy, and stem cell therapy R&D and manufacturing. Centered on bioreactor technology, we have established a comprehensive product ecosystem encompassing process monitoring, spectroscopic analysis, cell analysis, online sampling, sample treatment, and etc., providing a extensive product portfolio and technical support for domestic and international biopharmaceutical companies.

Applitech is headquartered in Guangzhou, with sales and after-sales service network covering the entire market in China. We have established branches and product exhibition and application centers in Shanghai and Beijing, offices in Chengdu and Xi'an, and service sites in Tianjin, Suzhou, Hangzhou, Wuhan, Nanjing, Lanzhou, Changchun, Qingdao, etc. Driven by our commitment to "technical expertise, considerate service and rapid response", Applitech is customer-oriented, and collaborates closely with its technology partners to safeguard the progress and development of the biopharmaceutical industry!

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# AbioPilot Stainless Steel Bioreactors

With nearly 20 years of experience in the biopharmaceutical industry and a dedication to craft high-end bioreactors, backed by a highly skilled R&D team of over 150 professionals, Applitech proudly presents the AbioPilot Stainless Steel Bioreactor.

Adopting a modular design philosophy, Applitech's stainless steel bioreactors cater to diverse user requirements. For pilot-scale operations, we offer standard volumes for cell culture and microbial fermentation tanks, simplifying the design process for pilot and small-scale production. For larger scales or non-standard volumes, we support fully customizable designs, with capacities up to 20,000 liters.

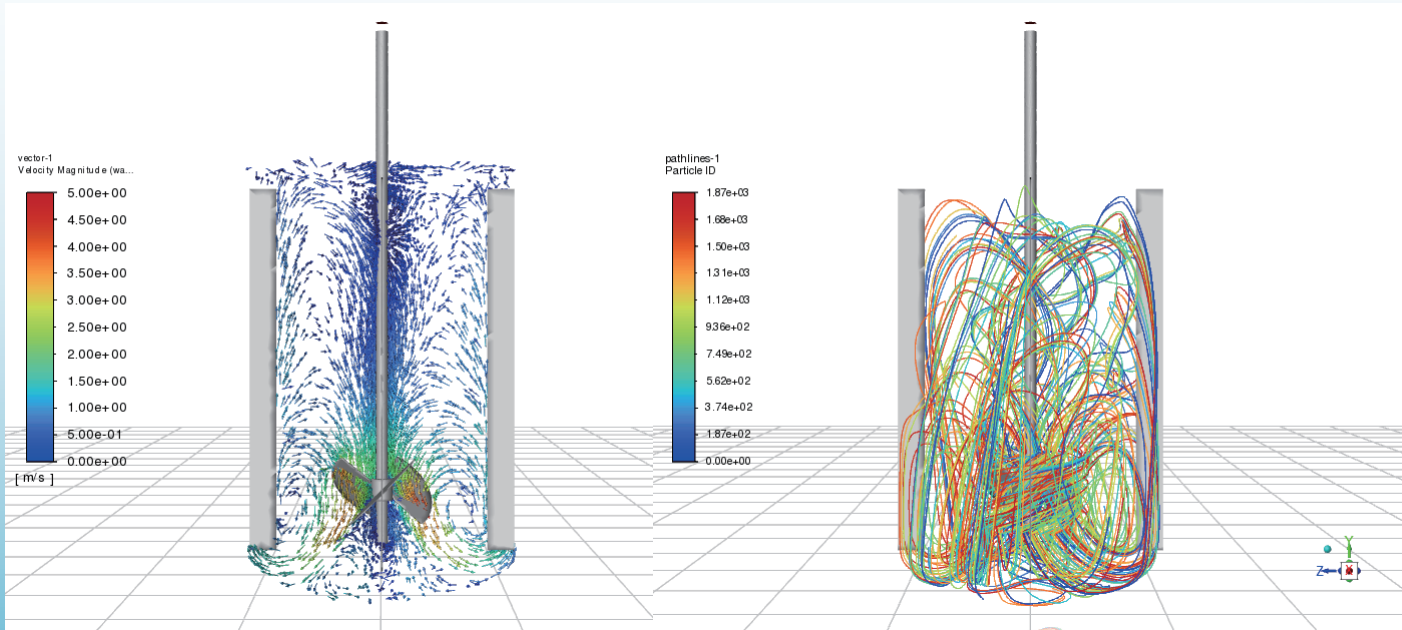
Applitech stainless steel bioreactors support cleaning options including CIP and SIP. During the design phase, we employ CFD fluid dynamics simulation models and 3D modeling. All designs adhere strictly to ASME BPE guidelines and meet GMP and GAMP validation requirements, offering seamless scalability from laboratory to production.

## Features

- Constructed with 316L stainless steel, with an external surface finish available in brushed or mirror-polished options for easy cleaning.
- All parts in contact with culture media are electropolished ( $Ra < 0.4\mu m$ ) to ensure efficient CIP cleaning.
- Open frame structure facilitates easy maintenance and operation. Modular design easily adapts to evolving process requirements.
- GMP-compliant design simplifies validation processes.
- Compact footprint saves space.

## Applications

- Designed to meet GMP standards, equipped with audit tracking functionality.
- Cultivation of mammalian cells, plant cells, insect cells, microorganisms, and fungi.
- Ideal for vaccine, antibody, and cell/gene therapy production and scale-up.
- Supports batch, fed-batch, perfusion, and continuous culture processes.
- Applicable for pilot-scale and large-scale production.



## Cell Culture Bioreactor Image



## Fermenter Image

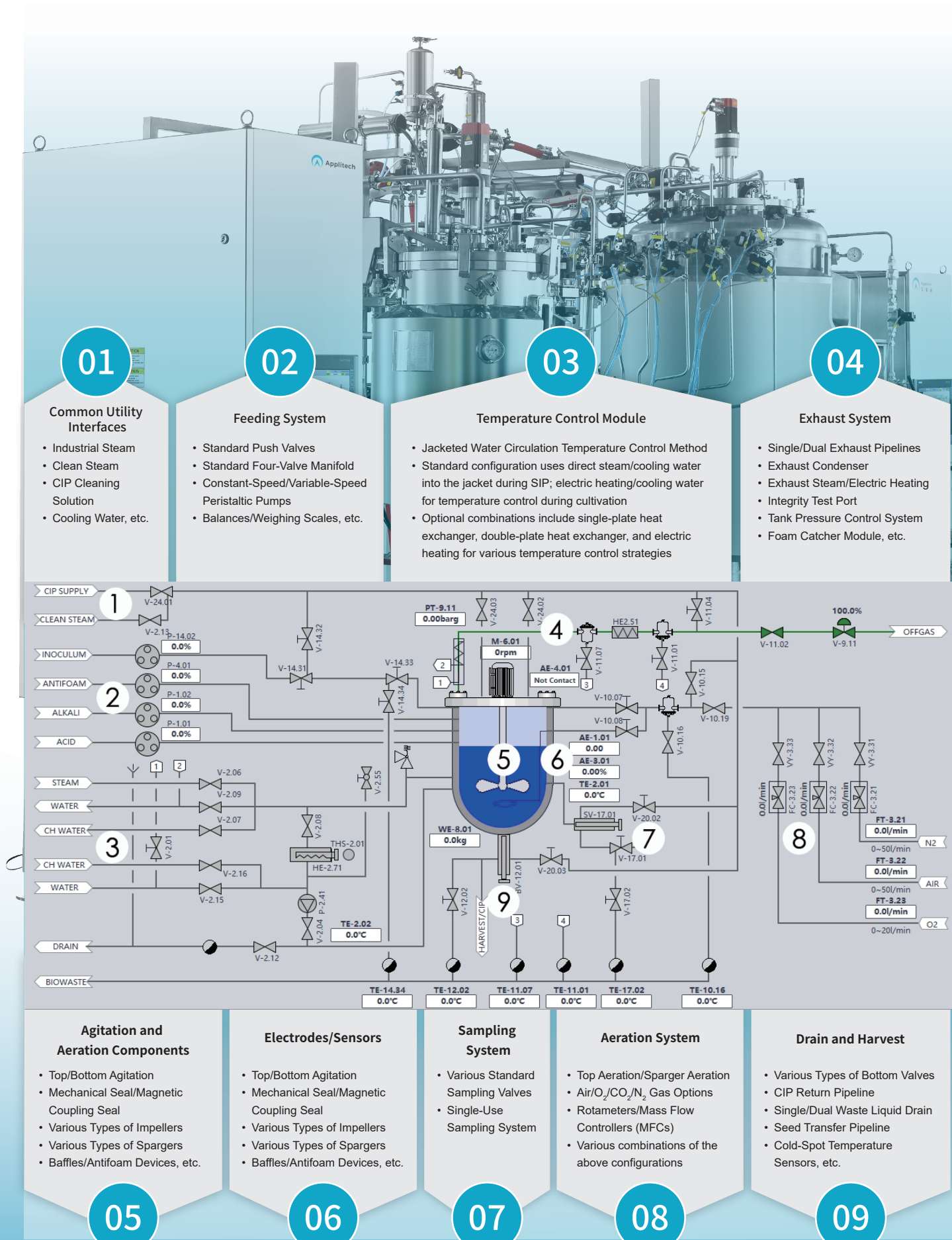


AbioPilot Technical Specifications

Parameters	Total Volume	Working Volume	Minimum Working Volume	Total Volume H/D Ratio	Working Volume H/D Ratio
30L Bioreactor	30L	20L	7L	2.0	1.8
45L Bioreactor	45L	30L	14L	1.5	1.1
75L Bioreactor	75L	50L	17L	1.5	1.1
130L Bioreactor	130L	100L	24L	1.5	1.1
300L Bioreactor	300L	200L	57L	1.5	1.1
30L Fermenter	30L	20L	7L	2.0	1.8
40L Fermenter	45L	30L	8L	3.0	2.7
70L Fermenter	75L	50L	13L	3.0	2.7
140L Fermenter	140L	100L	25L	3.0	2.7
270L Fermenter	270L	200L	41L	3.0	2.7

Drive	Bottom or top stirring, magnetic coupling, with optional mechanical seal.
Stirring Blade Tip Speed	5 m/s for fermentation; 1 m/s for cell culture.
Impeller	Rushton and marine impellers; diameter 0.33-0.5 times the tank inner diameter.
Sparger	Porous sparger, L-Sparger or Ring-type sparger.
Overlay	Optional gas overlay line.
Vent	Spiral or jacketed water-cooled exhaust condenser.
Sampling	Optional online repeat sterilizable sampling system; DN25 port on the tank sidewall.
Drain	Sterilizable bottom valve for online repeat sterilization.
Feed	Sterilizable accessories (push valve) and sterilizable feed valve.
pH	Measurement: 12mm pH electrode, DN25 port. Control: PID with acid pump/CO <sub>2</sub> (MFC or Rotameter) and base pump.
DO2	Measurement: 12mm polarographic or optical DO electrode, DN25 port. Control: (MFC or Rotameter)Combination of N <sub>2</sub> , Air, O <sub>2</sub> , stirring, or feed pump with PID algorithm.
Temperature	Measurement: Pt-100 temperature probe, DN25 port. Control: Heating and cooling via the jacket.
Foam	Measurement: Height-adjustable foam sensor electrode. Control: Antifoam pump.
Level	Measurement: Height-adjustable level sensor or weighing sensor. Control: Feed pump.

The table shows the parameters of standard volume reactors. Non-standard reactors can be customized, with the largest reactor being 20,000L.





# AbioExpert Process Information Management System

AbioExpert is a suite of specialized software for industrial biotechnology and biopharmaceutical applications. AbioExpert series software supports AbioBundle M/E/P series glass tank bioreactors, AbioPilot stainless steel bioreactors, and can also collect data from Nova/Kaiser and other on-line analyzers.

AbioExpert family of software is compatible with the Applikon my-Control/ez-Control/ez2-control series of bioreactors. It is divided into four versions according to different functions: Lite/Standard/Advanced/GMP

### Features

- Realize data management and information sharing within the whole company and among branches;
- Rapidly and efficiently meet bioprocess development and production needs;
- Improve efficiency, increase cost-effectiveness, and reduce engineering costs;
- Compatible with mainstream bioreactors on the market, able to communicate with analyzing and executing equipment and collect data from analyzing equipment at the same time.

### Access management

With password protection, user group settings, define access rights, operation permissions

### 21 CFR Part 11

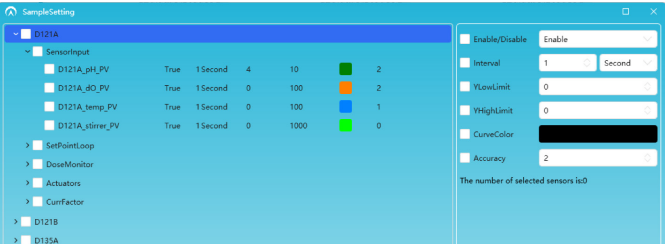
Multi-level security controls ,logged event logs, audit trails, and electronic signatures in accordance with 21 CFR Part 11 requirements

### Configure

It has various ways to configure the data acquisition port, and the system specifies the data import template file for the data acquisition channel of the device.

①With multi-device access capability, device connection parameter configuration, connection control strategy

②Perfect alarm function configuration:able to customize alarm strategy and response strategy



### OPC

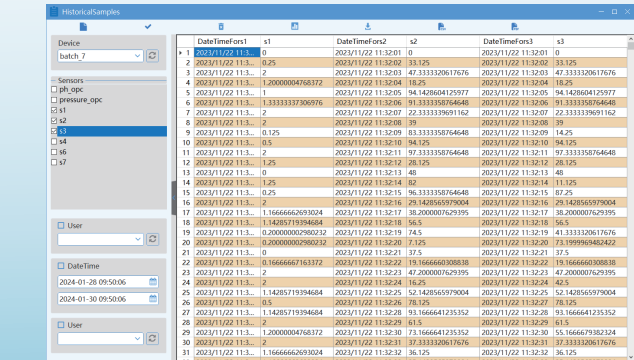
Based on the OPC platform, the OPC Client provides flexible connectivity to devices and improve the control of key process parameters;

### UI

The intuitive configuration flow simplifies the usage and speeds up task startup. You can use the navigation to quickly access all configuration-related information. When monitoring, you can jump to each module such as unit, trend, alarm, sample, etc.

### Data Monitoring & Management

Provide complete monitoring and history record storage functions, data recording with integrity and security, enabling fast, powerful and searchable high-quality data collection and management. Data and configuration information can be exported to generate reports; It has perfect traceability and query function of system log, alarm information and operation information;



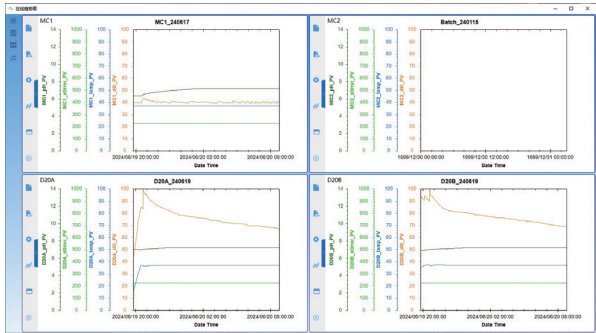
### CHART

Powerful chart tools - Trend window: View all relevant process parameters and configure online trends as required.

①According to the requirements, the chart can be zoomed in and out, moved, stretched, captured, curve style, time selection, parameters can be hidden or displayed, and individual charts can be added, edited or deleted as required;

②Allows comparison and tracking of all process data: .

Multiple historical batch data can be synchronously compared by process timeline



### MONITOR

Quickly switch to any of the 16 monitoring units and view all related information, and customize the display of the monitoring modules on the screen; the monitoring window allows you to view and navigate to all menu information, such as batch operation, alarm settings, recipe control, real-time trending, and sample collection, etc.

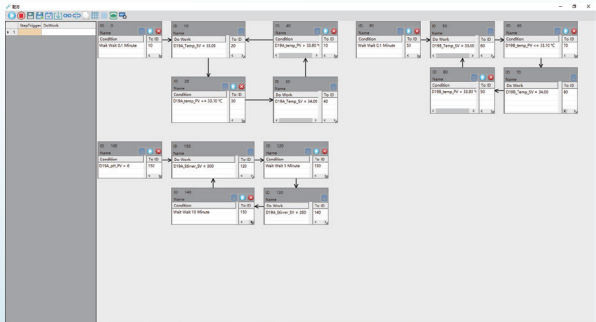


### CONTROL

The set values can be controlled individually or in batches;

### RECIPE: Easy-to-use recipe design

Provides easy-to-follow on-screen instructions that guide you through the configuration of a recipe from start to finish, and can be used to write advanced control strategies that automatically change setpoints based on incubation conditions and time. No programming skills are required; simply drag and drop logic blocks into place and configure conditional functions to generate branch, parallel, wait, loop, skip, and sequential logic;



### CALCULATOR- Efficient data conversion

Calculation of important bioprocess parameters and non-directly measurable variables in the calculation module and logical connections in the formulation module.

### Please note

#### Software Updates

All AbioExpert software will be updated continuously, and customers can upgrade the corresponding version for free.

#### Minimum System Requirements

**Processor/clock rate:** Multi-core processor 2.5 GHz

**RAM:** 8GB (16GB recommended)

**Hard disk space:** 256 GB

**Optical Drive:** DVD-ROM drive

**Network adapter:** 1+ LAN adapter, RJ-45, 100 Mbit Graphics: DirectX10,1 GB RAM (recommended)

**Screen resolution:** 1920x1080, 100% zoom and alignment

**Monitor:** 23.8-inch monitor

## AppliSoftec Series Software Feature List

AppliSoftec Specifications	AbioPIMS Lite AbioExpert Lite	AbioPIMS Standard AbioExpert Standard	AbioPIMS Advanced AbioExpert Advanced	AbioPIMS GMP AbioExpert GMP
GENERAL				
User interface languages	AbioPIMS: Chinese, English; AbioExpert: English			
Operating system	AbioPIMS: Windows 10 64-bit; AbioExpert: Windows 7 or later, 64-bit			
Communication drivers included	m-Control, e-Control, eDual-Contorl, p-Control; my-Control, ez-Control, ez2-Control			
Optional drivers for analytical Instruments	No	No	AbioExpert: Nova Flex2, Kaiser and more	
Number of supported process units	AbioPIMS: up to 24 units; AbioExpert: up to 16 units			
Measurement of process values from controllers	Yes	Yes	Yes	Yes
Control of process setpoints in process controllers	No	Yes	Yes	Yes
Starting and stopping of control loops	No	Yes	Yes	Yes
Programming of local process controllers	No	No	Yes	Yes
Reading of calibration data	No	No	Yes	Yes
Automatic report generation	No	Yes	Yes	Yes
21 CFR part 11 compliant	No	optional	optional	Yes
GAMP5 compliant	Yes	Yes	Yes	Yes
ISA S88 standard	Yes	Yes	Yes	Yes
Password protection	No	Yes	Yes	Yes
User definable access rights	No	Yes	Yes	Yes
Remote Access	No	optional	Yes	Yes
Process value alarms	Yes	Yes	Yes	Yes
Process value simulation	Yes	Yes	Yes	Yes
OPC UA/DA client	AbioPIMS: UA/DA; AbioExpert: UA			
Auto start after power failure	Yes	Yes	Yes	Yes
DATA MANAGEMENT				
Database management	AbioPIMS: Microsoft SQL/MongoDB; AbioExpert: MySQL			
Minimum sampling frequency	1 s	1 s	1 s	1 s
Sample frequency selectable per parameter	Yes	Yes	Yes	Yes
On line data collection	Yes	Yes	Yes	Yes
Off line data collection	Yes	Yes	Yes	Yes
Data export to Excel	Yes	Yes	Yes	Yes
Data export in ASCII format	Yes	Yes	Yes	Yes
Graph export in graphics format	Yes	Yes	Yes	Yes
On-line calculations using on-line and off-line data	No	Yes	Yes	Yes
Configuration management	No	Yes	Yes	Yes
Sample data management	No	Yes	Yes	Yes
DATA DISPLAY				
Line graphs	Yes	Yes	Yes	Yes
Maximum Number of y-axes per Graph	AbioPIMS: 6 y-axes; AbioExpert: 8 y-axes			
Procedure flow chart	No	Yes	Yes	Yes
Combination of current and historic data in graphs	Yes	Yes	Yes	Yes
Combination of different active batches in graphs	Yes	Yes	Yes	Yes
Measured data table display	Yes	Yes	Yes	Yes
Scatter plots	Yes	Yes	Yes	Yes
Storage of predefined graph settings	Yes	Yes	Yes	Yes
SUPERVISORY CONTROL				
Programming of time based actions	No	No	Yes	Yes
Programming of event based actions	No	No	Yes	Yes
Manual setting of local control setpoints	No	Yes	Yes	Yes
Recipe definition	No	No	Yes	Yes
OTHER				
Event viewer for system comments	Yes	Yes	Yes	Yes
Audit trail	No	optional	optional	Yes
Validation support	No	optional	optional	Yes
Service & support package	1 <sup>st</sup> year			