

# Cultivation Systems From Discovery to Production



## Applikon Biotechnology

Applikon Biotechnology is a world leader in developing and supplying advanced bioreactor systems from laboratory, to pilot, to production scale.

Our mission is to provide reliable solutions for the bioprocess market that will enable an improved quality of life. We support industrial microbiology and the pharmaceutical industry in their upstream process by implementing scalable platforms from initial screening through development to full-scale production. By minimizing scale-up risks and shortening the time-to-market for our customers, we contribute to the improvement of Life Sciences. And that is our passion!

#### Expertise

Applikon Biotechnology is known for bringing new technologies to the market. We continuously improve and launch new bioreactor systems as well as process analytics and software tools. These new technologies offer advantages in process efficiency and thus costs. In particular our small scale designs that offer a complete solution for results generation, make us unique in the mini and micro bioreactor range.

#### Complete upstream product portfolio

Our focus is on supplying you the best product offering now and in the long-term future. Our portfolio ranges from very small bioreactors to large volume cultivation systems. Whether used for laboratory applications, good manufacturing practices, or the full scale-up process from lab to production, we have the right solution.

#### Worldwide activities

Since we started in 1974 we have shown a healthy growth resulting in a global market leader role. In fact, an expansion was necessary to keep up with this growth. Therefore, we doubled our facility in June 2017 to 5.800 m² total surface. All R&D, design and engineering takes place in-house in our headquarters in Delft, The Netherlands. Furthermore, we have our own sales and service organizations in the USA and UK and a network of well-trained local distributors for sales and service in over 35 countries worldwide.

#### Cultivation Systems | From Discovery to Production









# Lucullus PIMS | From Idea to Report

One integrated software solution for the whole workflow around bioprocesses Idea & Recipe **Planning Preparation Execution Evaluation** IDEA & RECIPE PLANNING **PREPARATION EXECUTION** 

Lucullus Process Information Management System (PIMS) offers a new dimension in upstream bioprocess data management. Classic SCADA solutions are limited to data acquisition and supervisory control functions, but Lucullus can additionally control a heterogeneous collection of devices and bioreactors from different vendors. Furthermore, Lucullus integrates functionalities and activities around creation and planning of recipes, reactor allocation, Design of Experiments, media preparation, media component traceability, data analysis, data mining, automatic reporting and modelling. The integration of all these functions into one comprehensive software solution saves the scientists time, since all data is stored in one central Oracle® database. No more need for data export and import between different solutions. Lucullus integrates all functions needed for complete data management of your upstream process.

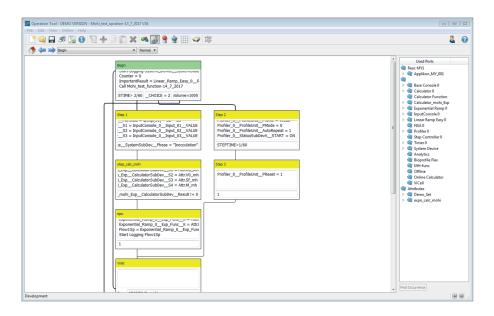


The ever increasing amount of process data generated by more sensors in smaller parallel bioreactor systems needs advanced software to turn this data into useful information. Lucullus PIMS offers a new dimension in data processing. Data management and data analysis is key for the future of R&D and process development in pharmaceutical industry. Lucullus PIMS software allows the user to monitor and control bioprocesses and offers an extensive toolbox for analyzing process data c ross platforms. Process information can be generated based on data generated in different brands of bioreactor types and wide range of different cultivation volumes. The combination of the software with the broad range of Applikon bioreactor systems offers the user a unique system for validatable fast track development and basic research.

### Idea & Recipe

#### Make your process idea come true with an intuitive tool to create your process recipe

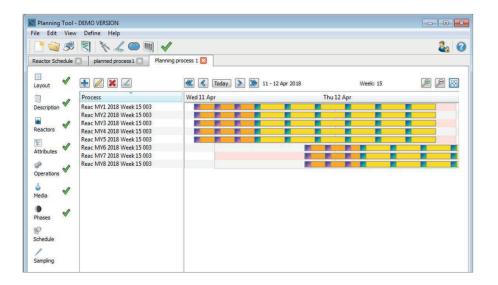
- Create your instruction sequences for simple or advanced processes and use them within multiple processes
- Integrate sequential calculations in your instructions based on time and events
- Receive Notifications, Emails, or SMS alarms in case your process deviates from your predefined limits



## Planning

#### Define everything in advance with an intuitive workflow to start processes with minimal effort

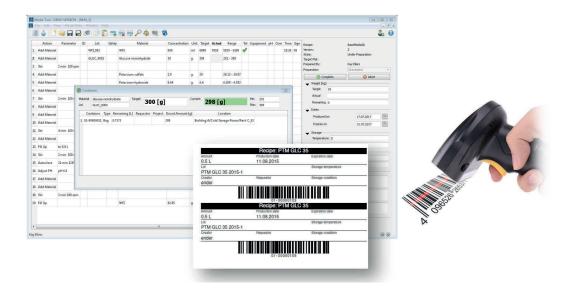
- Make optimal use of your shared resources using integrated scheduling tools
- Maximize your experiment efficiency by integrating third party DOE modules into your planning process
- Manage samples efficiently with overall strategies to coordinate sampling, sample tube preparation and barcoding
- Retrieve data automatically from at-line analyzers (E.g. Vicell, Nova pHOx, Nova Flex etc.)



### Preparation

#### Manage your Media center components and storage uniformly and efficiently

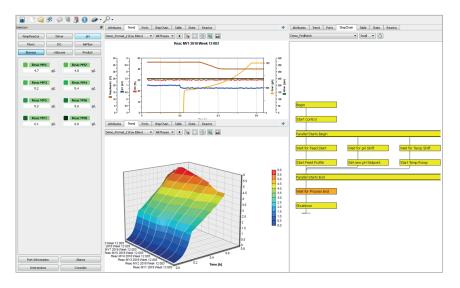
- Automate culture media creation
- Keep track of the availability of culture media in your storage
- Optimize the availability of raw materials in your storage
- Get more insight by keeping track of raw media components used in your culture runs



## Execution

#### **Execute recipes and monitor experiments**

- Execute a process based on a predefined recipe or planning
- Start several bioreactors in parallel and monitor them simultaneously
- Store process data in a safe and industry standard Oracle database
- Make well informed decisions by comparing multiple processes simultaneously
- Evaluate running processes via 3D graphs and tables



## Evaluation

#### Turn data into useful information using

#### a wide range of evaluation components

- Visualize process results by creating advanced graphs and tables
- Deepen your insight by using overlay graphs for a set of processes
- Turn data into useful information using advanced data analysis tools
- Automatically verify your process model against your experimental data
- Save time and achieve consistency by generating reports automatically





## Lucullus PIMS can be supplied in three different architectures

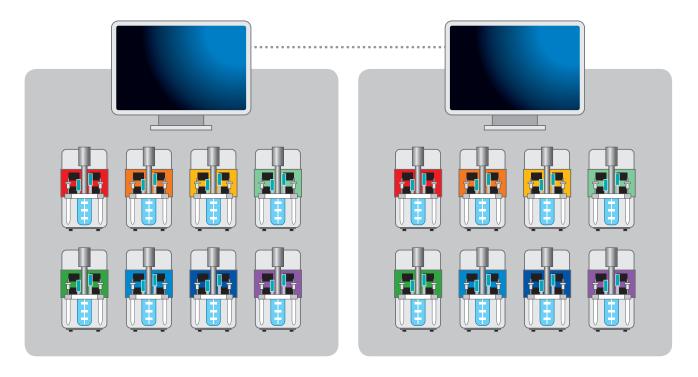
## 1 | Stand-alone edition

The stand-alone edition is used for up to 8 different bioreactors or one multi-bioreactor system on one computer. Data is stored in a local Oracle database and access to the process data can occur via the local computer or via a remote network link to this process computer. Interactions to the process can occur via the local computer in the laboratory.



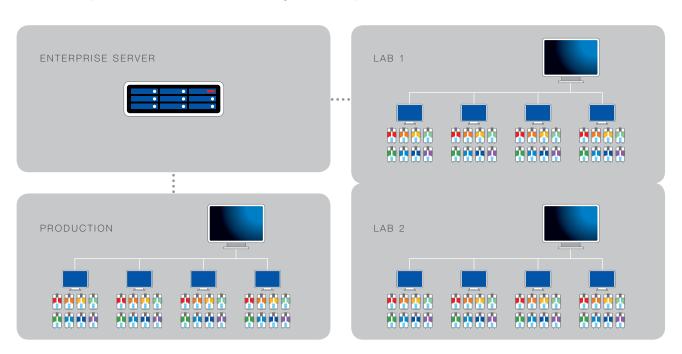
## 2 | Client Server Edition

The Client-Server edition is used for larger Lucullus installations, when different labs use the software. This distributed architecture allows the data to be stored in a safe location while the front end user interfaces are located near the bioreactors where they need to be. At the office, data can be reviewed via a direct link to the data server on the network. Data from different laboratories can be compared and can be used for process control or for reporting and making decisions for further process development.



## 3 | Enterprise Edition

For even larger Lucullus installations at different sites (and even in different countries) the Enterprise edition can be used. This version connects different installations of Lucullus and allows on the fly conversion and translation of process data. The authorized user can view and compare data between different sites. This could be a production site and a process development site, or could even be different development sites in different locations working on the same process.



## Lucullus PIMS: Turning Data into Information

## Specifications

Operating system	See table						
Computer Hardware Specifications	no specific demands						
	Lucullus	Lucullus	Lucullus	Lucullus			
	Lite	Standard	Advanced	Expert			
General							
Operating system	Linux, Windows 7 (64-bit), Windows 10						
Communication drivers include	my-Control, in-Co	my-Control, in-Control, ez2-Control, i-Control, SUB-Control					
Optional Controller drivers	no	Sartorius controllers, Eppendorf Controllers, NBS controller					
		Infors Controllers	Infors Controllers, Siemens PLC, AMBR, Shaker/Incubators				
Optional drivers for analytical instruments	no	Vicell, Nova Flex,	Vicell, Nova Flex, Nove pHOx, Flownamics and more				
Design of Experiments	no	no	yes	yes			
Media preparation planning	no	no	no	yes			
Analysis planning	no	no	no	yes			
Resource planning (reactors)	no	no	yes	yes			
Material Management	no	no	no	yes			
Lot preparation	no	no	no	yes			
Filling	no	no	no	yes			
Storage management	no	no	no	yes			
Data Acquisition	yes	yes	yes	yes			
Process Control	no	yes	yes	yes			
Monitoring and Alarms	no	yes	yes	yes			
Sampling planning and management	no	no	yes	yes			
Data Retrieval from Analytical Devices	no	yes	yes	yes			
Interactive Data Analysis	no	yes	yes	yes			
Performance Analysis	no	yes	yes	yes			
Automatic report generation	no	yes	yes	yes			
21 CFR part 11 compliant	no	optional	optional	optional			
GAMP compliant	yes	yes	yes	yes			
ISA S88 standard	yes	yes	yes	yes			
Password protection	no	no	yes	yes			
User definable access rights	no	yes	yes	yes			
Remote Access	no	yes	yes	yes			
Interactive Synoptic	no	yes	yes	yes			

## Specifications

	Lucullus	Lucullus Standard	Lucullus Advanced	Lucullus Expert
	Lite			
Data management				
Data storage system	Oracle database	Oracle database	Oracle database	Oracle database
Minimum sampling frequency	1 second	1 second	1 second	1 second
Sample frequency selectable per parameter	yes	yes	yes	yes
Data reduction definable per parameter	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
Dynamic Data Link to other programs	no	yes	yes	yes
On-line calculations				
using on-line and off-line data	no	yes	yes	yes
Data display				
Line graphs	yes	yes	yes	yes
Maximum number of y-axes per graph	8	8	8	8
Synoptic (P&I diagram)	no	yes	yes	yes
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	yes	yes	yes
Programming of event based actions	no	yes	yes	yes
Profiling of setpoints	no	yes	yes	yes
Manual setting of local control setpoints	no	yes	yes	yes
Recipe definition	no	yes	yes	yes
Other Notebook for process and				
equipment remarks	VAS	VAS	VAS	VAS
COURTER FORMAN	yes	yes	yes	yes
Event viewer for system comments	yes	yes	yes	yes



# V-Control for R&D |

The scalable DeltaV™ solution for bioreactors in your lab

- Improved user experience with advanced automation tools
- Minimized scale-up risks with easy technology and data transfer
- Reduced time-to-market and development costs

V-Control is the scalable DeltaV<sup>TM</sup> solution for bioreactors in your lab. It harnesses the power of DeltaV<sup>TM</sup> in an off-the-shelf configurable system at a low reduced price point. V-Control combines the best of DeltaV<sup>TM</sup> automation with Applikon bioprocessing know-how into one platform for process control and data management from discovery to production. Seamless technology transfer and scalable data transfer result in optimal bioprocesses with shorter development lead times and lower development costs.



## Features

- Native open-architecture DeltaV™ software with tailor-made functions
- User-friendly, alarm-based operator user interface
- Small benchtop footprint to connect up to 32 bioreactor systems per V-Control network
- Advanced automation tools for the best user experience:
  - Sensor calibration
  - Actuator calibration
  - Total gas flow
  - 3-point cascade
  - Cultivation mode
  - Bioreactor overview

## **Applications**

- Microbial and Cell cultivation
- Batch, Fed-Batch, Perfusion and Continuous cultivation
- Autoclavable bioreactors up to 20 liter volume
- Single-use Bioreactor processes

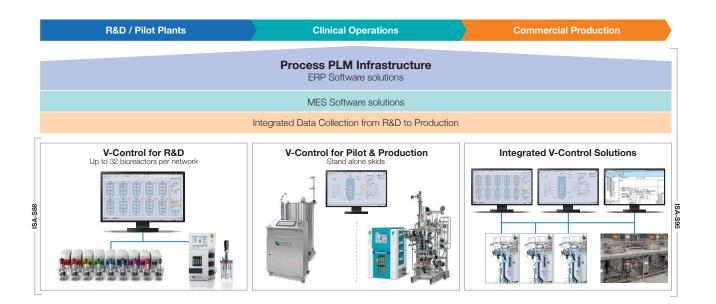
### How V-Control works

Appli-V is the application within the V-Control solution that is built by software engineers from both Applikon and Emerson. This openarchitecture software can easily be configured and is thus compatible with customized libraries. The fully interface is built using the default DeltaV<sup>TM</sup> PCSD library from Emerson to make it easy to use and to connect to existing systems. The end-user experience is enhanced and simplified with Emerson's Human Centered Design based interface, attracting your attention whenever and wherever needed. V-Control is also compatible with DeltaV<sup>TM</sup> Batch and Configuration Audit Trail & Version Management



## Related products

- my-Control
- ez2-Control
- ez-Control
- in-Control
- miniBio
- autoclavables
- AppliFlex ST
- Millipore Mobius™ CellReady
- SIP labscale
- Sensors



### V-Control Add-ons

#### Reporting & Data management

V-Control comes with the standard DeltaV Historian embedded with real-time and historical trending capabilities. Additionally, an Excel Add-in will be provided to export your data to Excel.

Alternatively, V-Control can also be connected to external 3rd party historians, like OSIsoft PI or Aspentech, through OPC if more integration of data networks is desired.

#### **DeltaV Discovery Operator Station**

Improve the efficiency of R&D laboratories by adding extra operator stations to the V-Control network.

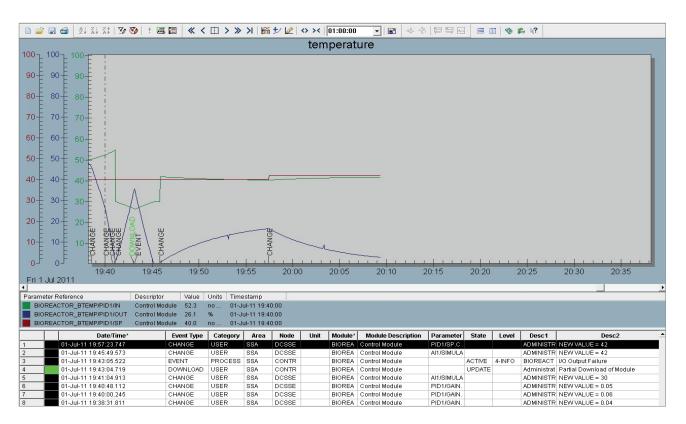
Do you want to operate your V-control system with a user-friendly interface, state-of-the-art graphics, real-time and historical trending capabilities, process alarms prioritized by the user, and system-wide, built-in security? Run your V-Control system using the DeltaV<sup>TM</sup> Operator Station. An Operator Station is made up of the Operator Station Software Suite and the DeltaV hardware to run it. Take advantage of single-click access to graphics, directories, and other applications. You get the most for your investment with the DeltaV Operator Station. This additional, independent operator station provides full operations capability for your V-Control system and enables that multiple workstations can be used simultaneously to work with the V-Control system.

#### **DeltaV Batch Executive**

The DeltaV Batch Executive manages everything from recipe execution to history collection. It is responsible for carrying out batch procedures, coordinating communication between phases, allocating equipment and other resources required by a batch, and send and receive recipe data from phases running in the DeltaV controllers. These events, along with all other recipe execution activities, are automatically generated and collected by the Batch Executive to provide detailed batch historical records.

#### DeltaV<sup>™</sup> Configuration Audit Trail & Version Management

Configuration Audit Trail is a powerful tool that tracks changes and manages revision information for any item in the DeltaV<sup>TM</sup> configuration database. This application creates and maintains a configuration change history for configuration items such as modules, SIS modules, phases, operations, unit procedures and user accounts. The DeltaV security system provides function locks, which allow the system administrator to control the privileges granted to individual users.



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Lithuania

**Poland** 

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