Lucullus Process Information Management System: Turning Data into Information

Lucullus Process Information Management System offers a new dimension in upstream bioprocess data management. Where classic SCADA solutions are limited to data acquisition and supervisory control functions, Lucullus integrates functionalities activities around the planning of recipes, reactor allocation, Design of Experiments, media preparation, media component trace-ability, 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 cross 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 offer the user a unique system for validatable fast track development and basic research.
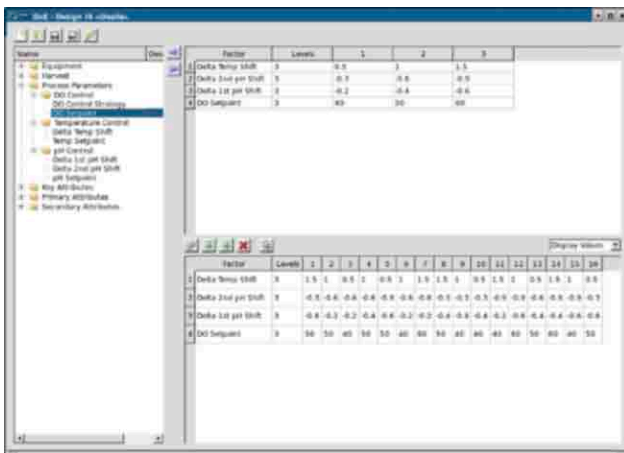
The main modules of Lucullus PIMS are

- **Planning:** activities around the planning of recipes, reactor allocation and Design of Experiments
- **Preparation:** media preparation, storage and component trace-ability
- **Execution:** process execution, data presentation, alarming and storage
- **Evaluation:** data analysis, presentation, automatic reporting, modelling and comparison of data between different cultures

Planning

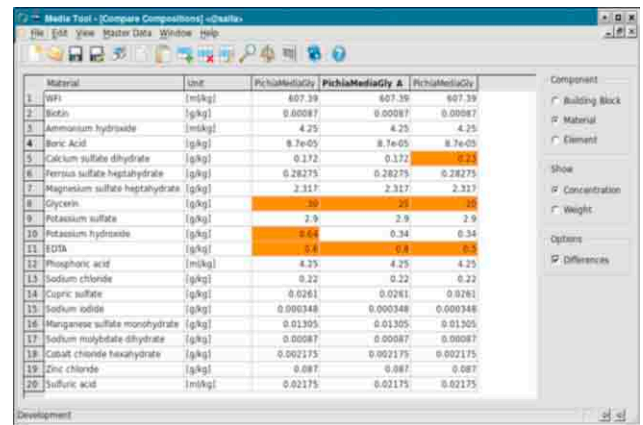**Activities around the planning of recipes, reactor allocation and Design of Experiments**

This module enables the user the optimum use of shared resources. The DoE module optimizes the experimental setup and guides the scientist through the optimal planning of experiments by selecting the different process parameters to be used in usually parallel experiments. The final result is doing more experiments with less resources due to optimal planning and coordination which leads to faster results in shorter time.

Preparation

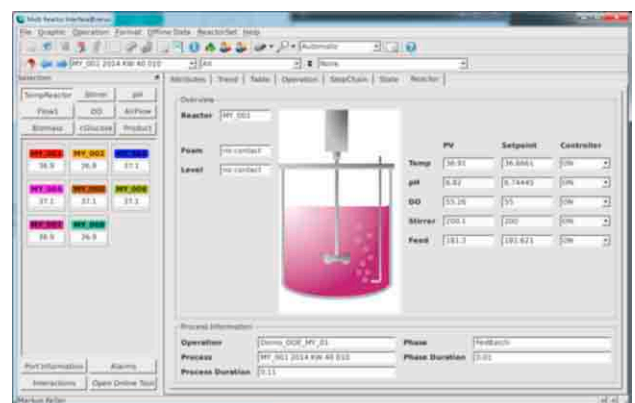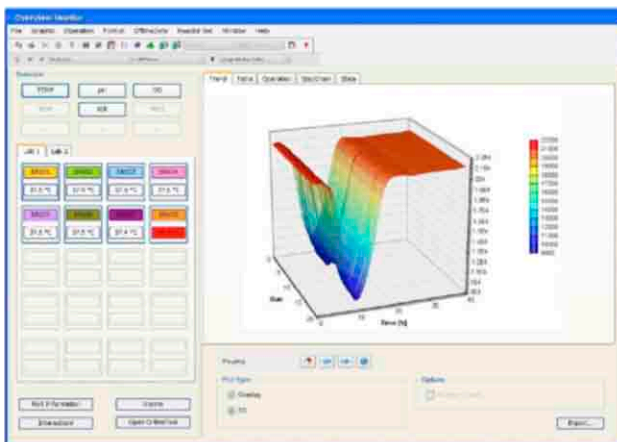**Media preparation, storage and component trace-ability**

This module guides the user through the media preparation, media storage and planning of the use of the available media. Another part of this module keeps track of the batch of the raw components used in the media to allow full trace-ability of materials during the process. The process results can later on be compared by raw materials used or batches of media being used in different experiments. The ultimate goal of this module is the optimal use of materials in media preparation and preventing wrong conclusions based on experimental results where media components or batches might have played an important role.

Execution

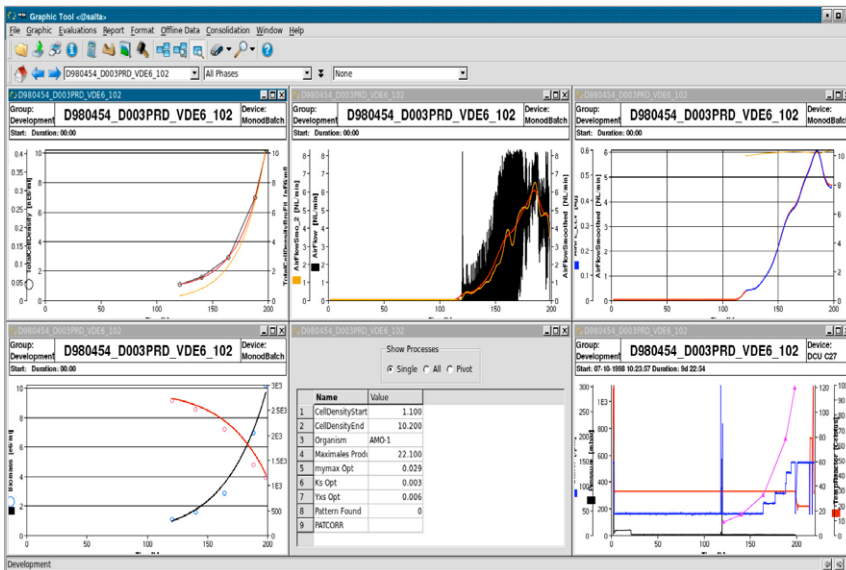**Data presentation, alarming and storage**

The execution module is the heart of the program and is the part that is present in most SCADA systems. The execution module allows the scientist to define and execute the recipe for the process and present the process data in an optimal format. Data reduction techniques can be used to limit the amount of data stored in the Oracle database. Process data is stored per process and per process phase allowing simple comparison of the growth or production data of different experiments. Time and event based actions can be based on current process data from all active processes or on older experimental data allowing the system to predict what will be happening and to take preventive measures.

Evaluation

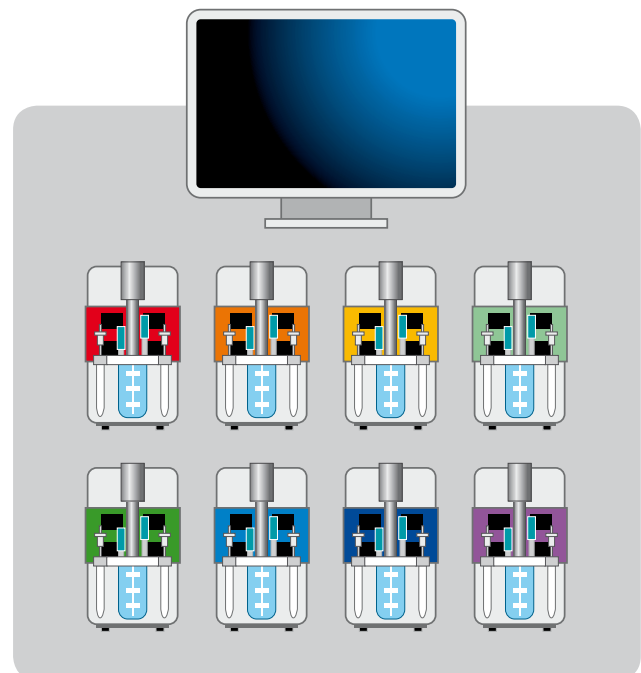**Data analysis, presentation, automatic reporting, modelling and comparison of data between different cultures**

Evaluation is the part that will turn your data into valuable information. Scientist are gathering more and more data from processes, but without the right data processing, these data are useless. The Evaluation module of Lucullus PIMS is focused on turning process data across different platforms into comparable information and can help interpreting these data. One the many features is a pattern recognition function that allows the scientist to select a specific measurement pattern and search the database for comparable patterns. Only this feature can save days or weeks of work by one simple mouse click. Another important function is the automatic generation of batch reports. This will supply standardized batch reports independent of the operator or the cultivation hardware that has been used. Standardized reporting eases data interpretation and saves the scientist valuable time.

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 be through the local computer or via a remote network link to this process computer. Interactions to the process can be done through the local computer in the laboratory. It is advised to use a data safety system on the local computer to make sure your valuable process data are secured in case of computer hardware failures.

2 | Client Server Edition

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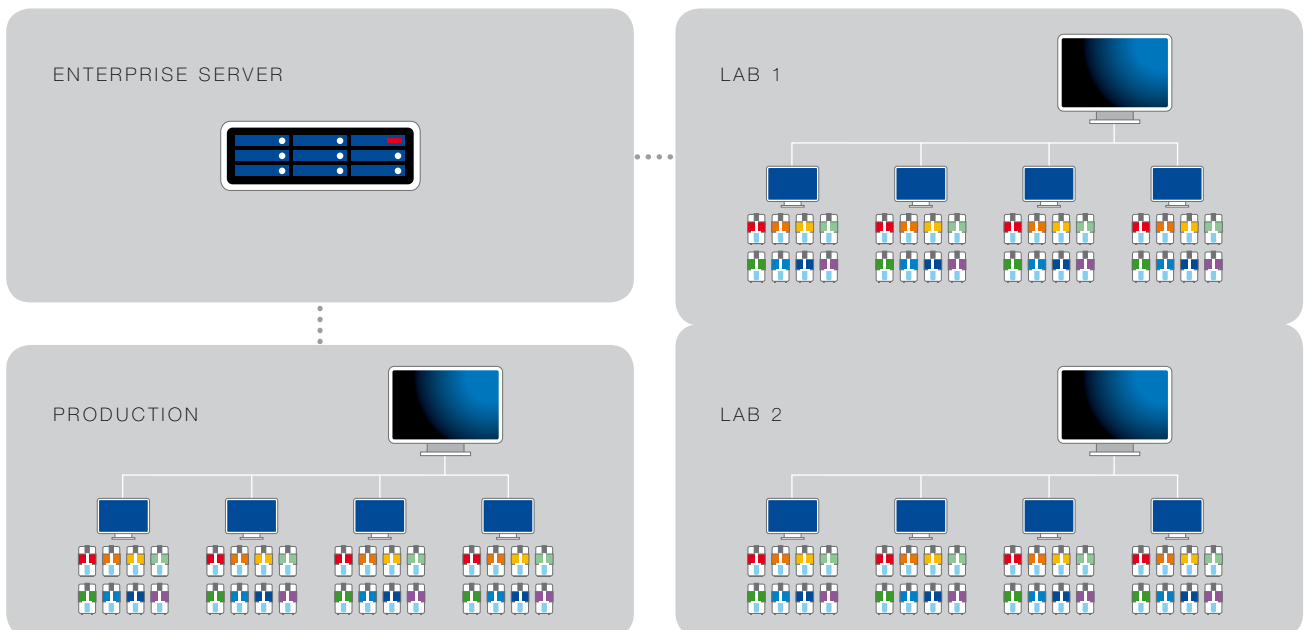data to be stored in a safe location while the front end user interfaces are located near the bioreactors where they need to be. Data can be reviewed in the offices by a direct link to the data server in the network. Data from different laboratories can be compared and can be used for process control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

3 | Enterprise Edition

For even larger installations with Lucullus installations at different site (even in different countries) the Enterprise edition can be used. This version connects different installations of Lucullus and allows in the fly conversion and translation of process data. When authorized the 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.

ENTERPRISE SERVER

LAB 1

PRODUCTION

LAB 2

Specifications

Operating system	See table			
Computer Hardware	no specific demands			
Specifications	**Lucullus Lite**	**Lucullus Standard**	**Lucullus Advanced**	**Lucullus Expert**
General				
Operating system	Linux, Windows 7 (64-bit)			
Communication drivers include	my-Control, in-Control, ez-Control, i-Control, SUB-Control			
Optional drivers	no	Sartorius controllers, NBS controllers, Infors Controllers, Siemens PLC, TAP AMBR, Shaker/Incubators		
Design of Experiments	no	no	yes	yes
Media preparation planning	no	no	yes	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 Aquisition	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		
Interactive Data Analysis	no	yes	yes	yes
Performance Analysis	no	no	yes	yes
Reporting	no	yes	yes	yes
21 CFR part 11 compliant	no	no	yes	yes
GAMP compliant	yes	yes	yes	yes
ISA S88 standard	no	no	yes	yes
Password protection	no	no	yes	yes
User definable access rights	no	no	yes	yes
Auto start after power failure	no	no	yes	yes

Specifications

Specifications	Lucullus Lite	Lucullus Standard	Lucullus Advanced	Lucullus Expert
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 pens per graph	8	8	8	8
Synoptic	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	yes	yes	yes	yes
Event viewer for system comments	yes	yes	yes	yes
Audit trail	no	no	no	no
Batch reports supported	no	yes	yes	yes