APPLIED MATERIALS®

Process Development and Manufacturing Optimization

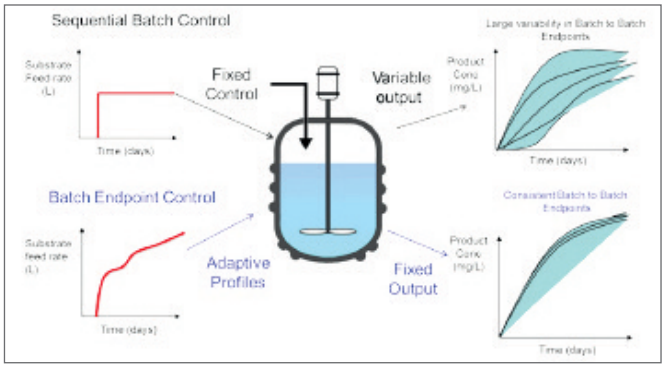
BioAPC® for BioPharma

BioAPC® is a software solution for the practical application of data analytics and advanced process control algorithms within biopharma manufacturing. It is underpinned by PharmaMV®, incorporating additional features to achieve continual monitoring and optimization of biopharmaceutical processes.

BioAPC® provides open interfaces to **DataHow AG** and **PSE gPROMS** biological models, built on a robust, real-time operational platform, for understanding precisely what's happening in your process. This enables automated adjustments for the control of Critical Quality Attributes, increasing yield, balancing inventory and minimizing waste, whenever possible.

The system employs a unique integration of Model Predictive Control (MPC) and multivariate statistical process monitoring tools. This powerful feature set provides understanding and control of the causes of variation, allowing rapid detection or correction of unexpected behaviour, to prevent process failure and minimise yield losses. With the **BioAPC®** system in place, users can now effectively monitor and control their manufacturing process, to achieve repeatable and reproducible runs.

- **Supports batch and continuous processes**
- **Flexible design and real-time execution of Design of Experiments studies with integrated sample management**
- **Offline data analysis, pre-treatment and visualization using BioAPC® Development**
- **Model Development and Maintenance facilities in-built**
- **Real Time MVA Quality monitoring, Control and Predictive Maintenance**
- **Comprehensive User-Configurable Dashboards**



BioAPC® for BioPharma

A Packaged Solution for R&D into Manufacturing

SOFTWARE

The suite comprises **BioAPC®** Development and Real-Time licences.

BioAPC® Development is a fully-featured platform for preliminary data mining, modelling and system design, for Batch and Continuous process unit monitors and controllers.

BioAPC® Real-Time interfaces directly to upstream and downstream process units via OPC, or similar third-party data connectors, to enable online data collection, PAT integration, execution of automated Design of Experiments, data driven models, real time MVA monitors, and real time endpoint optimisation of the batch.

PREDICTIVE MAINTENANCE

BioAPC® includes features needed to create a comprehensive predictive maintenance solution:

- **Open connectivity interface**
- **Multivariate Statistical Process Control with visualisation tools.**
- **Pareto Chart and Event Summary attached to SQL Database for easy management of process observations.**
- **Pre-configured Dashboards. All visualisation, SPC and Predictive Maintenance tools are provided in pre-configured dashboards. The dashboards are compatible with any HTML5 browser and as an option, can be embedded into third party SCADA.**
- **Secure Python interface, creating a User authenticated window for external Remaining Useful Life models**

CONSULTANCY SERVICES

Our biopharma offer includes expert consultancy to assist with installation, commissioning and qualification of the **BioAPC®** software platform.

DOCUMENTATION

A documentation pack is provided, consisting of a Project Quality Plan, System User Guide and software platform documents. The software is also supplied with in-built, context-driven help.

TRAINING

A system training session and associated User Guide is provided. Further training workshops and 1-3-day training courses can be provided for in-depth coverage of BioAPC's capabilities.

SOLUTION FEATURES AND BENEFITS

The **BioAPC®** solution can be deployed on any upstream or downstream process units, through standard interfaces to the existing automation system.

It provides a cost-effective tool to enhance the system's capabilities for product and process development, leading to an operational platform for monitoring, control and optimisation. At the core of the software are data-driven models and accompanying machine-learning algorithms.

The MVA monitoring platform creates an end-to-end operational solution for biopharmaceutical production, with user configurable displays to enhance process understanding and provide performance diagnostics.

Repeatable production runs using MVA Monitoring

Fault Diagnostics

Batch Classifier with Abnormality Detection

21 CFR PART 11 COMPLIANCE

BioAPC® provides a comprehensive audit functionality, which enables compliance with legal requirements and 21 CFR Part 11. The key audit function blocks of the software are:

- **System safety and authorization controls**
- **Electronic signatures**
- **Recording of all changes to data sets**
- **Version control for objects, such as methods, models and configuration settings**

APPLIED MATERIALS®

Email: SmartFactory_Rx@amat.com
www.appliedsmartfactory.com