



PharmaMV provides a comprehensive suite of tools for monitoring, controlling and optimising pharmaceutical processes, to meet the challenges unique to batch production.

pharmaMV

OVERVIEW

PharmaMV is a suite of analysis, modelling and visualisation tools designed to detect and eliminate faults in pharmaceutical production plants. The package combines Multivariable Monitoring techniques to identify the root causes of abnormal process behaviour, with Model Predictive Control functionality to maintain or increase operational efficiency and product quality. This powerful combination helps derive knowledge from historical data to improve future operation.

PharmaMV provides two complementary environments, each compliant with 21 CFR Part 11.

A fully-featured **development** environment includes all of the practical techniques required by industrial process control and process improvement engineers. It is structured to guide the user through the initial data mining exercise, into multivariate data analysis, process monitoring, model-based process control and optimisation. This development system allows the user to not only build and test process models, but perform post-production analysis.

The online system is a robust platform enabling the developed models to be deployed in the real-time environment. This is where the power of multivariate monitoring can be combined with the capabilities of model predictive control to ensure that your production objectives are met every time.

A HOST OF POWERFUL TOOLS, A SINGLE INTERFACE

PharmaMV is designed for compatibility. Universal connectivity, combined with a single user interface, provides a full toolkit for engineers to switch seamlessly between multivariate monitoring, control and optimisation, for both batch and continuous production streams. Process data, quality data and spectral data from PAT instruments data can be incorporated, allowing calibration models to be applied in real-time. *PharmaMV* enables the efficient development of complete process improvement solutions, irrespective of the lab historian, spectral analyser, or the underpinning PLC, SCADA or DCS automation platform.



IMPROVING QUALITY, INCREASING PRODUCTIVITY

Process understanding can unlock the potential benefits of applying model-based technologies only as part of a PAT programme. The FDA's PAT and QbD initiatives are designed to reduce or eliminate process variability, increase process knowledge and optimise product quality – but critically they also open the way for innovation, repeatability and improved asset productivity. *PharmaMV* enables Pharmaceutical and Biotechnology manufacturers to reveal and exploit the lost opportunities open to them.



**PERCEPTIVE
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PharmaMV is the driver to unlock the potential in your plant and operations.

PharmaMV FEATURES

DATA ANALYSIS – CSV, TXT, XLS, SPC and JDX Data Import, Copy and Paste Data Import, Data Spreadsheet View, Flexible Trending, Outlier Detection, Bad Data Plots, Bad Data Replacement, Filtering/Smoothing/Averaging, Spline Fitting, Scatter Plots, Parallel Co-ordinate Visualisation, Auto and Cross-correlation Visualisation, Superimposed Batch Trends.

SPC, MVSPC & MODELLING – Shewhart Charts, EWMA and CUSUM Charts, Process Capability Charts, Distribution Plots, Scatter Plots, Correlation Matrix, Spectral Plots, Automated Outlier Detection, Soft Independent Modelling of Class Analogues (SIMCA), K-Means Clustering, Principal Component Analysis, Partial Least Squares and Extended Partial Least Squares, Batch-Wise and Variable-Wise Multi-Way PCA/PLS for Batch Processes, Concatenated Batch Analysis PCA/PLS Technology, Time-Series PLS/RLS Modelling (FIR/ARX), PLS-Based Endpoint Prediction, Non-Linear Artificial Neural Networks, Phase Modelling.

PROCESS MONITORING – Single Variable SPC Alarm Thresholds, Multivariable Alarm Thresholds, Operating Zone Classification, Fault Detection, Fault Identification, Multi-Model Operating Modes, Fault Fingerprints, Fault Diagnosis, Conditional Classification, Contribution Plots.

CONTROL ENGINEERING – Controller Tuning Analysis (Ziegler Nichols, Cohen & Coon, Lambda), Controller Design and Evaluation, Advanced Controller Tuning (Non-Linear Control, Error Squared Model Controller, Cascade Control), Model Predictive Control, Smith Predictor, Batch Model Predictive Control, Latent Variable Control.

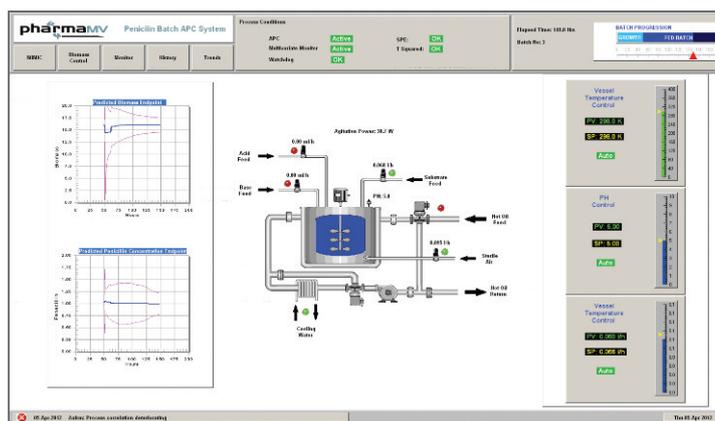
OPTIMISATION – Optimisation Matrix Configuration, Linear Programming (LP), Quadratic Programming (QP), Real-time Optimisation Engines, Sequential Quadratic Programming (SQP), Batch Endpoint Optimisation.

FACING THE CHALLENGES OF BATCH MANUFACTURING

Batch manufacturing poses some unique challenges, including time-varying dynamics, changeover issues, lack of flexibility and inconsistent quality. *PharmaMV* gives operations staff the ability to make informed decisions on the status of each batch, as it progresses.

- Faults are highlighted early in the production cycle and their causes identified.
- Statistical metrics predict the batch endpoint properties, providing detailed insight into batch progression.
- Optimum batch trajectories are estimated and reliable data on whether to continue or end a batch are provided to operators.
- Quality variables that cannot be measured during operation can be continuously estimated from regular process and on-line analysis measurements in **real-time**.

These on-line features enable improved batch production by reducing downtime and changeover durations, delivering higher yields and greater productivity. All relevant information is recorded and stored – invaluable in speeding up validation projects and batch record activity.



WHAT CAN PharmaMV BRING TO MY ORGANISATION?

PharmaMV is the driver to unlock the potential in your plant and operations, delivering:

- Improved product quality, stability and consistency.
- The ability to push plant constraints and optimise your plant's output capabilities.
- Increased efficiency and agility of production.
- Higher ROI and ROCE on deployed plant.
- Manufacturing sustainability through lower utilities and energy costs, and reduced waste.
- Faster time to market, through greater understanding and management of process constraints.

TRAINING

As a company we place great emphasis on training to make sure our clients are familiar and comfortable with the technology and software they are using. This 'knowledgeable ownership' enables users to fully exploit the opportunities presented by using *PharmaMV*.



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