

MANAGE • MONITOR • CONTROL

YOUR PROCESS, IMPROVED

RT Manager

THE CHALLENGE

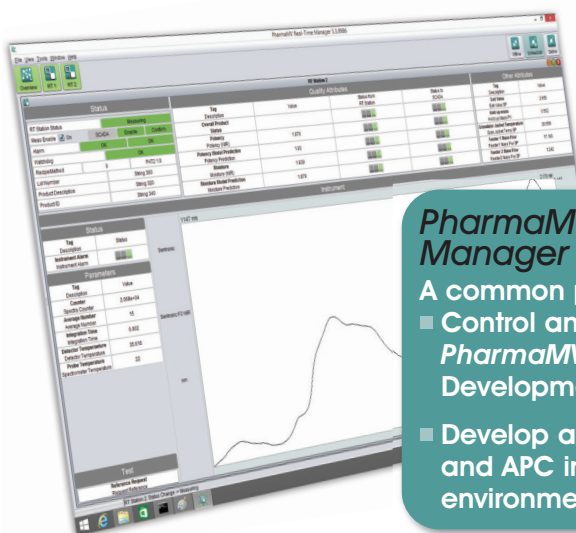
In recent years Pharmaceutical high-value manufacturing has seen a significant shift towards the online application of Process Analytical Techniques (PAT). The application of online spectroscopy, Chemometrics and calibration modelling allow Critical Quality Attributes to be predicted and monitored in real-time.

The challenge is to manage these PAT instruments and associated data quality, methods and models in a regulatory environment. The investment made by Pharmaceutical companies to address these needs in the routine manufacturing environment is significant. In many cases the payback from this investment can be maximised through the application of Advanced Process Control (APC) and optimisation techniques to “close the loop” on the Critical Quality Attributes.

There is much advantage to be gained in applying a combination of PAT and APC, in development as well as in routine manufacturing. The combination of these techniques ensures product quality at any scale. Furthermore, as the industry moves from batch to continuous operation the ability of APC to provide tight control of product quality in the presence of raw-material variation becomes critical.

INTEGRATED MANAGEMENT, MONITORING AND CONTROL

The Real-Time Manager (*RT Manager*) from Perceptive Engineering is a platform for control and management of PharmaMV applications. The combination of the RT Manager and PharmaMV provides a distributed capability for all multi-variable techniques from PAT management and monitoring through to Advanced Process Control and Optimisation. This offering is unique in the Pharmaceutical industry. It allows the investment in PAT to be maximised by providing all the tools required for process improvement in an integrated environment without the need for third-party software.



PharmaMV Real-Time Manager

A common platform to:

- Control and manage PharmaMV Real-Time and Development systems.
- Develop and deploy PAT and APC in the production environment.

OUR PLATFORM FOR DISTRIBUTED PAT AND APC

- Data storage in SQL and Oracle databases.
- Data extraction and modelling using PharmaMV Development.
- Manage PharmaMV Real-Time instances to:
- Control a wide range of PAT instruments including Mid-IR, NiR, FBRM, Raman and UV.
- Deploy Chemometrics, Continuous Process Verification (CPV), Statistical Process Control (SPC), Advanced Process Control and Optimisation.
- An OPC interface to process automation systems.
- User-friendly and customisable secure remote displays. These can be embedded into production systems.
- Powered by Perceptive Engineering's *PharmaMV* software for deployment in a GxP production environment.



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ENSURE ANALYTICAL INSTRUMENT INTEGRITY

POWERFUL DATA VISUALISATION AND ADMINISTRATION TOOLS

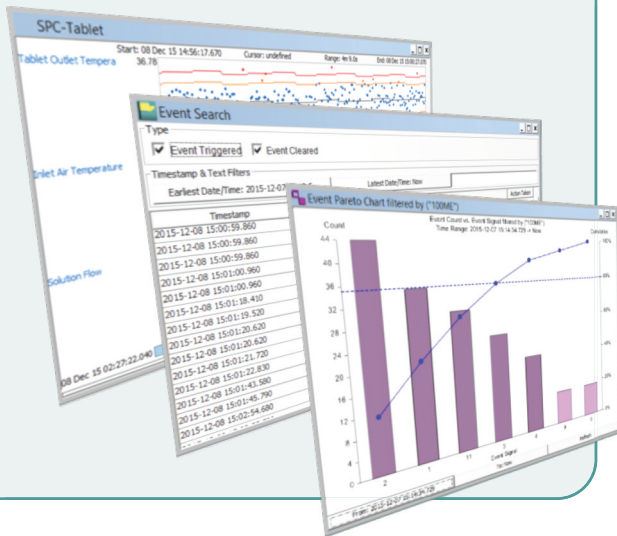
RT Manager provides an extensive set of distributable visualisation tools with integrated user access controls:

■ ADMINISTRATION INTERFACE

Provides controlled access to the system configuration. Pre-defined screens show the spectra, status and prediction results for each Real-Time System.

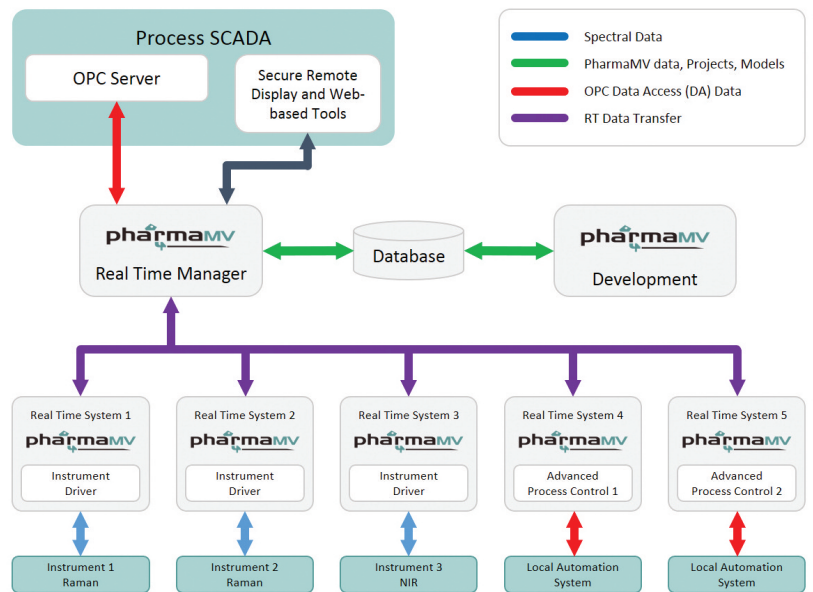
■ SECURE REMOTE DISPLAYS

The RT Manager's remote displays are available as standalone applications or can be embedded in any process automation system that has browser support. These displays include MVSPC and Model Predictive Control interfaces, spectral displays, trends and Statistical Process Control charts.



REGULATORY COMPLIANCE TOOLS

RT Manager is specifically designed to meet the regulatory requirements of the Pharmaceutical industry:



- Version control and management of data, methods and models through the database.
- Production automation system recipe manager integration. The PAT/APC method code can be part of the product recipe allowing automatic deployment of the required model.
- Real-time data transfer of model predictions, CQA quality, uncertainty estimations and performance metrics generated by the Real-Time Systems
- User management and access controls.
- A searchable Audit Trail for system events and changes.

FLEXIBLE LICENCING

A single licence is applied for the RT Manager with individual licences per PharmaMV Real-Time or Development instance. Licences are available in portable USB format for convenience.

