Understand and Improve Crystallisation: AT ANY SCALE

crystalMV

OVERVIEW

Crystallisation is widely used in the Pharmaceutical and speciality chemicals industries for separation and purification. It is critical to secondary processing, as it can dictate essential product-quality attributes such as particle size distribution, crystal morphology and solid state form. These in turn have a significant effect on downstream processing stages such as filtration.

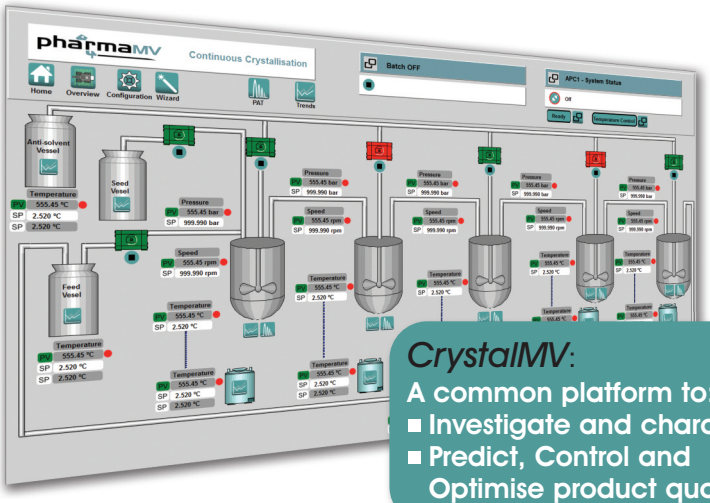
Currently, most crystallisation processes are developed empirically using fixed profiles and recipes. This approach presents significant challenges during process scale-up, where changes in reactor kinetics impact properties such as meta-stable zone boundaries.

At manufacturing scale, these processes require high levels of manual intervention to maintain suitable operating conditions. Often these adjustments do not compensate effectively for external disturbances, such as variation in raw-material qualities.

There is much advantage to be gained in applying a combination **of Process Analytical Techniques (PAT)** and **Advanced Process Control (APC)**, in development as well as in routine manufacturing. The combination of these techniques ensures product quality at any scale, in both batch and continuous systems.

REPEATABLE QUALITY, IMPROVED YIELD

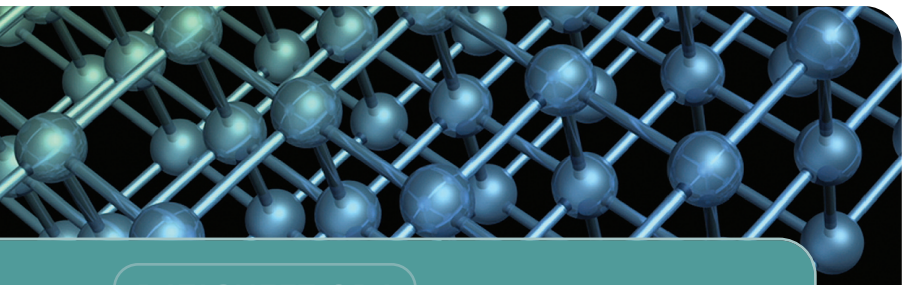
Your crystalliser needs to deliver repeatable product quality, to minimise waste and ensure the efficient operation of downstream processes. This is achieved by controlling critical quality attributes such as particle size and morphology whilst optimising yield.



CrystalMV:
A common platform to:
- **Investigate and characterise.**
- **Predict, Control and Optimise product quality.**

CrystalMV – YOUR PLATFORM FROM LAB TO PRODUCTION

- Integrate with all common crystallisation process equipment and PAT devices, including Mid-IR, FBRM, Raman and UV.
- Control and optimise any crystalliser including continuously stirred, oscillatory baffled and moving fluid reactors.
- User-friendly and customisable operator displays.
- In-built Advanced Process Control for vessel temperature, super-saturation and Particle Size Distribution (PSD) control.
- Programmable experimental methods to automate common tasks such as Meta-Stable Zone determination and crystallisation sequencing.
- Powered by Perceptive Engineering's *PharmaMV* software for deployment in a GxP production environment.



PERCEPTIVE ENGINEERING LTD

www.perceptiveapc.com/crystal

Reduce Development Time, Deliver Repeatable Quality

A SCALABLE SOLUTION FOR CRYSTALLISATION

CrystalMV from Perceptive Engineering works with all crystallisers, large or small.

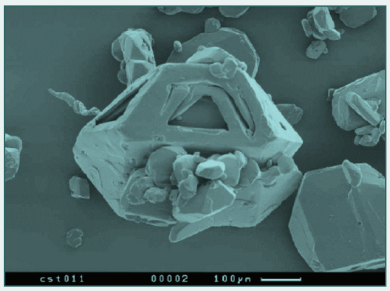
The system features a comprehensive set of **Real-Time Interfaces** allowing seamless integration of data from process and analytical devices. This data is fed through a **Data Quality Monitor** to detect and reject faulty or suspect information.

Once data integration is complete, the crystalliser and drug-product can be characterised using a user-friendly **Programmable Method**. The method can be used to execute Design of Experiment (DoE) tests, establish meta-stable zone boundaries and/or generate data for calibration modelling.

Next, **Model-Based Control** techniques are applied to generate dynamic models capable of controlling the process, to precisely attain the desired product parameters. **Profile Tracking Control** is employed to provide the most accurate control of reactor temperature possible.

Finally, several **Super-Saturation** and **PSD** control strategies are provided. These strategies can be selected to ensure repeatable crystal properties and efficient conversion.

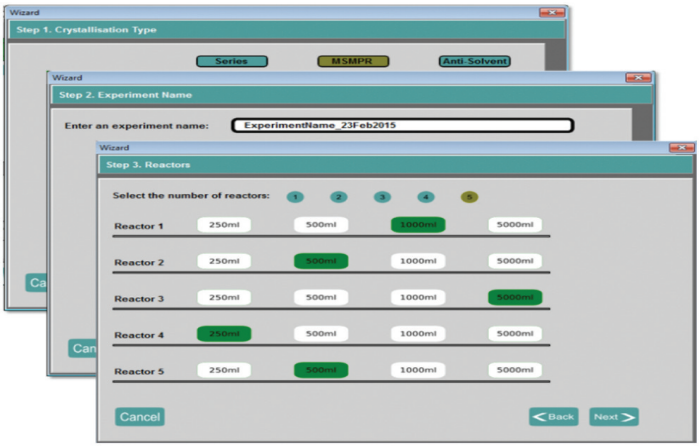
As new drug-products are examined in the system, the user simply has to re-run the automated methods to characterise the compound.



PRODUCT DEVELOPMENT, PROCESS CONTROL: RIGHT AT YOUR FINGERTIPS

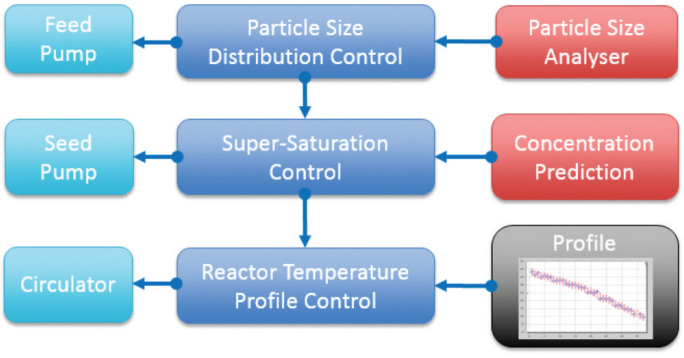
You need a platform for crystallisation process and product development and you would like to take these solutions through to routine manufacturing.

CrystalMV provides this platform, combining a powerful mix of chemometrics, process monitoring and advanced control tools in a single, intuitive package. *CrystalMV* can be configured and customised to control any type of crystallisation process. Multiple-reactor and PAT configurations, as well as different drug-products, can be accommodated using pre-defined set-up wizards.



THE RESULTS

- Reduced cycle time and improved repeatability.
- Optimisation of quality, yield and throughput.
- Reduction in particle size spread particle size spread by 30-60%.
- Reduced scale up effort through rapid characterisation of reactors.
- Rapid characterisation of new drug-products through automated experimental methods.



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Perceptive Engineering Limited
Vanguard House, Daresbury Science and Innovation Campus,
Keckwick Lane, Daresbury, Cheshire WA4 4AB, UK.
t. +44 (0)1925 607150 **e.** water@perceptiveapc.com
f. +44 (0)1925 607161 **w.** www.perceptiveapc.com/nutri