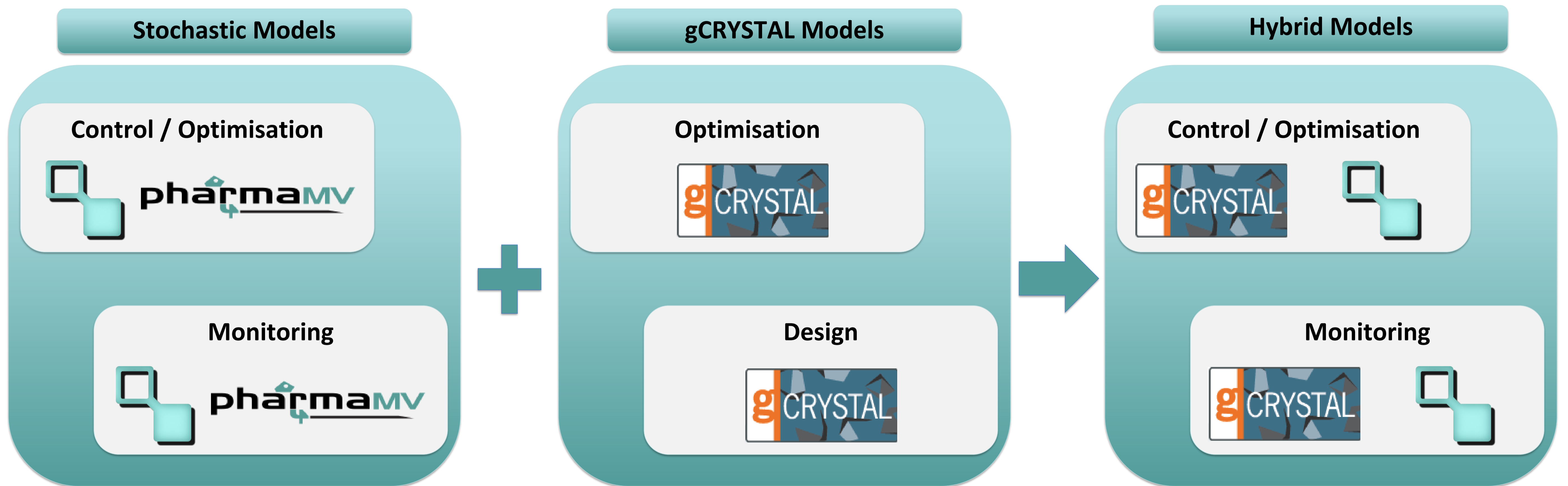


Background

The ADDoPT project (Advanced Digital Design of Pharmaceutical Therapeutics) seeks to enable the delivery of medicines to patients quicker and more effectively, through the sophisticated definition, design and control of optimised pharmaceutical processes.

As part of this, Perceptive Engineering Ltd (PEL) are leading an activity in conjunction with Process Systems Enterprise Ltd (PSE) and Britest Ltd to address the challenges in ensuring the precise control and optimal operation of new manufacturing processes, in as efficient a manner as possible.

Incorporating hybrid modelling to combine the benefits of mechanistic models, with the classical data-driven techniques used in automation, there are additional requirements to develop methodologies to easily implement control systems, provide adaption as new products and product grades are introduced, and transfer relevant process knowledge and learning as production is scaled up from one development system to the next.

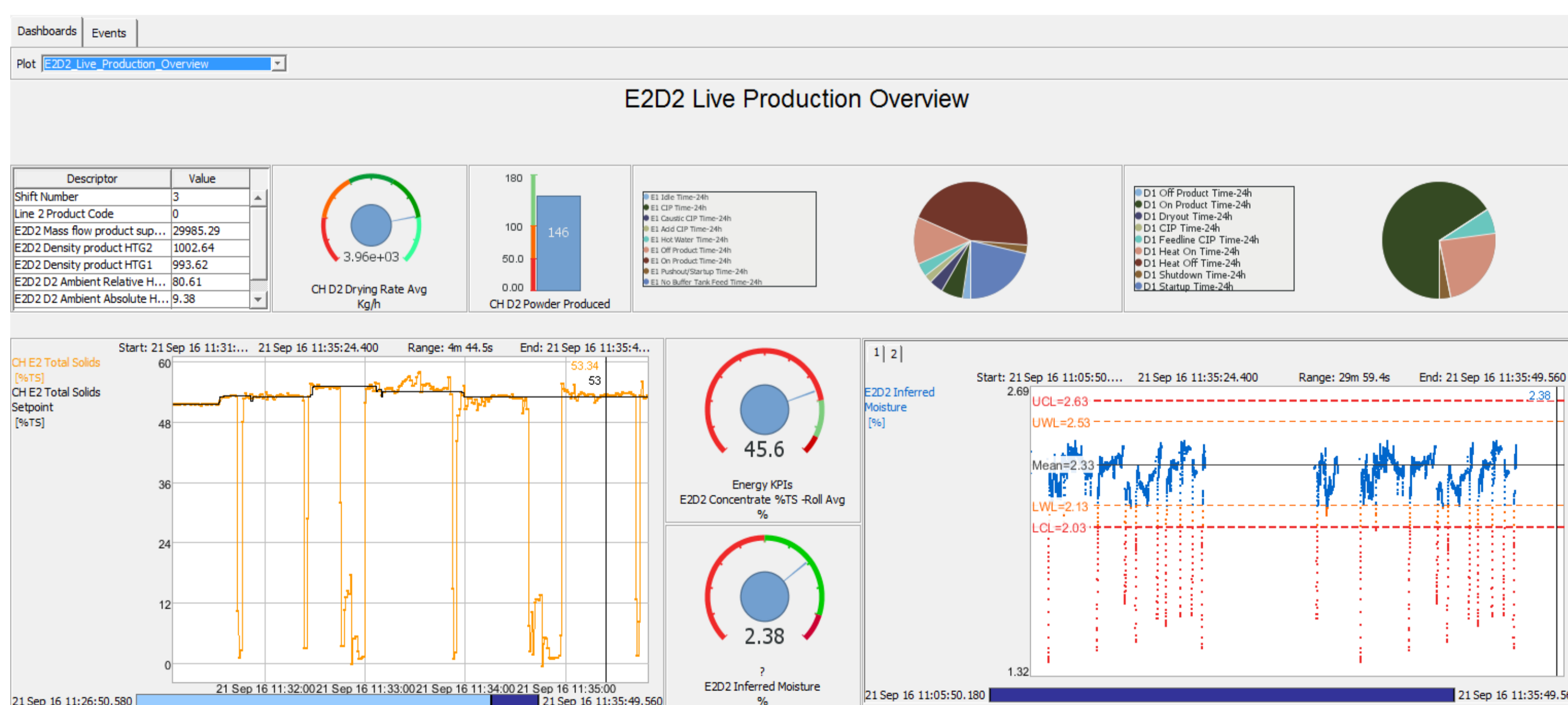


The Challenges

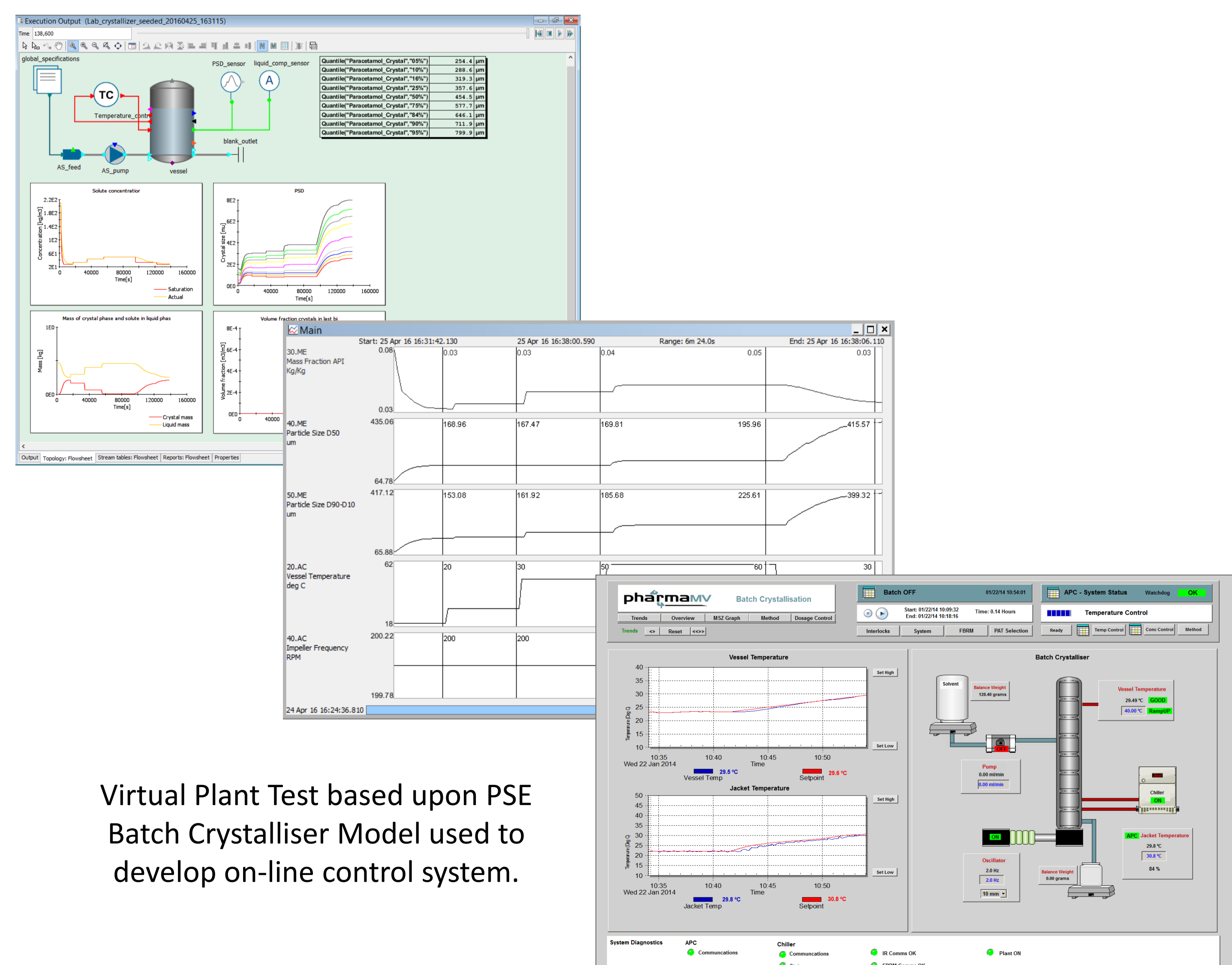
- Coverage of the broad range of commercial manufacturing units from Integrated Batch Operations to more recent Continuous processing systems.
- Management of “Instrument and Data” Integrity.
- Establishing a sensible Control Space within the Design Space that provides near optimal operation within a risk based framework.
- Handling the inclusion of uncertainty in the model based controller (or any controller).
- To reveal the estimation uncertainty associated with adapted models prior to their inclusion in the Real Time platform.
- Development of a demonstrable “Lock Down” capability for the set of models (Calibration, Process Monitoring, Control, Optimisation).
- To track and manage models in a readily auditable manner
- Education of pharmaceutical engineers less familiar with dynamic models and closed loop control.

The Benefits

- Capability to use Process Development models within commercial manufacturing units to achieve dynamic control, gaining maximum value from modelling investment
- Reduction in costly process design and control space identification trials.
- Reduced commissioning time.
- Optimal production rapidly reached even for short production runs.
- Consistent and auto-generated documentation from Product Development to Manufacturing.
- Traceability



Example of PharmaMV Process Performance Monitoring Dashboard



Virtual Plant Test based upon PSE Batch Crystalliser Model used to develop on-line control system.