pharmaMV

Centre for Process Innovation
## National Formulation Centre

cpi

Introduction

The Centre for Process Innovation (CPI) recently developed a physical rig to enable understanding of the process scale-up of complex liquid products. The new facility has two major functions:

1. Understanding and controlling dynamics of scale-up of formulation processes.

2. Developing and validating new sensor technologies and process analytics capabilities

The new facility's flow loop consists of two main parts: Four vessels increasing in size from 1-1000l, and a flow skid comprising pumps and additional instrumentation. The configuration is highly flexible and can be adjusted to the need of the project.
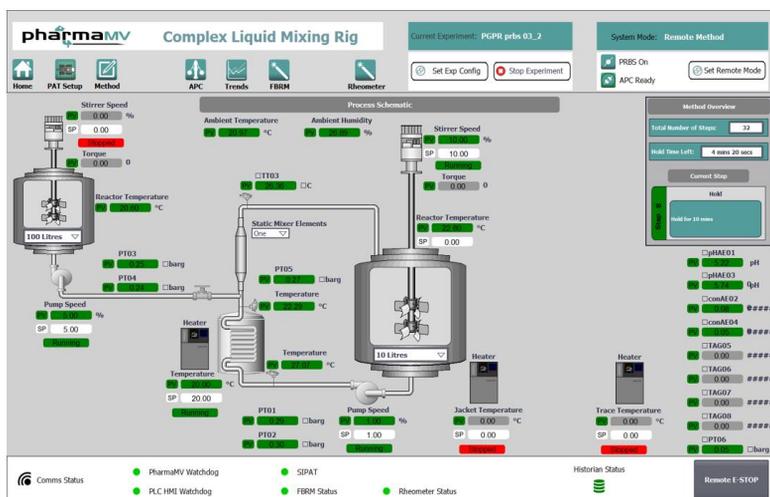

Benefits

- **Facilitate rapid learning of how formulated product properties discovered at the lab scale can be manufactured economically and flexibly.**

- **Understand the dynamics of manufacturing formulations at different scales and enable predictive scale-up of batch formulation processes.**

- **Develop, validate and utilise new sensor technologies and process analytics technologies**

- **Develop automated process monitoring and control schemes.**

Perceptive Solution

Perceptive's software has been selected as the Automation platform for the CL4IR rig. PharmaMV provides a full suite of analytical and modelling tools, all within one platform. It allows the client to gather real-time data from the process and from a range of sensors and spectral (PAT) devices, then align and visualise that data; to provide a clear understanding of how the process is behaving under varying test conditions.

PharmaMV also allows the customer to build statistical models of the process, which are used to detect abnormal operation and predict the quality of finished product.

This work will enable manufacturers to establish manufacturing control schemes where process parameters can be adjusted in real time to optimise processing time, narrow specification tolerances and limit off-specification product.

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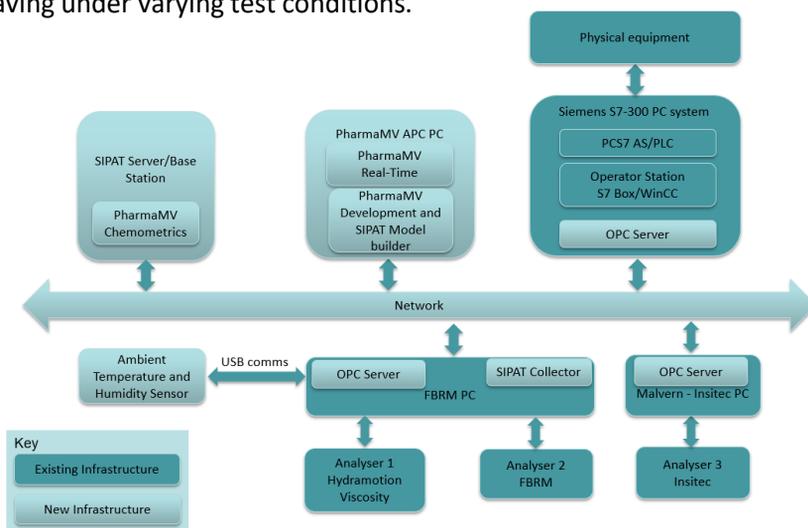
What We Delivered

Perceptive Engineering developed a control system for the flow rig capable of monitoring and controlling product quality attributes. This includes:

(a) A remote human machine interface (HMI) to allow control of the rig.

(b) A data acquisition system for process, lab and spectral (PAT) data.

(c) Capability to implement process models for the real time prediction of process parameters.

(d) Capability to detect process abnormalities in "real time" through the application of model based fault detection.
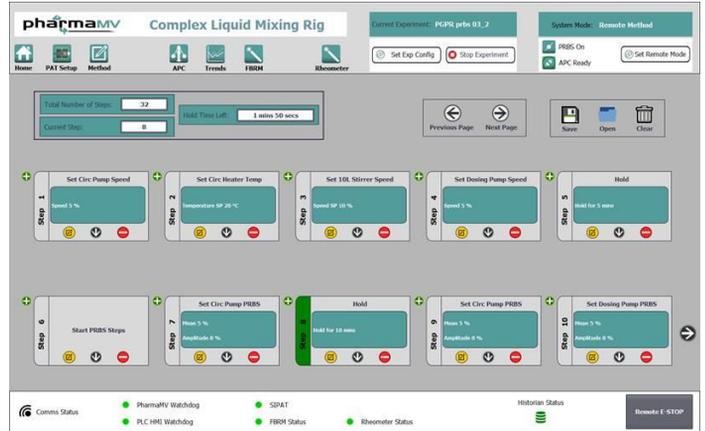
Results

Early tests of the MPC show that it is possible to drive the formulation towards set points, and to reduce the variability in the system. It was shown that the control approach is robust against disturbances.

Dr Katharina Roettger – Senior Scientist at CPI – reports that "together with Perceptive Engineering Ltd we developed a model predictive controller (MPC) that we will utilise in the future to allow us to modify the formulation to mimic a wide range of products".

The CPI's scientist are currently Perceptive's solution to optimise the scaling up of the HIPE model system.

| MPC provides a clear reduction of process variability | MPC drives the process towards the desired setpoints | MPC makes the necessary adjustments to reach the desired setpoints | MPC robust against disturbances |

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