DATASHEET

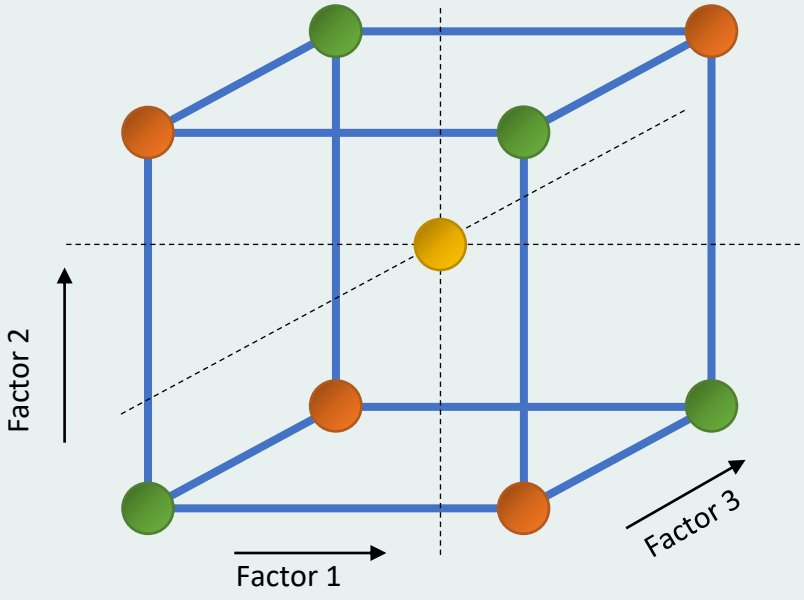
Streamlined Pharmaceutical Research & Development

engineering for a better world

AUTOMATED DESIGN OF EXPERIMENTS and ADVANCED MODELLING for CONSIGMA 1 ™

GEA Pharma system's ConsiGma 1 R&D process is designed to allow you to test and develop ndividual process steps with a minimal amount of product, on small-scale equipment, but using the same parameters that would be required on production assets such as the ConsiGma-25.

Through a collaborative partnership, GEA Pharma systems and Perceptive Engineering have developed a "bolt-on" software solution that extends the product and process development capabilities of the ConsiGma™ 1, by adding tools for automated experimental design and advanced data-driven modelling techniques.



The solution is deployed in Perceptive's PharmaMV™ Advanced Process Control platform. It can be applied to any ConsiGma 1 and provides the following capabilities:

- Flexible design and real-time execution of Design of Experiments studies with integrated sample management.
- Offline data analysis, pre-treatment and visualisation using PharmaMV™ Development
- Model Development and Maintenance facilities for Multi-Variate Analysis.
- Real Time Quality monitoring and Statistical Process Control.
- Comprehensive User-Configurable Dashboards

PERCEPTIVE ENGINEERING

PACKAGED SOLUTION FOR R&D

The ConsiGma 1 PharmaMV solution is offered through the delivery of the following:

SOFTWARE

The software package consists of PharmaMV Development and Real-Time licences. PharmaMV Development is a fully-featured platform for preliminary data mining, pre-processing and analysis through to monitoring, control and process optimisation. The PharmaMV Real Time system interfaces directly to the ConsiGma 1 via the existing OPC server. It allows online data collection, execution of Design of Experiments, data driven models and data visualisation.

METHOD

The pre-configured PharmaMV method is supplied with the following features:

Design of Experiments Manager, for execution of experimental tests with configurable tools for steady-state detection, inbuilt sample entry tools and results review.

Statistical Process Control with Univariate and multivariate visualisation tools. Real Time Shewhart, EWMA and CUSUM charts with Western Electric Rules, automated Outlier detection and alarming. Statistical Process Control charts, plots, trends.

Preconfigured Dashboards. All visualisation, SPC and DoE tools are provided in pre-configured dashboards. The dashboards are compatible with any HTML5 browser and as an option, can be embedded in the GEA SCADA.

CONSULTANCY SERVICES

The solution includes a consultancy services pack to install, commission and test the PharmaMV software and method.

DOCUMENTATION

A documentation pack is provided, consisting of a Project Quality Plan, System User Guide and software platform documents. The software is also supplied with in-built, context-driven help.

TRAINING

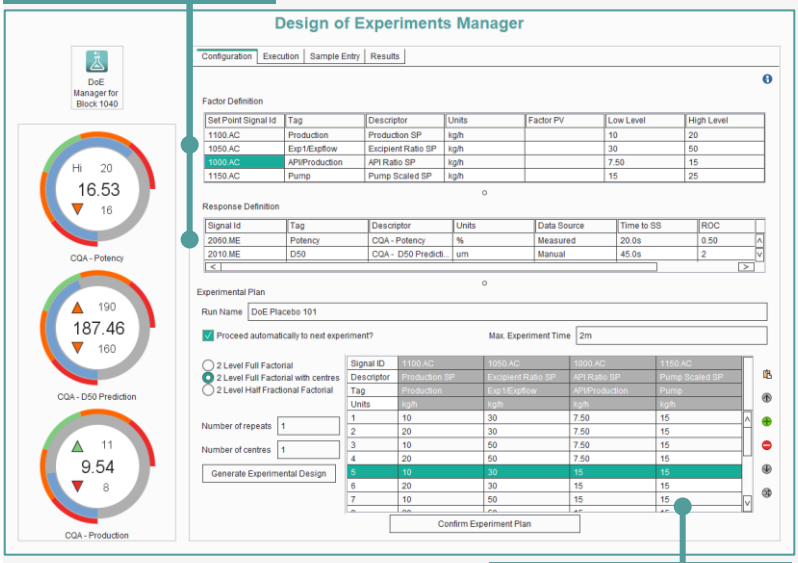
A system training session and associated User Guide is provided. Further training workshops and 1-3 day training courses can be provided for in-depth coverage of PharmaMV's technology.

FEATURES and BENEFITS

The PharmaMV solution can be fitted to any ConsiGma 1 without modification to the existing automation system.

It provides a cost-effective tool to further enhance the system's capabilities for product and process development. At the core of the solution is the Design of Experiments Manager. This tool allows Experimental plans to be generated, edited or imported. Once confirmed, the DoE can be automatically executed on the ConsiGma ™ 1.

Definition of Factors and Responses



Automated Experimental Plan Design

During execution the DoE Manager will minimise raw material usage by automatically moving to the next experiment when steady-state is detected. The sample entry manager streamlines the collection of offline samples by providing automatic timestamping and data alignment. Once an experimental set is complete the subsequent offline results can be entered against the pre-defined experiment and timestamp metadata.

21 CFR Compliance

PharmaMV provides a comprehensive audit functionality, which enables compliance with legal requirements and 21 CFR Part 11. The key audit function blocks of the software are:

- System safety and authorization controls
- Electronic signatures
- Recording of all changes to data sets
- Version control for objects, such as methods, models and configuration settings.

PERCEPTIVE ENGINEERING

Perceptive Engineering Limited
Vanguard House
Sci-Tech Daresbury
Cheshire WA4 4AB UK
+44 1925 607150
info@perceptiveapc.com

Perceptive Engineering Pte Limited
Galaxis Work Loft #05-51
3 Fusionopolis Place
Singapore 138523
t +65 6250 7565
www.perceptiveapc.com

Perceptive Engineering Ltd (Ireland)
Nexus Innovation Centre,
University of Limerick
Republic of Ireland
t +65 6250 7565