



# A Workshop for improving the Efficiency and Robustness of Pharmaceutical Batch and Continuous Manufacturing Processes



## BENEFITS:

- Improve manufacturing robustness
- Improve process capability and OEE
- Increase process understanding
- Understand PAT connectivity and monitoring
- Understanding Industry 4.0

## THE NEXT STEP IN PHARMACEUTICAL MANUFACTURING

There are a number of obstacles to consistent and efficient operation in the pharmaceutical sector. Despite considerable research, process optimisation generally remains an off-line task. Ideal operating policy is determined in advance but is frequently compromised due to:

- Significant changes to process dynamics over the course of a batch
- Variations in the feed material
- Limited product quality measurements

Manufacturing procedures largely rely on the expertise of plant operators rather than automated control systems. All too often this leads to a high degree of variability in the final product.

## IMPLEMENTATION OF ADVANCED CONTROL

Experience in processing industries has demonstrated that the variance of key quality variables can be reduced by at least a factor of 1.5. Plant throughputs can often be significantly increased, by driving the process to its dynamic constraints.

## PATNAV

*PATNAV* methodology has been developed by Perceptive Engineering to demonstrate when to, (and when not to) integrate PAT to enable improved controllability and process optimisation within pharmaceutical processes. The benefits sought are focussed around the reduction in process variability, yielding improvements in both quality and productivity.

*PATNAV* comprises a two-day workshop, providing the toolset and skills for identifying the production assets which offer the greatest opportunity for optimisation, while demonstrating how to add PAT.

Using leading-edge software, delegates will learn how to analyse process variability using new PAT and identify when it's appropriate to apply real time statistical monitoring or whether feedback control offers greater benefits.

## THE PERCEPTIVE PATNAV WORKSHOP

The Perceptive *PATNAV* Methodology involves a detailed review of the manufacturing units at site, with a focus on data analysis to better understand the cause-effect relationships across the individual production units within the overall production process.

The workshop - and associated technical roadmap that underpin *PATNAV* - provide an efficient way to ramp up the QbD initiative within your company. Through the workshop we:

- Introduce the concepts of Quality by Design, Process Analytical Technology, Process Optimisation
- Teach the basics of Process Capability and Robustness for batch and continuous processes
- Demonstrate how to communicate to a PAT device and build a calibration model
- Demonstrate how to improve process operations using Advanced Process Control techniques.
- Develop a strategic plan appropriate to the particular stage that your company has reached with QbD.



# Process insight combined with practical know-how, enabling Pharmaceutical Scientists to get the most out of QbD

## Introduction

- Workshop Objectives

## Quality by Design, Process Analytical Technology

- Introduction to current industrial practice
- Align QbD requirements with Customer site

## Process Improvement Tools

- Process Capability, Robustness - Techniques, Examples
- Measurement Requirements for improved controllability
- Accuracy, Sampling Frequency
- Intro to SPC techniques
- Quantify the impact of process variability
- Within Batch Variability / Batch to Batch Variability

## Intro to Advanced SPC (and Multivariate SPC) Analysis

- EWMA, CUSUM, Autocorrelation
- Principal Component Analysis, Partial Least Squares Regression

## Process Understanding using Parallel Co-ordinates

- Parallel Coordinate analysis using customer data if available
- Assessment of what CPPs are missing to clearly infer the CQAs

## Workshop Day 1 Ends

## Review Day 1

Objectives for the Workshop

## Introduction to Advanced Process Control techniques

- Define Models for calibration, monitoring, control and Optimisation
- Inferential ("Soft" sensor) applications
- Model Predictive Control; what, why, when, where!

## Practical Interfacing PAT

- PAT Real Time manager/SIPAT
- "Hands on" interfacing to PAT
- Communication Link, Protocol
- Calibration Model
- Analyser Monitoring

## Demonstration of PATNAV Methodology: Spray Drying or Crystallization case study

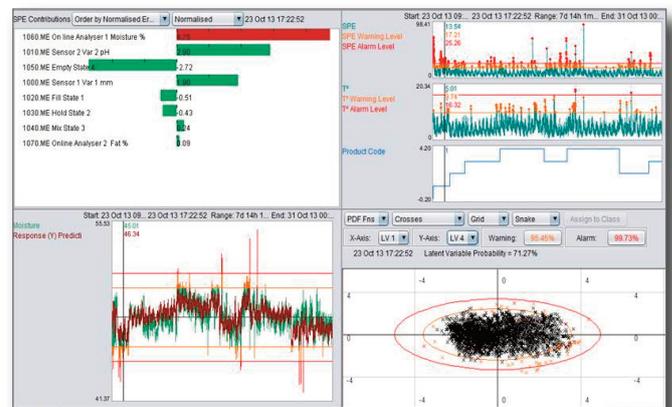
- PAT, SPC, MVA and APC working together
- Improving productivity using a combination of feedback/feedforward control and SPC monitoring
- Business Case

## Workshop Day 2 Ends

## PERCEPTIVE ENGINEERING LTD

works with some of the most innovative companies, including Pfizer, Abbott, GSK, Merck, Takeda and many others as partners in designing, developing and deploying Advanced Process Control strategies.

As a company in the Advanced Digital Design of Pharmaceutical Therapeutics (ADDOPT™), we are at the forefront of developments in the digitalisation of the Pharmaceutical Industry. We partner with many of the Continuous Manufacturing centres around the world including Rutgers (C-SOPS), CMAC and A\*STAR, and continue to contribute towards the future of pharmaceutical manufacturing.



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