How to Ensure Quality by Design: A Practical Online Workshop

1000-1200 (BST), 28th, 30th September and 2nd October 2020

Sponsored by the RSC Process Chemistry and Technology Interest Group and JMP®

Learn how to develop consistently better processes with a strategic focus on risk, understanding and control with Martin Owen and Walkiria Schlindwein.

In this online workshop, industry and academia experts introduce you to the fundamentals of Quality by Design (QbD) and Design of Experiments (DoE). You will see how QbD enables organisations to consistently deliver high quality products in the face of complex technologies, risk factors and many sources of variation.

This workshop was organised with the Royal Society of Chemistry Process Chemistry and Technology Group to work towards meeting their challenge of 'increasing the uptake of QbD methodologies in all industries and chemistry types'. It is intended to be helpful, practical and wide-ranging for novices or those who want to expand their current knowledge.

You will learn…

- How the different elements of Quality by Design fit together for chemical processes
- How QbD and DoE support customer-focussed process and product development, and manufacture
- A pragmatic risk-based and data-driven approach
- The meaning of the ICH terminology (QTPP, CQA, CPP) through implementation in case-studies
- How to apply Quality Risk Management including risk identification and risk-ranking tools
- Sequential experimental design: screening, optimisation, robustness, verification to gain information from data
- How to develop a risk-based data-driven Control Strategy
- How to use tools and techniques in the accompanying Learning Journal Workbook

Who should attend:

This introductory course provides relevant content of interest to all levels of professionals in the pharmaceutical field, especially those working in the following types of organisations, job roles or product types:

- Pharmaceutical, R&D and Manufacturing organisations, including those developing novel or making generic products, Contract Manufacturing, and 'virtual' companies, post-graduate chemists in academia
- Scientists, analysts, development, production, engineers, and support functions such as validation
- Chemical processes and products, including Active Pharmaceutical Ingredients (API) and intermediates, food, consumer health care

Price:

Workshop places are priced at £100 per attendee. This is a generously subsidised price to support the chemistry community at this difficult time.

Bursaries are available for students and those not currently in employment (please contact PCTG via https://www.procchem.group/contact to apply)

Places will be strictly limited to ensure a high level of interactive support

Course Description:

> *Quality by Design is "a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management." (ICH Q8)*

This course comprises of three 2-hour online sessions. It provides a hands-on, interactive opportunity to explore the development of a risk-based, data driven control strategy for the manufacture of products and processes. It will demonstrate how understanding and monitoring leads to the continuous improvement product and process performance.

There will be an introduction to the overall QbD 'process flow' and the basics and benefits of experimental design methodology.

There will be an introduction to the ICH guidelines, terminology (e.g. Quality Target Product Profile, Critical Quality Attributes, Critical Process Parameters) and latest expectations and practices for effective QbD implementation to enable a practical Control Strategy to be put in place. This will be briefly related to the product lifecycle Process Validation Stages.

Companies must be able to assess risk and prioritise risk mitigation activities in order to

- reduce operational uncertainty, batch failures, product recalls and manufacturing costs. Practice the use of qualitative risk analysis techniques include Ishikawa diagram, Failure Mode Effect Analysis, Cause and Effect Matrix, 5 Whys
- increase process understanding and robustness, quality assurance, regulatory flexibility and development efficiency using experimental design methodology

The workshop will explore good practice to collect information-rich data and build up knowledge sequentially. Emphasis is placed on the amount of resource used and the information gained.

Participants will see examples of different experimental designs, as part of a sequence of resource-efficient "fit-for-purpose" experimental designs are discussed in the context of minimising risk and developing a robust control strategy. Participants will interpret data to generate process understanding, make decisions confidently and communicate the rationale to their colleagues.

The target outcome is to demonstrate an understanding of a planned set of controls, derived from current product and process understanding that ensures process performance and product quality.

These controls can include parameters and attributes related to materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the associated methods and frequency of monitoring and control.

Knowing the tools is not enough. Knowing when and how to use them is critical to success.

The on-line course will be interactive. The workshop modules contain an entertaining mix of theory, "sixty second science" data generation, case studies, simulations and "back of the envelope" quality risk assessment, and DoE planning discussions that draw on the wisdom of the virtual classroom. Participants be encouraged to transfer classroom learnings to their own areas of interest through questions and answers, using an off-line Learning Journal workbook.

The workshop will use Excel and a statistical package JMP. The emphasis will be the application of experimental design and data visualisation rather than how to use the software package. Participants may wish to attempt to build and analyse the data in their own statistical software packages, but these will not be specifically supported during this workshop

Course Tutors:

Martin Owen and Walkiria Schlindwein have a reputation for being engaging trainers, focussing on what participants want.

- Martin Owen graduated in Chemistry and has spent most of his career in Process Development and Manufacturing Tech Transfer. He established the Process Development Automation Group at GlaxoSmithKline, designed parallel experimentation robots and used these to investigate chemical processes across GSK's worldwide R&D and Manufacturing sites. His focus is the application of modelling and data visualization applied to problem solving, quality and process improvement. He now runs his training and consultancy company, helping organizations in industry and academia make better use of data. Martin is a part-time lecturer at De Montfort University for their Quality by Design MSc program.

- Walkiria Schlindwein graduated as a Chemical Engineer. She has over 20 years of experience in academia and is currently Associate Professor of Pharmaceutics at the Leicester School of Pharmacy. Her current research projects are in the areas of pharmaceutical formulations with interest in integrating quality by design in continuous pharmaceutical product development and manufacture. Walkiria is the programme leader of two Postgraduate courses in Pharmaceutical Quality by Design (QbD) and a key member of the academic teaching staff. She oversees all aspects of the distance learning programme including curriculum development, assessment, recruitment, and support of students. In addition, she has a strong research interest in the science underpinning QbD and has developed collaborations with numerous organisations that are active in this field. She is member of the Academy for Pharmaceutical Sciences Regulatory Focus Group and of the Continuous Manufacturing and Advanced Crystallisation (CMAC) International Advisory Board.