SCIENTIFIC UPDATE

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3 day Course

2020

NEW QBD COURSE

QUALITY BY DESIGN IN PHARMACEUTICAL DEVELOPMENT

NEW COURSE

30

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1989 - 2019

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QUALITY BY DESIGN IN PHARMACEUTICAL DEVELOPMENT

A 3-day course by Paul Murray Catalysis Consulting Ltd

INTRODUCTION

QbD is an industry initiative supported by regulators. However, it is also a systematic method of process development which delivers consistency, robustness and increased process knowledge.

This course introduces QbD across all areas of pharmaceutical development including synthesis, formulation and analysis and suggests practical recommendations for the implementation of QbD.

Participants will learn how to identify and prioritise process parameters, determine and manage risk, and implement control strategies. The use of experimental design (DoE) in QbD, the identification of potential mixing and scale-up problems and the safe scale up of processes to pilot and manufacturing plants will also be discussed.

For the benefit of process scientists, engineers, formulators, analytical chemists and manufacturing personnel, this course includes highly interactive, hands-on workshops, based on several case studies.

COURSE OUTLINE

Introduction:
> Course objective, introduction to the principals of QbD, FDA objective with QbD.

The QbD process:
> QTPP, assessing risk, working through unit operations to determine CPPs and CMAs

QbD in Action:
> breakout workshop and case study

Process design, criticality and control strategies:
> different levels, monitoring and control, post-approval changes

Consideration of impurities:
> ICH M7, control strategies, case study

Scale-up considerations:
> process complexity, mixing, mass transfer, heat transfer, modelling

Process capability, process analytical technology, QbD and continuous processing

Quantification of CPPs. Introduction to DoE:
> where does DoE fit in QbD

Implementation of QbD:
> QbD in formulation, method development, chemical development and manufacturing

Examples and Case Studies

Summary and Questions

COURSE OBJECTIVES

- To provide a comprehensive understanding of QbD including current uses and promised use
- To provide a step-by-step process for successful QbD
- To introduce DoE for QbD purposes
- To apply QbD to develop safe and robust processes
- To use a comprehensive manual with examples and case studies to further educate on the QbD process

At the end of the course, participants will have gained:

> A comprehensive understanding of QbD including the process and all associated definitions

> The ability to develop and use Quality Target Product profiles (including identifying CQAs, identifying, prioritising and quantifying process parameters and material attributes)

> An understanding of different risk assessment techniques to determine and manage risk

> Ways to determine and implement control strategies

> The skills required to develop and understand the robustness of processes

> The tools to identify potential mixing and scale up problems

> An understanding of DoE in relation to QbD

> An appreciation of the benefits of continuous manufacturing from a QbD perspective

> An appreciation of QbD in analytical chemistry, formulation, process development and manufacturing

> An appreciation of PAT in QbD

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Registration 8.45
Start 9.00am on Day 1
Course adjourns 5.00pm on Day 3

Course fees include a comprehensive course manual, refreshments throughout each day, lunches and one course dinner on the first evening

For all prices and dates please refer to our website

IT'S EASY TO REGISTER ONLINE

COURSE TUTOR

Paul Murray

Paul Murray is a consultant with expertise in the fields of Catalysis, Design of Experiments, Principal Component Analysis, Process Development, and Quality by Design.

Paul has a proven track record of the timely delivery of innovative solutions to projects resulting in significant reductions in costs and resources for customers.

Paul worked as a Process Development Chemist at AstraZeneca before becoming a consultant and trainer, and has spent his career using DoE to develop robust processes with enhanced process understanding. QbD is a risk-based strategy to control the desired quality attributes of a drug and DoE is an important method to investigate and understand the relationship between the factors and the quality attributes. Paul regularly delivers training courses, works on client projects for the efficient development of chemical processes, and has 21 publications and 9 patents to date.

IN-HOUSE COURSE

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We will sign a CDA and discuss your project by telecom or webinar to assess what benefits we can offer. This initial consultation (up to 4 hours) is free of charge. After which we will offer a detailed proposal with the service we can provide tailored to your individual requirements.

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Use our **fast online booking system by visiting www.scientificupdate.com**

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Should you be unable to attend and cancel in writing no later than 1 month before the start of the course, Scientific Update will refund your registration less £300.00 (or equivalent in €/$) processing fee. Unfortunately refunds are not possible after that date. Substitutions can be made at any time.

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EVENT:

DATES: **LOCATION:**

No. of attendees **Price**

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