QbD and Lifecycle Management of Analytical Methods

21 & 22 May 2020, London UK

Recent regulatory guidance has encouraged a lifecycle approach to pharmaceutical product development. One of the advantages of such an approach, including a Quality by Design (QbD) framework for development, is the promise of easier post-approval changes. For example, the draft ICH Q12 guideline (Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management) introduces the concept of established conditions, within which changes are allowed, and post-approval change management. The key to the successful implementation of a lifecycle approach to analytical methods is an effective risk management strategy, based upon sound scientific principles and knowledge of the method's performance in routine use. A Design of Experiments (DOE) approach to evaluating method robustness is recommended. The potential advantage of a QbD and lifecycle management approach is robust methods that produce consistent, reliable data throughout their lifecycle, with fewer method transfer failures or OOS/OOT results.

This two-day course discusses the advantages of a lifecycle approach during development, validation and transfer/verification of analytical methods. Such advantages include a better understanding of the magnitude and sources of method variability as well as a potentially easier route to post-approval method changes. The role of effective method documentation is discussed.

The course focuses on HPLC methods, but the principles of lifecycle management may be applied to any analytical method.

Course objectives

The course aims to give participants a thorough grounding in the principles of Quality by Design and lifecycle management as they apply to analytical methods. It draws on the draft guidance for analytical lifecycle management in ICH Q12, but also the more general guidance on pharmaceutical development, risk management and quality systems contained in ICH Q8, Q9 and Q10.

The course:

- Compares traditional and QbD/lifecycle approaches
- Shows how to apply QbD and lifecycle approaches to the development, qualification and transfer of analytical methods
- Discusses ways of controlling analytical method variability
- Shows how to save effort through the application of a risk-based approach to analytical method lifecycle management

Who Should Attend?

This two-day course is valuable for managers, supervisors and laboratory analysts involved in the development, validation, transfer, verification or amendment of analytical methods in the pharmaceutical industry, including the following functions:

- Quality assurance
- Quality control
- Regulatory affairs
- Contract analysis
- Analytical development

The course material includes slides, handouts and case studies. Attendees will also participate in group workshops and practical exercises and will be encouraged to ask questions throughout the course.

PROGRAMME

Day 1

8.45 Registration and Coffee

9.00 - **Regulatory guidance**

- Analytical methods in context – drug safety and efficacy
- ICH guidances Q2, Q8, Q9 and Q10
- ICH Q12 (draft) – lifecycle management
- ICH, US FDA, WHO and PDA method validation guidelines
- Lessons from recent regulatory enforcement letters

Discussion: problems with the current regulatory approach

10.30 Break

10.45 - **The 2015 US FDA method validation guidance**

- Scope and status
- Recommendations for lifecycle management
- The application of quality risk management, design of experiments, ongoing performance verification and knowledge management to method lifecycle management
- Equipment qualification
- Trending method performance

Exercise: evaluating ongoing method performance

12.30 Lunch

13.30 - **The lifecycle approach**

- Advantages
- Application to design, development, validation and ongoing verification of analytical methods
- Lifecycle management and QbD: comparison
- Regulatory status
- Method transfer and compendial method verification

Discussion: experience with method transfer – risk evaluation

- Importance of risk management

14.45 Break

15.00 - Rational approach to method development

Discussion: current approach to method development

Workshop: what do we need our method to do?

When is method development finished?

Regulatory expectations for HPLC method performance

16:30 End of Day 1

Day 2

9.00 -**The analytical target profile**

- Definition
- Comparison with current approach
- Advantages and limitations
- Measurement uncertainty and the method uncertainty budget

Workshop: writing an ATP based on product specifications

10.30 Break

10.45—**Risk control in analytical method documentation**

- Common problems with analytical method documentation
- Regulatory expectations: contents of analytical methods
- A risk-based approach to analytical method documentation
- Change management during method development

Exercise: identifying risks in documented analytical methods

12.30 Lunch

13.30—**Method validation**

- Method validation SOP
- ICH Q2 requirements
- Typical validation experiments
- Method robustness: what and how much?
- Design of experiments for method robustness
- Statistical tools for results evaluation
- Acceptance criteria examples

Exercise: setting method validation acceptance criteria

14.45 Break

15.00**—Ongoing performance verification**

- Aims of ongoing performance monitoring
- Using system suitability results
- Control charts
- Method changes and permitted adjustments
- When to revalidate
- Trending OOS and OOT results
- Continuous improvement

Discussion: barriers to implementing a lifecycle approach

16:30 End of course

Venue:

London: DoubleTree Hilton Hotel, 60 Pentonville Road, Islington London N1 9LA **Website:** www.doubletree3.hilton.com

Nearby Hotels: Premier Inn Islington, Premier Inn Euston, Premier Inn Kings Cross, Premier Inn London St Pancras Travelodge Kings Cross

Numbers are limited to give participants the opportunity for thorough discussion of the issues to be covered by the programmes and one-to-one consultation with speaker(s)

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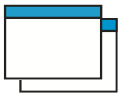

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Course Speaker - Dr Mark Powell

Mark is a Fellow of the Royal Society of Chemistry with over twenty years' experience as an analytical chemist. His PhD project involved the characterisation of bitumen by chromatographic, spectroscopic and thermal methods, providing a good grounding in a wide range of analytical techniques.

He then worked for five years in the environmental industry, with responsibility for the development of analytical methods capable of quantifying very low levels of pollutants in drinking water and a variety of other sample types.

Having joined Liverpool John Moores University's School of Pharmacy and Chemistry in 1997 as a Senior Lecturer, Mark was responsible for the University's MSc programme in analytical chemistry, and was also active in research and consultancy.

In 2003, he joined the newly-formed Quay Pharmaceuticals, a contract research and manufacturing organisation specialising in early-stage drug development, where he was responsible for analytical development. Since 2010, as Scientific Manager, Mark was involved more generally with drug development programmes and also established collaborations with a number of UK universities and instrument manufacturers. His work at Quay has resulted in a number of published papers and presentations at scientific conferences.

REGISTRATION DETAILS:

QbD and Lifecycle Management of Analytical Methods:
21 & 22 May 2020

Full Fee: 2 day course £1200.00 (+ VAT if applicable, see VAT NOTES)

Early-bird rate 2 day course £1080.00 (+ VAT **if applicable, see VAT NOTES)** for registering and paying by 1 April 2020

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