Quality by Design for Effective Bioprocess Characterisation and Validation

Get expert guidance on choosing on how best to integrate QbD, DoE and PAT into lifecycle approach to process characterisation

27 FEBRUARY – 02 MARCH 2017

Held at the Department of Biochemical Engineering, UCL, London, UK
Who should attend?
This module is suitable for scientists and engineers working in the biotech sector that are involved or liaise with people in Process Development, Process Characterisation, Validation, Manufacturing, Quality and Regulatory activities.

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Duration: 4 Days  Location: UCL, London

A series of stimulating interactive lectures from experts in the field and teamwork activities will enable you to:

- Learn about the latest FDA and EMEA regulations with regards to QbD, PAT, process characterisation and validation.
- Understand current and future perspectives of the impact of QbD and PAT on the effort required for process characterisation.
- Learn how to perform Risk Assessments to determine Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs).
- See examples of how to combine scale-down models with historical knowledge and DoE to map out Design Space.
- Understand the principles behind the characterisation and validation of unit operations, such as fermentation, filtration, chromatography, formulation through to supply chain logistics.
- Learn how to apply QbD to continuous operations, e.g. perfusion culture and filtration operations.
- Explore the impact of single-use components on validation needs.
- Apply QbD when implementing pre/post-approval process changes.
- Network with sector leaders and subject matter experts.
Programme

Emphasis is on teaching through interactive problem solving case studies in small classes for effective learning.

**DAY 1**

- Quality by Design – the enhanced route for process development
- PAT challenges for bioprocessing
- QbD: current industry practices and regulatory expectations
- The Roche Genentech QbD approach

**WORKSHOP:** Comprehensive QbD efforts for a new product

**DAY 2**

- QbD in fermentation: an industrial view
- QbD applied to process characterisation of purification processes
- QbD challenges with continuous perfusion cell culture
- Process changes – pre and post product approval: case studies and approaches
- Application of quality by design principles to the development and technology transfer of a major process improvement for the manufacture of a recombinant protein
- QbD applied to cell therapies
- How QbD informs the PV end game: how PV is impacted by FDA process validation guidance

**WORKSHOP:** What is the relationship between extent of process change and the revalidation needs?

**DAY 3**

**WORKSHOP:** FDA inspection role play

- Application of QbD to tangential flow filtration processes

**WORKSHOP:** How to perform a tangential flow filtration QbD study

**WORKSHOP:** Process validation for the production of biotherapeutics based on industrial case studies

**CASE STUDY:** Integrating QbD into bioprocess characterisation and validation

**Previous Expert Speakers Include**

- Suzanne Farid, UCL (Module Leader)
- Richard Francis, Francis Biopharma (Module Leader)
- Suzanne Aldington, Lonza Biologics
- Paul Bird, Fujifilm Diosynth Biotechnologies
- Sarah Callens, Cell and Gene Therapy Catapult
- Gregor Kalinowski, Pall Life Sciences
- Annika Kleinjans, Roche
- Mairead Looby, Pfizer
- Graham McCartney, Eli Lilly
- Anthony Newcombe, Parexel International
- Patrick Sheehy, Janssen Biologics
- Angus Thompson, Fujifilm Diosynth Biotechnologies
- Ron Wheeler, Promega
- Mike Hoare, UCL

The MBI® courses are UCL-accredited short courses in bioprocessing, designed specifically for industrialists, that can be taken as stand-alone modules or can be combined for Certificate, Diploma or Masters qualifications.

For further information and bookings please contact:

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T: +44 (0) 20 7679 9619

www.ucl.ac.uk/mbi
The award winning Modular Training Program for the Bioprocess Industries (MBI®) is acknowledged as the leading international provider of innovative UCL-accredited short courses in bioprocessing. These courses are designed to support continued professional and technical development within the bioindustry. Stakeholder impact is high with over 70 senior industrial experts contributing to the design and delivery of cutting-edge modules each year. MBI® plays a central role within the context of our larger knowledge transfer continuum which ensures cutting edge research is undertaken to capture the value of integrating engineering with complex and fast moving biology so that we can keep the global industry ahead in manufacturing. Modules are designed for flexible professional and technical development with options for achieving Certificate, Diploma or Masters level qualifications.

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Other Short Courses and CPD from the UCL Advanced Centre for Biochemical Engineering:

**MBI® Courses**

3–5 October 2016
Principles of Fermentation Processes

17–19 October 2016
Rapid Fermentation Process Design

14–17 November 2016
Downstream Processing – From Cell to Column

28 November – 1 December 2016
Downstream Processing – Chromatography

23–25 January 2017
Current Challenges in Mammalian Cell Processing

27 February – 2 March 2017
Quality by Design for Effective Bioprocess Characterisation and Validation

13–15 March 2017
Design of Experiments for Bioprocess Optimisation

24–26 April 2017
Industrial Biotechnology: Biocatalysis through to Synthetic Biology

24–27 April 2017
Analytical Data Analysis for the Bioprocessing Industry

5–8 June 2017
Bioprocess Design & Economic Evaluation

26–29 June 2017
Bioprocess Facility Design

27–29 June 2017
Vaccine Bioprocess Development and Commercialisation (held at MIT, US)

10–12 July 2017
Single Use Technology for Rapid Manufacturing

**Short Courses**

6–8 March 2017
Cell and Gene Therapy Manufacturing: Getting it Right from Start

Stem Cell Training Course: Human Pluripotent Stem Cells in Culture
contact us for 2017 course dates

14–16 September 2016
UCL Vision Leadership Core Course (held at KGI, US)
contact us for 2017 course dates

**VISION Leadership Training**

14–16 September 2016
UCL Vision Leadership Core Course (held at KGI, US)
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