



Copenhagen
Summer
University



19 – 23 AUGUST 2019, 9:00 – 16:30



EUR 2,680 / DKK 19,900 EXCL. DANISH VAT

Copenhagen Summer University

QUALITY BY DESIGN (QbD) IN PHARMACEUTICAL DEVELOPMENT

Quality by Design lies at the very heart of modern pharmaceutical development. The implementation of QbD principles provides a cost-effective approach to delivering high quality medicines to patients. Regulatory authorities, such as the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), are placing increasing importance on the QbD component as a part of regulatory filing. As such, QbD has become a crucial element in a streamlined drug development process.

“Very inspiring and relevant for my daily work and upcoming challenges in both development and commercial manufacturing”

Steffen Uebel, Manager Quality Assurance, STADA Arzneimittel AG

This course will provide you with insight into the key principles of QbD including quality risk management, formal experimental design and process analytical technology (PAT). Leading QbD experts from industry, from the regulatory side and from the academic world will acquaint you with the current knowledge on QbD and offer ideas about how this knowledge can be applied in your company. The course includes practical demonstrations.

WHAT YOU WILL LEARN

After the course, you will be able to:

- Summarize the principles of the QbD approach in pharmaceutical development and manufacturing
- Demonstrate basic knowledge of risk management, Design of Experiments (DoE) and Process Analytical Technology (PAT)
- Demonstrate basic knowledge of how the QbD approach can be applied in design space and further in the regulatory framework
- Apply basic risk analysis and experiment with design techniques using practical case studies
- Identify and suggest suitable process analytical tools for a given manufacturing environment
- Work in a multidisciplinary risk management team
- Plan and implement a basic DoE approach
- Suggest a QbD approach for constructing a design space

COURSE CONTENT

The course will introduce the underlying principles and tools required for QbD-based pharmaceutical development and manufacturing:

- Basic risk analysis techniques
- Constructing the Quality Target Product Profile (QTPP)
- Identification of Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs)
- Design of Experiments (DoE): Basic screening designs and expanded designs
- Process Analytical Technologies (PAT): Basic principles of multivariate data analysis (chemometrics), looking at examples of process measurements applied to both small molecules and biopharmaceuticals, and for batch and continuously operating

processes

- Risk-based regulatory framework

PARTICIPANTS

The course is intended as Continuing Professional Development (CPD) for professionals in the pharmaceutical industry, particularly in production, regulatory affairs and quality functions. The course serves as an excellent introduction for those less familiar with QbD, while participants who have more experience with QbD will gain new insight into how to further implement the company's QbD programme.

The course is preapproved as an elective in the Master of Industrial Drug Development (MIND) programme and the Master of Medicines Regulatory Affairs (MRA) programme. It has been developed in co-operation with the Steering Committee of the EUFEPS QbD and PAT Sciences Network (EUFEPS, European Federation for Pharmaceutical Sciences).

Participants must:

- Hold a relevant bachelor degree or equivalent
- Have a minimum of 2 years of relevant job experience
- Be proficient at English

COURSE DIRECTORS

Jukka Rantanen, Professor, Department of Pharmacy, University of Copenhagen

Poul Bertelsen, Honorary Associate Professor/Principal Scientist, University of Copenhagen/LEO Pharma

COURSE FEE

EUR 2,680 / DKK 19,900 excl. Danish VAT. Fee includes teaching, course materials, examination and all meals during course.

EXAMINATION

An optional examination is available, worth 3 ECTS credits at Master's level. This takes the form of an essay, based on a comprehensive literature list, to be handed in at 14:00 on the 30th of September 2019. The course has been preapproved as an elective in the MIND and MRA programmes at the University of Copenhagen. The exam is obligatory for Master's students.

For more information and registration

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