COPENHAGEN SUMMER UNIVERSITY

14 – 18 AUGUST 2017 / UNIVERSITY OF COPENHAGEN

QUALITY BY DESIGN (QbD) IN PHARMACEUTICAL DEVELOPMENT

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

This course will provide insight into the key principles of QbD covering quality risk management, formal experimental design and process analytical technology (PAT). Leading QbD experts' from industry, the regulatory side and the academic world will introduce the current knowledge on QbD and provide participants with ideas about, how this knowledge can be implemented 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 about risk management, Design of Experiments (DoE) and PAT
- Demonstrate basic knowledge about the relationship of the QbD approach into design space and further into the regulatory framework
- Apply basic risk analysis and experiment design techniques into practical cases
- Identify and suggest suitable process analytical tools for a given manufacturing environment
- Work in a multidisciplinary risk management team
- Plan and implement a basic design of experiments (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 chemometrics, examples of process measurements both with examples of small molecule and biopharmaceuticals
- Risk-based regulatory framework

"It has been a fantastic course – the best I have attended in years! All persons that gave lectures were very enthusiastic and dedicated to their work – this was so GREAT and motivating – thanks."

Birgit Sølvkær Jensen, LEO Pharma A/S

"The course was very well organised and gave an excellent mix of activities through-out each day."

Susan Fetherston, Development Engineer, QPharma AB

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 will offer an excellent introduction for those less familiar with QbD. Those with more experience with QbD gain access to new ideas on how to further implement the companys QbD programme. The course is preapproved as an elective in the Master of Industrial Drug Development (MIND) programme and the Master of Pharmaceutical Regulatory Affairs (MPRA) 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
- Have proficiency in English

COURSE DATES

5 days, 14 – 18 August 2017, 9:00 – 16:30 at the University of Copenhagen, Frederiksberg Campus.

COURSE DIRECTORS

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

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

OTHER COURSE TEACHERS

Staffan Folestad, Professor, Senior Principal Scientist, Astra Zeneca, Sweden

Wim Oostra, PhD, Technical Manager, Abbott Healthcare, The Netherlands

Øyvind Holte, PhD, Scientific Officer, Norwegian Medicines Agency, Norway

Erik Skibsted, PhD, Principal Scientist, Novo Nordisk A/S, Denmark

Morten Allesø, PhD, Pharmaceutical Scientist, H. Lundbeck A/S, Denmark

Additional speakers may be included.

COURSE FEE

EUR 2,600 / DKK 19,000. Fee includes teaching, course materials, and all meals during course and examination.

EXAMINATION

An optional examination is provided, 3 ECTS credits at Master's level, if an essay, based on an extended literature list, is handed in 2/10-2017. The course has been preapproved as an elective in the MIND and MPRA programmes at the University of Copenhagen. The exam is obligatory for master's students.

FOR MORE INFORMATION AND REGISTRATION:
copenhagensummeruniversity.ku.dk