Quality by Design is at the very heart of modern pharmaceutical development. The implementation of QbD principles provides a cost-effective approach to delivering high quality medicines for 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.

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 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 chemometrics, looking at examples of process measurements applied to both small molecules and biopharmaceuticals
- Risk-based regulatory framework

“Very educational. Teachers are very passionate and knowledgeable.”

*Wendy van Loon, Quality Assessor, Medicines Evaluation Board, Utrecht*
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 serve as an excellent introduction for those less familiar with QbD. Participants who have more experience with QbD will gain new ideas on 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 DATES
5 days, August 20-24, 2018, 9:00 – 16:30 at the University of Copenhagen, South Campus.

COURSE DIRECTORS
Jukka Rantanen, Professor, Department of Pharmacy, University of Copenhagen
Poul Bertelsen, Honorary Associate Professor/Principal Scientist, University of Copenhagen/LEO Pharma

OTHER COURSE TEACHERS
Staffan Folestad, Professor, Senior Principal Scientist, AstraZeneca, 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, NNE, Denmark

Additional speakers may be included.

COURSE FEES
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, if an essay, based on a comprehensive literature list, is handed in before 2nd October 2018 at 14:00. 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:
copenhagensummeruniversity.ku.dk

“I enjoyed speakers with different backgrounds.”
Lukas Taujėnis, Scientist, Thermofisher Scientific, Vilnius