APV Expert Workshop

Quality by Design based formulation strategies in continuous processing

5./6. September 2018
Leicester, England

Course no. 6746

Pharmaceutical Manufacturing

In cooperation with

DE MONTFORT UNIVERSITY LEICESTER

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Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V.
Gemeinnütziger wissenschaftlicher Verein
International Association for Pharmaceutical Technology

With TechnoPharm® exhibition!

Pharmaceutical manufacturing

Introduction

In recent years, DMU has pioneered an innovative partnership with pharmaceutical employers. Key players from the industry including AstraZeneca, Pfizer, GlaxoSmithKline and Bristol-Myers Squibb have been working alongside DMU's experts in pharmaceutical education and research to deliver postgraduate training in Pharmaceutical Quality by Design (QbD). The term Quality by Design, now commonly referred to by its acronym, QbD, is a holistic approach to a pharmaceutical product development initiative to modernise pharmaceutical manufacture.

BASF offers comprehensive solutions to the pharmaceutical industry, ranging from a broad, high-quality excipient portfolio to chemical raw materials. With its long-lasting expertise in polymer chemistry, its worldwide R&D capabilities and the company's commitment to developing value-adding products, BASF continuously creates valuable solutions to demanding challenges in the pharmaceutical industry.

A wide range of highly effective solubilisers and a profound understanding of the corresponding process technologies have established BASF as the leading partner in overcoming bioavailability and solubilisation hurdles.

QbD methodology seems a logical and more efficient way to develop drug products. Nevertheless, there is still limited knowledge in the field of continuous process with respect to critical process factors compared to formulation factors.

This workshop will focus on a strategy to shift from an empirical univariate to a systematic multivariate approach using hybrid batch/continuous manufacture processes with the aim of enhanced process understanding.

Seminar leaders

Walkiria Schlindwein
Associate Professor, MSc QbD leader, DMU

Thorsten Cech
Manager European Pharma Application Lab, BASF SE

Mariana Bezerra
PhD student, DMU Technical Support

Continuous Pharmaceutical Manufacture

The level of interest in the pharmaceutical industry in continuous-manufacturing strategies has increased recently. These strategies can accelerate the full implementation of the QbD paradigm for the next generation of pharmaceutical products. In addition to its flexibility and time and cost-saving features, continuous manufacturing is easily amenable to model predictive design, optimization, and control methods.

Continuous Pharmaceutical Processing

In September 2016, the pharmaceutical technologies group at the School of Pharmacy pioneered the first practical QbD workshop that integrates QbD principles in continuous pharmaceutical product development and manufacture (Figure 1). This project was developed in collaboration between De Montfort University and various industry partners. This flexible training platform is based on continuous extrusion processes.

Figure 1 - Hybrid batch/continuous platform for accelerated product development and manufacture using QbD approach at DMU.

The use of QbD methodology and PAT tools for product design and continuous process monitoring in pharmaceutical product manufacture can offer clear advantages to ensure product quality.

Main outcomes of this workshop

The aim of this workshop is to provide a practical experience to delegates with the objectives of:

- Make real drug products – from powder to tablet, using QbD approach
- Understand the concept of continuous manufacturing, with focus on HME technology as a case study
- Understand the implementation of a systematic formulation strategy for optimising the product development

Workshop programme

The workshop will be delivered to two/three groups of max. ten delegates. Each group will experience the full manufacture of tablets from dispensing powders to manufacturing processes and product characterisation.

Wednesday, 5 September 2018, 09:00-17:00

Welcome
APV

Continuous processing and continuous manufacturing, major trend in the pharmaceutical industry
Walkiria Schlindwein (DMU)

Continuous processing using twin screw extrusion technology, and its use in HME application
Thorsten Cech (BASF)

Challenges of poorly soluble APIs & formulation strategies
Walkiria Schlindwein (DMU)

Excipients and formulation strategies for HME processes (incl. case studies)
Thorsten Cech (BASF)

Practical session
Groups 1, 2, and 3

- Hot melt extrusion process
- In-line UV-Vis process monitoring
- API and polymer considerations

PAT solutions, focus on UV/Vis (incl. case studies)
Andreas Berghaus (CoVisTec)

Introduction to QbD based formulation development
Thorsten Cech (BASF)

Networking dinner

Thursday, 6 September 2018, 09:00-17:00

Data management & analysis + DoE
Walkiria Schlindwein (DMU)

Practical session
Groups 1, 2, and 3

- Optimising an HME process using a DoE approach
- Conducting a Risk Assessment for an HME process
- Developing a Design Space
- Implementing a Control Strategy

QbD based formulation development (incl. case studies stability of polymers)
Walkiria Schlindwein (DMU)

TechnoPharm® exhibition

We are offering table top exhibition spaces to you. One taple top includes: 1 table, 2 chairs and electricity.

For only 990 Euro plus one mandatory full conference registration you will get the ability to display your company, products and services to a very focused and international target market.

Please get in touch with Anna-Maria Pötzl ap@apv-mainz.de. She will provide you with the current floor plan and any other helpful information.

The Leicester School of Pharmacy

The Leicester School of Pharmacy is one of the UK's most established pharmacy schools, with more than 100 years of teaching experience; renowned for academic expertise, professional development training and world-leading research. We provide a diverse range of undergraduate, postgraduate and research opportunities that have been developed for traditional undergraduates as well as experienced practitioners looking to up-skill. Our professional accreditations, strong links with industry and direct input from registered practitioners ensure we consistently produce graduates of the highest calibre.

Registration by fax 0049 6131 97 69 69 / by e-mail apv@apv-mainz.de

Location

Leicester School of Pharmacy
Gateway House
Leicester LE1 9BH
United Kingdom

I herewith repealable authorise the organizers to use my e-mail address to send me relevant material including current programme information. My acceptance can be cancelled at any time in writing.

Date

Course no. 6746
05 September 2018 09:00 h
to 06 September 2108 17:00 h

Registration fee

Industry	1390 EUR
Authority/University	695 EUR
Students*	178 EUR

(free of VAT according to § 4,22 UStG)

Coffee breaks, luncheon, dinner and electronic proceedings included.

* Limited places for full time students available; written evidence must be submitted.

Registration

APV-Headquarters
Kurfürstenstraße 59
55118 Mainz/Germany
phone 0049 6131 97 69 0
fax 0049 6131 97 69 69
e-mail apv@apv-mainz.de
web www.apv-mainz.de

You will receive a confirmation of your registration with the invoice.

Hotel reservation

For hotel reservation in Leicester we recommend the booking platforms booking.com or hrs.de.

Participants should make their own hotel reservation.

Mainz, March 2018

APV Expert Workshop - Quality by Design based formulation strategies in continuous processing, 05 to 06 September 2018, Leicester, United Kingdom, Course no. 6746

Registration
As soon as you have found a seminar of your interest, it is very easy to register for it via fax, e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.

Registration confirmation
After your registration was successfully processed, you will receive a confirmation.

Before the event
A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

After the event
You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

Follow-up
After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have.

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