

## ORGANISER

### Dr Walkiria Schlindwein

Associate Professor of Pharmaceutics  
Leicester School of Pharmacy  
De Montfort University

## SPEAKERS

### Dr Cameron Brown

Research Fellow  
CMAC Future Manufacturing Research Hub

### Dr Alan Carmody

Associate Research Fellow  
Pfizer Ltd

### Dr Alastair Coupe

Senior Director  
Pfizer Ltd

### Mr Bruce Davis

Director  
Global Consulting

### Mr Jordan Dickens

Senior Formulation Scientist  
Quotient Clinical

### Prof Dennis Douroumis

Professor in Pharmaceutical Technology and  
Process Engineering  
University of Greenwich

### Dr Timo Gerhring

Head of Production  
Peptido GMBH

### Dr Carolyn Gordon

Regulatory CMC  
AstraZeneca

### Dr Birgit Hollenbach

Scientific Officer  
ColViTec AG

### Mr Ian McCubbin

Independent Pharma Specialist  
Keirbridge Ltd

### Dr Matthew McGirr

Senior Associate  
Reckitt Benckiser

### Prof Kendal Pitt

Senior Technical Director  
GlaxoSmithKline

### Mr Colm Reddington

Assessment Unit Manager  
Cardiovascular & Diabetes  
MHRA

### Dr David Rudd

Consultant in Business Improvement  
Octobersong Ltd

### Dr Furqan Tahir

Engineering Consultant  
Perceptive Engineering Ltd

### Dr Roger Weaver

Consultant  
Weaver Pharma Consulting

### Prof Axel Zeitler

Professor of Microstructure Engineering  
University of Cambridge

## MODERATORS

### Mr Bruce Davis

Director  
Global Consulting

### Dr Mingzhong Li

Reader in Pharmaceutical Science  
Leicester School of Pharmacy  
De Montfort University

### Prof Gordon Muirhead

President  
GMPharma Ltd

### Dr Mustafa A Zaman

Principal Consultant  
PAREXEL International Consulting



## 6TH QUALITY BY DESIGN SYMPOSIUM MEDICINES MANUFACTURE: ROAD MAP TO INNOVATION

### Wednesday 21<sup>st</sup> March 2018

The Venue@DMU, 20 Western Blvd, Leicester, LE2 7BU

#### Symposium Chair:

Dr Walkiria Schlindwein  
Associate Professor of Pharmaceutics  
at Leicester School of Pharmacy,  
De Montfort University, Leicester

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 would like to thank our sponsors:-



After five successful annual symposia since 2013, we are delighted to be hosting the 6<sup>th</sup> Quality by Design Symposium on 21<sup>st</sup> March 2018. We planned this event to bring together academics, regulators and industrial experts to share academic research aligned to the QbD agenda as well as progress in 'real-life' QbD implementation. The Symposium will focus on "Medicines Manufacture: Road Map to innovation".

In collaboration with:



# PROGRAMME

**08:00** Registration and coffee

**09:00** Welcome and Opening remarks  
Dr Walkiria Schlindwein

**09:10** “Quality”, who really cares?  
Mr Ian McCubbin

**09:50** Continuous technologies: From design, to clinical, to commercial  
Dr Alastair Coupe

**10:20** When innovation meets regulation  
Dr Carolyn Gordon

**10:40** Coffee break and poster session

## Open Forum: Industry/Regulators/Academia

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**11:00** Medicines manufacture: Road map for innovation:  
Open forum introduction  
Mr Bruce Davis

**11:05** Industry perspective  
Prof Kendal Pitt

**11:20** Regulatory perspective  
Mr Colm Reddington

**11:35** Academia perspective  
Prof Dennis Douroumis

**11:50** Open discussion  
  
*Moderator: Mr Bruce Davis*

**12:30** Network lunch and poster session

## Academia & Industry Partnership Success Stories

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**13:30** QbD in practise: risk minimisation and optimisation  
of an API synthesis  
Dr Timo Gehring

**13:50** Application of QbD in a fast-moving consumer goods environment  
Dr Matthew McGirr

**14:10** Novel applications of QbD for early phase development  
Mr Jordan Dickens

*Moderator: Dr Mingzhong Li*

## Quality by Design in Practice

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**14:30** Risk assessment strategies for rapid product development  
and manufacture  
Dr Roger Weaver and Dr Alan Carmody

*Moderator: Dr Mustafa Zaman*

**15:00** Coffee break and Poster prize presentation

## Innovation and Technology

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**15:20** Measuring tablet porosity with terahertz spectroscopy  
- Working towards a RTRT dissolution assay  
Prof Axel Zeitler

**15:40** Enhancing formulation and process understanding by using in-line  
combined UV-Vis, NIR and Raman Spectroscopy for HME applications  
Dr Birgit Hollenbach

**16:00** Digital twins and microfactories for future manufacturing  
Dr Cameron Brown

**16:20** Improving continuous pharmaceutical processes using advanced  
process control, process monitoring and soft-sensing: HME example  
Dr Furqan Tahir

**16:40** Time for change? A brief guide to innovation ... including how,  
when and who  
Dr David Rudd

*Moderator: Prof Gordon Muirhead*

**17:15** Organisers' Closing Remarks