

TABLETTING SCHOOL

De Montfort University, Leicester

Especially designed to address the needs of formulators working in galenical research and development.

Meet various experts from academia, pharma industry, equipment and excipient manufacturer.

19th & 20th February 2020



About De Montfort University

De Montfort University

De Montfort University (DMU) is a dynamic institution with a long and vibrant history of improving people's lives through education. Originally founded as the Leicester School of Art in 1870, the university has evolved through many incarnations including the Leicester Colleges of Art and Technology and Leicester Polytechnic. Art, pharmacy, corsetry, footwear, physical sciences and architecture were taught at the Schools and are still in evidence at DMU today, either as courses in their own right, or as integral components of more modern courses. The university has grown and evolved over the years, but it is still dedicated to providing inspirational teaching to students and it has a significant impact on the world around it.

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. The school provides 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. Professional accreditations, strong links with industry and direct input from registered practitioners ensures The Leicester School of Pharmacy consistently produces graduates of the highest calibre.



TABLETTING SCHOOL

De Montfort University, Leicester

Agenda Day 1, 19th February 2020

08:30 Registration

09:00 Welcome

09:15 Lectures

Real world examples of tableting development and manufacture

Kendal Pitt

Characterising the processability of a tableting blend in accordance with USP guidelines

Thorsten Cech

Coffee break

Powder compaction: fast product development with a new generation of tableting instruments

Bruno Leclercq

Exploring the benefits of using Quality by Design methodology in tableting development and manufacture

Walkiria Schlindwein

12:30 Lunch

13:15 Introduction to practical workshops

13:30 Parallel hands-on workshops in small groups

Workshop 1/2: Examples of pharmaceutical product development

API and excipients considerations, definition of QTPP/CQAs, risk assessment exercise, introduction of sequential experimental design

Workshop 3: Compaction experiments with STYL'One Nano

Perform compaction of placebo formulations. Investigate the impact of formulation excipients on tablet properties

Workshop 4: Physical characterisation of tablets

17:00 Wrap-up day 1 and closing remarks

17:30 End of day 1

19:30 Dinner

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Agenda Day 2, 20th February 2020

09:00 Welcome & introduction day 2

09:15 Lectures

Materials classification system: A proposal for oral solid dosage forms

Kendal Pitt

Virtual pharma assistants

Ferdinand Brandl

Coffee break

Parallel hands-on workshops in small groups

Workshop 5: Formulation development using QbD principles and ZoomLab™

Use ZoomLab™, understand materials classification system and selection of excipients for the API example

Workshop 6: Data analysis using empirical models

Use data from DoE examples to perform statistical analysis

12:30 Lunch

Workshop 7: Compaction simulation

Perform compaction experiments of DoE

Workshop 8: Tablet compaction data analysis

Data analysis examples following USP guidelines

Coffee break

Lectures

Scaling-up a tableting process using rotary press equipment

Thorsten Cech

Identifying processing risks and improving process robustness and reliability

Thorsten Cech

16:30 Podium discussion

17:00 Closing remarks

17:30 End of event

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Learning outcomes day 1:

- ✓ Understand formulation development using QbD methodology (QTPP, CQAs, RA)
- ✓ Propose experiments using multivariate approach (DoE)
- ✓ Interpret the USP 1062 tablet compression characterisation guidance
- ✓ Analyse the relationship between formulation factors and compaction responses
- ✓ Conduct compaction simulation experiments using STYL'One Nano

Learning outcomes day 2:

- ✓ Understand materials classification system
- ✓ Use of virtual tools to aid formulation development
- ✓ Retrieve and analyse experimental data

Speakers



Dr. Walkiria Schlindwein

Pharmaceutical Quality by Design course leader for De Montfort University

Walkiria has over 25 years of experience in academia and is currently Associate Professor in Pharmaceutics at the Leicester School of Pharmacy, De Montfort University. She has led the creation of the first MSc in Pharmaceutical Quality by Design (QbD), in collaboration with partners from the pharmaceutical industry and related supply chain. Her expertise is in the areas of polymer science and technology, advanced techniques for materials' characterisation, pharmaceutical Quality by Design, continuous processes for early phase product development and manufacture using in-line monitoring process technology and design of experiments. She was responsible for the development and implementation of innovative teaching and research initiatives for the MSc in QbD programme. These include a new e-learning platform and a new state-of-the-art "hands-on training facility" based on continuous manufacture and QbD practices. She has collaborative projects with national and international universities and works in close collaboration with industry.



Professor Kendal Pitt

Senior Technical Director in Global Manufacturing and Supply for GlaxoSmithKline

Kendal Pitt, Ph.D (London University), B.Pharm (University of Nottingham), is a Senior Technical Director in Global Manufacturing and Supply for GlaxoSmithKline based at Ware, UK. He is a Fellow of the Royal Pharmaceutical Society (FRPharmS) and a Fellow of the Academy of Pharmaceutical Sciences (FAPS). Kendal has worked in the Pharmaceutical Industry for over 30 years, with Wellcome Foundation Ltd., Roche Pharmaceuticals and more recently for Merck. He has headed groups in both the United States and Great Britain and has led project teams responsible for the successful filing and launch of both tablets and freeze-dried oral dosage forms. Primary research interests are in powder compaction, powder flow and granulation process optimisation, including the use of compaction simulators in tablet and capsule product development. He has additionally published in the areas of formulation and design for nasal delivery of pharmaceuticals and on statistical design of experiments, and has co-authored chapters on formulation, tableting and on strength testing.

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Speakers



Thorsten Cech

Application Expert Pharmaceutical Technology and Manager European Pharma Application Lab for BASF

Thorsten has worked in the pharmaceutical industry for some 30 years, mainly in the galenic R&D centres of different pharmaceutical companies such as Boehringer Ingelheim. He is a process engineer with a focus on pharmaceutical technology. His main profession lies in the formulation development, process optimization, and up-scaling of solid oral dosage forms. Since 2005, Thorsten is Manager of the European Pharma Application Lab for BASF, based at headquarters, Ludwigshafen, Germany. In his current position, he supports customers in Europe, CIS Countries, Middle East, and Africa in the field of product applications, feasibility studies, formulation development, process optimization, and scale-up. His field of expertise comprises the development of nasal sprays, syrups, and solid oral dosage forms, including orally disintegrating, modified release, and film coated dosage forms. Furthermore, he intensively worked in the field of solubility enhancement via hot-melt-extrusion.

Thorsten has written several publications, articles and book chapters and holds different



Dr. Ferdinand Brandl

Head of laboratory, Development Pharma Solutions, BASF SE

Dr. Ferdinand Brandl studied pharmacy in Regensburg, Germany. After receiving his PhD in pharmaceutical technology, he was a postdoctoral fellow at the Massachusetts Institute of Technology, Cambridge, MA, USA. Before joining BASF SE, he was a research associate at the Department of Pharmaceutical Technology, University of Regensburg, Germany. Since 2016, he is part of R&D for pharmaceutical excipients and drug formulations at BASF SE.



Dr. Bruno Leclercq

Business Development, Pharmacist for Medelpharm

Bruno Leclercq is a senior pharmacist working in business development at Medelpharm, headquartered in Lyon, France, an international company dedicated to a continuous search for innovative solutions in powder compression and processing technologies in order to create the ultimate tool for scientists in R&D.

Bruno is an experienced pharmaceutical technical Manager with extensive knowledge in solid form technology and processes. He can look back to more than 15 years of International experience in meeting, advising and solving customers' formulations and production problems in Europe, SEA and the US.

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Good to know

Venue

The Venue@DMU
20 Western Blvd
Leicester
LE2 7BU
United Kingdom

Car Park

Please note there is no parking available at the venue. NCP car parks can be found at St Nicolas Circle or HighCross Shopping Centre.

If you need accessibility parking at The Venue, please contact gemma.andrews@dmu.ac.uk

Train travel

The nearest train station is Leicester. It is a 15–20 minutes walk to The Venue@DMU.

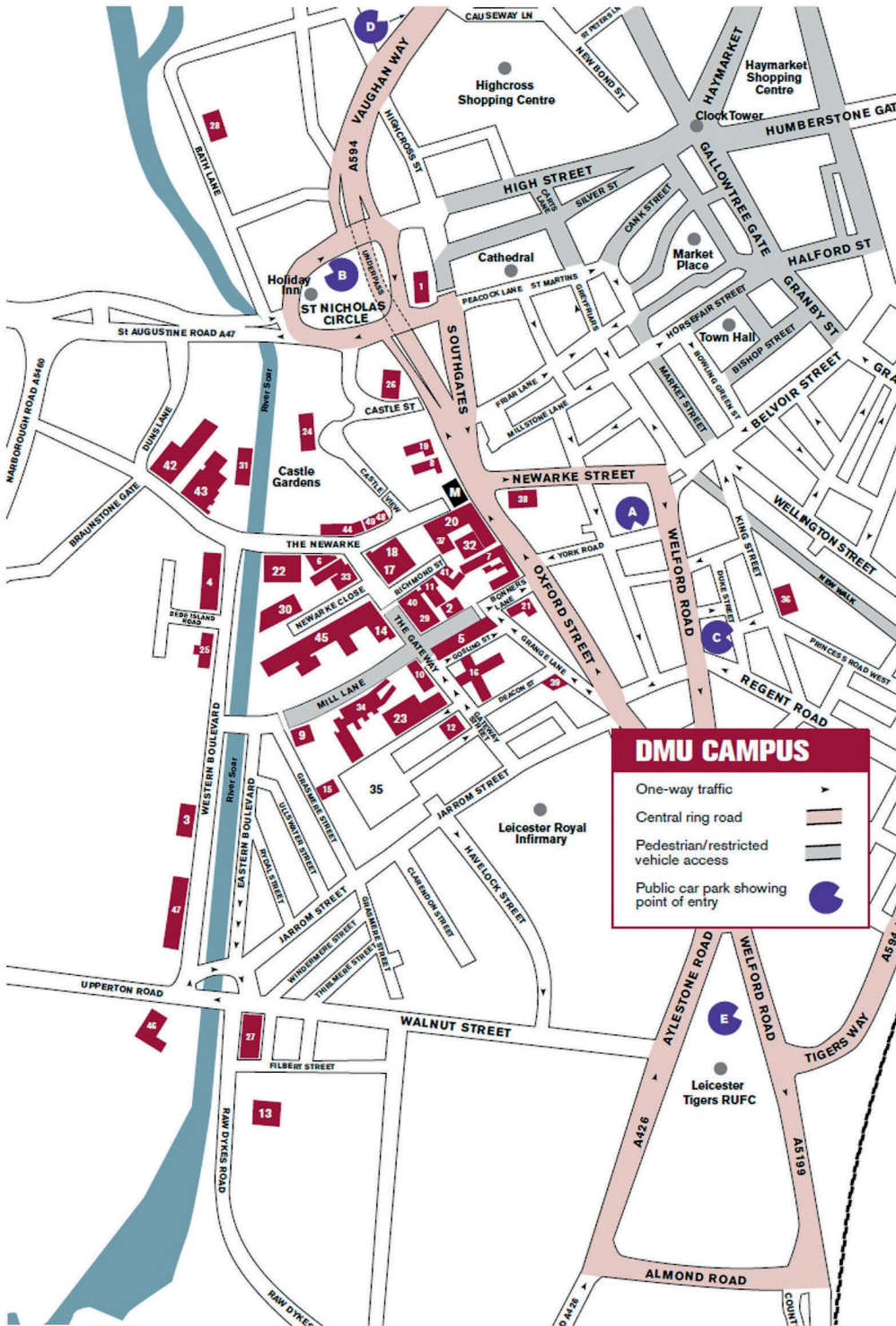
Hotel reservation

For hotel reservation in Leicester we recommend the booking platforms [booking.com](https://www.booking.com) or [hrs.de](https://www.hrs.de). Participants should make their own hotel reservation.

Dress code

Casual. Please consider the workshop sessions where e. g. powders are handled.

Good to know



The Venue@DMU

The Venue@DMU
20 Western Blvd
Leicester
LE2 7BU
United Kingdom

The Venue is number 43.

Public car parks

A. Newarke Street LE1 5SP

Multi-storey, operated by Leicester City Council
Approx five minute walk from campus
Open Mon–Sat 6.30am–1am
Open Sundays
Charges (pay on foot): from £1.40 for one hour
Disabled Badge Holders free
Free cycle racks and free parking for motor cyclists

B. St Nicholas Circle LE1 4LF

Multi-storey, operated by NCP
Approx 10 minute walk from campus
Open 24 hours
Charges (pay on foot): from £3.30 for two hours

C. Welford Road LE2 7AD

Multi-storey, operated by NCP
Approx seven minute walk from campus
Open 24 hours
Charges (pay on foot): from £4.40 for two hours

D. Highcross

LE1 4QJ (John Lewis car park, Vaughan Way, open 24 hours)
LE1 4AN (rooftop car park, Freeschool Lane, open 24 hours)
Multi-stories, operated by Highcross
Approx 12 minute walk from campus
Charges: from £2.50 for two hours

E. Granby Halls LE2 6BE

Surface level, operated by NCP
Approx 15 minute walk from campus
Open 24 hours
Charges (pay and display): from £2.90 for two hours