BASF
We create chemistry

Tabletting School 2024

De Montfort University, Leicester

Especially designed to address the needs of formulators working in oral solid dosage form research and development.

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

Leicester (UK), 18th & 19th June 2024

DE MONTFORT UNIVERSITY LEICESTER

KORSCH The Specialist.

MEDELPHARM the tableting instrument company

GEA Engineering for a better world.

sotax Solutions for Pharmaceutical Testing

Tabletting School

Concept

"*Tabletting is a method of forming medicines as tablets. A powder or granule mixture is prepared, a dye mould is filled, and then the mixture is compressed and ejected. In pharmaceutical applications, drug tablets are constrained to shapes and sizes that can be swallowed easily.*" According to Wikipedia, the process of tablet making is simple and straight forward. And yes, in theory it is. However, trouble starts when theory meets real world in tablet development and production.

Starting with formulation development and conceptional design, followed by up-scaling, and subsequent production scale manufacturing, the tabletting process has a huge variety of various challenges in store. To manoeuvre successfully through the rough waters of tablet development and processing, profound knowledge of the process, the excipients, and the technology is required. Tabletting School will introduce you to experts from all disciplines, bringing together experienced formulators from industry, well-respected professors from university, excipient experts, and process engineers. As an insightful community with decades of experience, the team of Tabletting School provides valuable practical advices, explains modern concepts of drug product development, and provides hands-on-experience.

"*Tell me and I forget, teach me and I may remember, involve me and I learn.*" These famous words of Benjamin Franklin are the mantra of Tabletting School. Theoretical lectures and presentations are reduced to a minimum. Tabletting School intends to provide plenty of options to lay hands on equipment, to actually use software-tools, and to touch excipients and products. In a series of workshops, small groups of participants will get guided, hands-on, experience; providing plenty of opportunities for direct discussions with the experts.

Target group

While providing valuable recommendations regarding the operation of tabletting equipment, discussing modern concepts of drug product development, and underpinned by the practical content with scientific explanations, Tabletting School addresses the needs of operators, formulators and lab heads or managers in an equal way.

Learning outcomes

- Introduction to the tabletting process: equipment, tools & critical parameters
- Accelerating drug product development by employing a compaction simulation.
- Benefitting from computer aided systems in early drug product development.
- Using QbD methodology (QTPP, CQAs, RA) during formulation development.
- Utilising the benefits of experimental design (DoE) using a multivariate approach.
- Interpreting the USP 1062 tablet compression characterisation guidance.
- Analysing the relationship between formulation factors and compaction responses.
- Scaling-up a tabletting process from small to production scale equipment.
- Insight into continuous manufacturing principles.

Networking

During breaks at The Venue, and during dinner, there are plenty of opportunities to connect with the Tabletting School Team. Attendees building a solid network, which can be utilised to receive support at later times, is a part of the concept of Tabletting School. The relaxed atmosphere helps to allow attendees to discuss ideas, current challenges, to find out things they wanted to know or just socialise and enjoy your time at Tabletting School.

Lectures

Theoretical courses/discussions (Day 1)

Quality by design (QbD) applied to tabletting: Real world examples
Speaker: Kendal Pitt (former GSK)

QbD can be defined as good science and common sense. Science can be applied during development by assessing the compactability, compressibility, tabletability and disintegration properties of a tablet to ensure a tablet formulation is fit for purpose.

Concept of modern drug product development
Speaker: Thorsten Cech (BASF)

Time to market and limited quantities of API are pressing aspects in early drug product development. By combining computer aided formulation concepts, with a systematic and scientific based working pattern, both aspects can be addressed successfully. The presentation discusses the benefits of such an approach.

Scaling-up of tabletting processes
Speaker: Friederike Gütter (KORSCH)

Compaction simulation does not only allow for a drug product development with a minimum quantity of API, but it is also a sound base of up-scaling procedures. In small scale essential parameters can be determined, evaluated, and optimised, which are key for a successful production on rotary presses.

Theoretical courses/discussions (Day 2)

Manufacturing Classification System (MCS) A proposal for oral solid dosage forms
Speaker: Kendal Pitt (former GSK)

The manufacturing classification system (MCS) is intended as a tool for pharmaceutical scientists to rank the feasibility of different processing routes for the manufacture of oral solid dosage forms based on selected parameters of the API. Depending on its position within each class, the MCS will also inform how robust a manufacturing process is likely to be.

Employing continuous manufacturing in modern pharmaceutical manufacturing
Speaker: Gavin Reynolds (AstraZeneca)

Continuous processing presents significant opportunities to address the challenges of modern pharmaceutical manufacturing. This presentation will give an overview of the benefits and common technologies used. Key concepts such as residence time distributions and real-time control strategies will also be discussed.

Exploring the benefits of Quality by Design
Speaker: Walkiria Schlindwein (DMU)

The focus of this presentation is to show how QbD principles and tools can be used to drive the design and development stages of oral solid dosage pharmaceutical products including, formulation and process design, risk assessment, control strategy and a summary of the benefits by adopting this approach.

Design of experiments: A tool to develop tablet formulations
Speaker: Mariana Bezerra (GSK)

An introduction to design of experiments followed by a case study to illustrate steps to build a data-driven model to estimate tablet quality attributes to support formulation development.

Workshops (Day 1)

Practical courses/hands-on trainings

Evaluation of a powder blend using a compaction simulator
Facilitator: Bruno Leclercq (MEDELPHARM)

Data-driven methodology for material characterisation and formulation development in a material-sparing approach on STYL'One Nano compaction simulator.

Formulation assessment and process optimization on R&D rotary press XL 100
Facilitator: Friederike Gütter (KORSCH)

In R&D, formulation properties and tablet press parameters should be aligned to enable optimal manufacturing. Within this practical session tablet press parameter optimisation regarding to formulation properties will be demonstrated.

Continuous Production and Coating of challenging tablets
Facilitator: Dirk Vanderroost (GEA)

In this session, we will focus on the elements of a continuous manufacturing line that enable the production and coating of challenging tablets (for example oddly shaped tablets or micro-tablets). During a live link to our lab, you will see the process in real time and are able to see the speed and accuracy of the coating process. Integration of PAT, such as Raman, allows follow-up of the critical parameters for almost the whole batch, allowing much better control of the coating process and creating opportunities for new applications, such as API coating.

Tablet characterisation
Facilitator: Sunny Singh (Sotax)

This interactive demonstration will show case the use of a SOTAX ST50, semi-automated hardness and dimensions tester. Robust and easy-to-use, the compact multi-parameter tester ensures high-precision results and increases lab efficiency. A SOTAX DT50, bathless disintegration tester with automatic end-point detection, short heating times, and continuous temperature measuring. The modular design allows to add up to 3 additional testing stations anytime; and a SOTAX FT2, single or dual drum tester with calculation of percent friability / weight loss. Connect your external analytical balance to automatically transfer weight readings. With applications from R&D, IPC to QC, automation and data integrity can be achieved with the use of q-doc software.

Systematic characterisation of an active ingredient as starting point of formulation development
Facilitator: Nils Rottmann (BASF)

Drug product development must be tailored to the active ingredient to be formulated. Consistently, a sound scientific characterisation is key for a fast and successful development. This practical session allows you to characterise a model API and to deduce formulation concepts, based on the results.

Tabletting tooling
Speaker: Robert Blanchard (I Holland)

During this session we will detail how I Holland Ltd have developed a predictive model (TSAR) that can predict single particle adhesion of API's and excipients to its range of PharmaCote anti-stick coating solution. The TSAR (Tableting Science Anti-stick Research) model reduces the need to carry out expensive and detailed compression trials to identify a tooling solution to eradicate sticking. We will also detail the root causes to sticking and how I Holland's solutions address these issues.

Workshops (Day 2)

Practical course/hands-on training

Bilayer tablet formulation, from R&D to production
Facilitator: Bruno Leclercq (MEDELPHARM) + Friederike Gütter (KORSCH)

Definition of optimal process parameters to reach tablet quality attributes for a bilayer formulation on STYL'One Evo before production on KORSCH X3 tablet press.

Employing USP 1062 in the daily working pattern
Facilitator: Thorsten Cech (BASF)

Modern formulation development demands for a systematic investigation of the tabletting blend. This includes the evaluation of compressibility and compactability, both features being the base of the tablettability profile, which is the diagram typically employed for evaluation.
The practical session discusses the advantages of employing USP 1062 in a daily routine and utilising the benefits of the additionally gained information.

PAT
Facilitator: Joana Faustino (GEA)

In a continuous manufacturing process, process analytical technology (PAT) tools are often used as an integral part of the control strategy. During our workshop we will focus on model development for monitoring blend uniformity and discuss tools available for this. We will also focus on the importance of optimal presentation of the product to the probe in a production line, for which specific components have been developed which will be on display and explained.

Design of Experiments and data analysis
Facilitator: Stuart Little (JMP)

This practical session demonstrates how to use Design of Experiments (DOE) to build detailed understanding of your processes. Through this, you'll gain experience of how to apply the basic principles of DOE to set up designs using a range of factors.
We will use data from a designed experiment to build and test hypotheses and build simple process models. These models will then be used to explore suitable operating conditions for the process.

Employing the virtual formulation assistant ZoomLab™ to assist in early formulation development
Facilitator: Nils Rottmann (BASF)

Digital tools gained an increasing relevance in formulation development. The majority of tools support the formulator in data analysis (e.g., DoE planning and evaluation). In contrast, the algorithm of ZoomLab™ is capable to predict the best suitable formulation concept. Based on the characteristic of an active ingredient, the algorithm of ZoomLab™ can predict prototype formulations for tabletting, heeding special demands e.g., regarding compatibility of the formulation components.
The practical session provides hands-on experience with this tool.

Tabletting School Team

Professor Walkiria Schlindwein

Pharmaceutical Quality by Design course leader for De Montfort University

Walkiria has over 25 years of experience in academia and is currently Professor of 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

Former Senior Technical Director in Global Manufacturing and Supply for GlaxoSmithKline

Kendal G. Pitt, Ph.D (London University), B.Pharm (University of Nottingham) has worked in the Pharmaceutical Industry for over 30 years, most recently as Senior Technical Director, Solid Dosage Forms, Global Supply Chain at GlaxoSmithKline based at Ware, UK. Currently he is an Honorary Professor at Leicester School of Pharmacy, De Montfort University and a visiting Professor at the Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde. He is a Fellow of the Royal Pharmaceutical Society (FRPharmS), Associate Fellow of the Institute of Chemical Engineers (AFIChemE), and a Fellow of the Academy of Pharmaceutical Sciences (FAPS). In addition, he is and has worked at the Welcome Foundation Ltd., Roche Pharmaceuticals and 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, capsules 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 authored chapters on pharmaceutical formulation, on tabletting, and on mechanical strength testing.

Professor Gavin Reynolds

Pharmaceutical Technology and Development, Operations for AstraZeneca

Gavin Reynolds is a Senior Principal Scientist in Process Engineering and Digital, based within Pharmaceutical Technology and Development at AstraZeneca, Macclesfield and is also a Visiting Professor in the Department of Chemical and Biological Engineering at the University of Sheffield. His interests include applying mechanistic modelling and simulation to pharmaceutical processes and driving the implementation of digital twins. He is a Fellow of the IChemE and has authored over 80 peer-reviewed publications.

Tabletting School Team

Dr. Mariana Bezerra

Senior Formulation Scientist for GlaxoSmithKline

Mariana is formulation scientist in drug product R&D at GSK. Previously, at De Montfort University, she investigated how in-line UV-vis spectroscopy can be applied to characterise quality attributes of hot-melt extrusion products and how data-driven models can drive development of amorphous dispersions solid dosage forms.

Thorsten Cech

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

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 patents in the field of pharmaceutical technology.

Nils Rottmann

Project Manager Technical Service Europe for BASF SE

Nils Rottmann studied Pharmaceutical Technology and Quality Management at the University of Applied Science in Lippe & Hoexter. He gained first practical experience during an apprenticeship as a pharmaceutical production worker at Baxter Oncology between 1999 and 2002. After his studies, he joined BASF in 2007 as project engineer in the Global Research and Formulation Group. Since 2009 he is part of the Technical Service team of BASF SE in Ludwigshafen/Germany.

Rob Blanchard

Research, Development & Quality Systems Manager – I Holland Ltd

Since joining I Holland in 2004 Rob has been instrumental in the development of I Holland's PharmaCote® range of surface treatments and coatings for tablet compression tooling designed to improve properties such as wear resistance, corrosion resistance and antistick characteristics. He was also part of the Eurostandard steering committee and responsible for I Holland's registration to ISO 9001:2015.
Rob holds multiple patents linked to solid dose manufacture. Rob also co-ordinates I Holland's close collaboration with various respected academic research bodies.

Tabletting School Team

Dr. Friederike Gütter

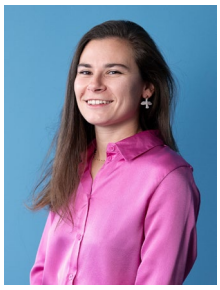
Process Specialist for KORSCH

Since 2020 Dr. Friederike Gütter is Process Expert at the KORSCH Innovation Centre Lab in Berlin, helping customers with tablet formulation development and tabletting process related inquiries. After studying pharmacy at TU-Braunschweig, she completed her PhD in pharmaceutical technology at the CAU Kiel in 2018. Afterwards, she intensified her knowledge in solid dosage forms as project manager at the contract manufacturer Rottendorf Pharma GmbH, Ennigerloh.

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.



Lucile Kubiak

Formulation Scientist for MEDELPHARM

Lucile Kubiak is a formulation scientist supporting MEDELPHARM Science Lab customers in their powder material characterization, tablet formulation development, troubleshooting and scale up projects. After her double degree Pharmacist/Engineer from IMT Mines Albi in France, she completed her PhD in industrial pharmacy at the University Toulouse in France. Her previous experience involved technical transfer at Skyepharma, CDMO in France and preformulation studies at Oculis in Iceland.

Dirk Vanderroost

Area Sales Manager Continuous Technologies for GEA

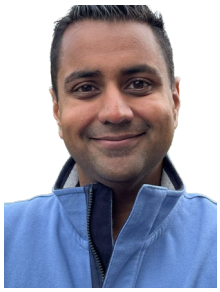
For almost a quarter of a century, Dirk has been involved in a wide variety of different pharma processes, first in an R&D environment for pharma excipients, later in pharma processing equipment.
At the birth of GEA's Continuous Technology back in 2006, Dirk joined GEA as a senior process specialist. He was heavily involved in process development for ConsiGma® applications, as well as customer projects for more than 15 years. In the last 2 years, he joined GEA's Sales team in order to share his process experience with GEA's customers.

Tabletting School Team

Dr. Stuart Little

Systems Engineer for JMP

Stuart Little is a Systems Engineer at JMP, where he applies his chemistry background to help provide solutions to a broad range of data and statistical problems. Prior to joining JMP, he was a Lead Research Scientist at Croda, and holds a PhD in Chemistry from the University of Sheffield. His interests include the application of statistical methods, and in particular DOE and modelling, to build practical understanding of the performance of industrial processes.



Sunny Singh

Sales Specialist for SOTAX

Sunny Singh, has an MSc in Pharmaceutical Analysis (Distinction) from the University of Strathclyde, Glasgow and a B Pharm (First class) from Panjab University, Chandigarh. He started his career in PR&D, AZ, Macclesfield first as a student researcher and then an analytical chemist. Worked in analytical development at Patheon, Swindon for over 5 years. Gaining extensive experience with a variety of formulation types from initial development, feasibility to clinical batch release and stability testing. Before moving into commercial roles with companies like Wiley publishers, VWR, Eurofins and now as Sales Specialist (UK) at SOTAX. Responsible for equipment for dissolution, physical testing, automation of sample prep and software for DI and 21 CFR part 11 compliance.

About the venue

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.

Good to know

Venue

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

Registration

The registration fee is 690 GBP (incl. VAT). The fee includes the participation, catering during the two workshop days, and a casual dinner on 18th June 2024.

Please visit the DMU home-page for registration and register via the DMU web-shop:
Tabletting School Workshop 2024 | De Montfort university (dmu.ac.uk)

Don't forget to drop information on your diet.

Visa

If you need to apply for a visa for the United Kingdom, please contact hdouds@dmu.ac.uk to receive a Letter of invite.
Please provide the necessary information required to issue the document (name, surname, date of birth, place of birth, passport number/issued by, date of issue, and expiry date).

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 hlsrco@dmu.ac.uk

Train travel

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

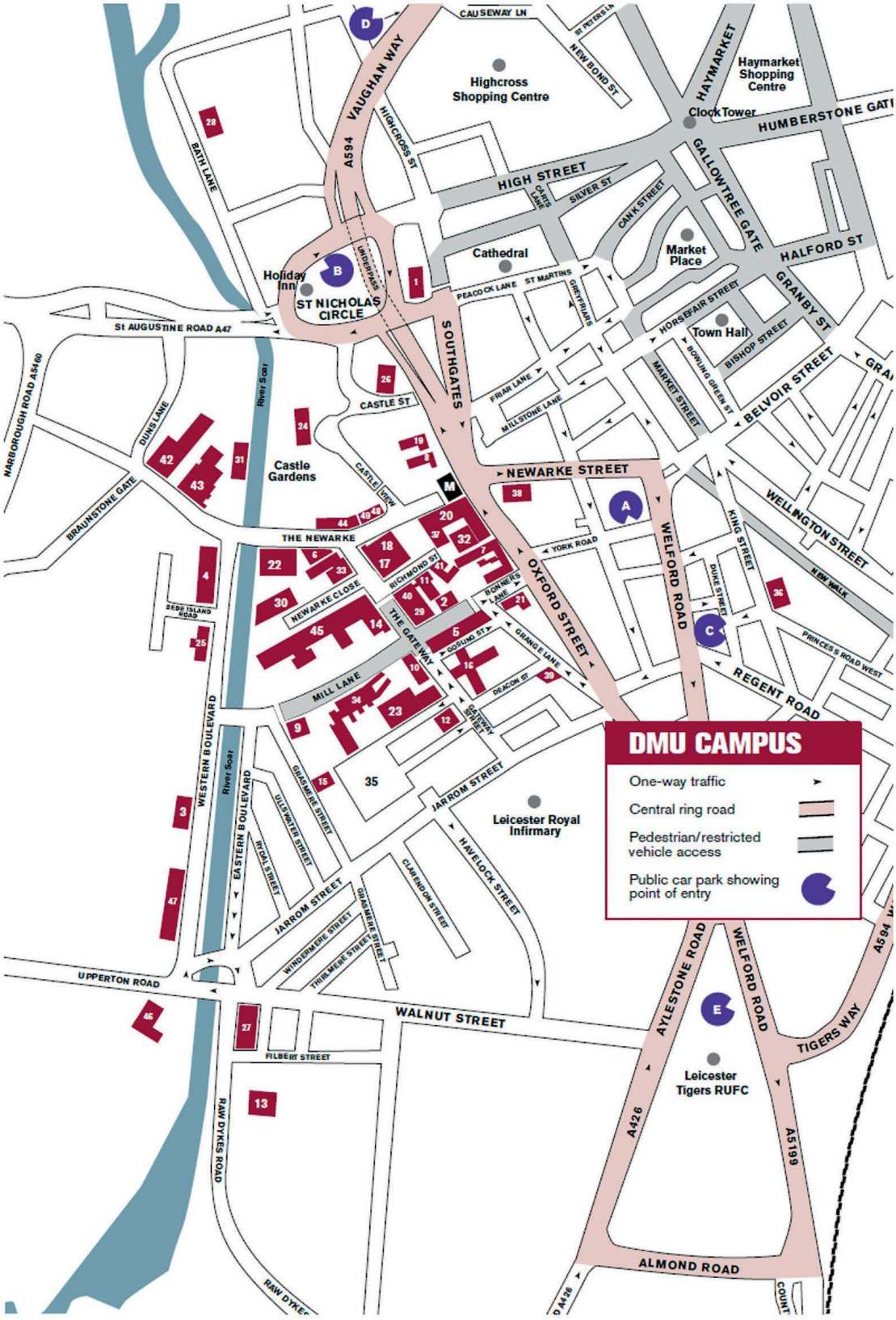
Hotel reservation

We recommend the booking platforms booking.com or hrs.de for hotel reservation in Leicester.
Participants are asked to make their own hotel reservation.

Dress code

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

Good to know



Venue

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