

European Continuing Education College

Managed by PharmaCourses Ltd

Pharmaceutical Granulation and Compression

29 & 30 & 31 October 2018, London UK

Three Day Intensive Course with an Emphasis on High Speed and Fluid Bed Granulation, Layering, Pellet Manufacture, Roller Compaction, Oral Dispersion Technology, Scale-Up, Transfer Technology, Melt Extrusion, Spray Drying and Compression Machinery

Course Background

Granulation and compression are two very important processes that are carried out extensively by most pharmaceutical companies. However, the theory of granulation is little understood and the selection of a particular machine and granulation method, is often done on the basis of tradition, rather than by using strict scientific or cost-benefit criteria. The basic techniques have changed dramatically in recent years and granulation for controlled release, extrusion, spheronisation, fluidisation techniques, spray drying, melt extrusion, oral dispersion technology and roller compaction are new technologies that are increasingly being used in modern pharmaceutical production, which exhibit many advantages over previously available techniques. As with granulation, compression is also little understood and why some materials/formulations will compress well whilst others compact with difficulty, is slowly being elucidated.

The Course will examine current granulation and compression theory and practice. Emphasis will be made as to how this theory and practice relates to current pharmaceutical development and production, with special reference to the machinery used. Scale-Up, Transfer Technology and SUPAC will also be addressed. A particular feature of the Course will be the workshop on new melt extrusion technology.

Course Objectives

The aims of the Course are to provide a comprehensive and sound understanding of the theory and practice of tablet granulation and compression and to appreciate the various processes batch or continuous, that are available. The importance of the granulation process in producing good quality tablets will be emphasised. The modern techniques of extrusion, spheronisation, powder layering, roller compaction, fluid-bed processing, spray drying, melt extrusion, oral dispersion technology and tablet compression will be covered. The Course will be taught primarily by industrial scientists who have been closely involved with investigating these granulation and compression processes and thus a pragmatic approach will be adopted throughout.

Summary of Key Benefits of Attending

At the end of the Course participants will have:

- An understanding of the fundamental principles of granulation and the advantages, disadvantages and potential of the various granulation, layering, spray drying, oral dispersion, extrusion and spheronisation methods
- An understanding of the techniques and processes available for granulation in relation to controlled release products
- Detailed knowledge on current ideas and thoughts on Scale-Up, Transfer Technology and SUPAC An appreciation of some of the compression problems that can arise and how they can be overcome
- A knowledge of the factors that should be taken into consideration when selecting granulation and compression equipment
- Specialist knowledge on fluid-bed granulation, roller compaction, layering, spray drying, oral dispersion technology and melt extrusion Detailed knowledge on compression machinery
- An appreciation of the techniques available and their limitations for end-point granulation control
- A knowledge of the reasons why problems arise in the granulation and compression processes and how these problems can be avoided

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Who Should Attend

All who are working in pharmaceutical research, formulation, development, production, QA/QC and registration who require a sound understanding of the various granulation and compression methods and who wish to appreciate some of the advantages of the newer methods of granulation, spheronisation, roller compaction, layering, melt extrusion and compression that are now available.

Course Outline

Methods and Reasons for Granulating

- Overview of granulation and compression
- Techniques available
- Theory of granulation.

Excipients Review of available excipients;

- Advantages and disadvantages
- Rationale for selection

Properties of Granules Measurement of granule properties.

- Ideal granule characteristics.

Granulation for Controlled Release

Review of current methods.

High Speed Granulation and End-Point Control

- Introduction and history.
- Machine design.
- Fixed bowl vertical; fixed bowl horizontal.
- Removable bowl.
- Operation.
- Practical experiences.
- Review of suppliers.
- Granulation end-point.
- Diosna probe.
- Review of techniques of monitoring impellor torque.
- Slip meter control.
- Automated control of whole process.

Integrated Mixer-Granulator Dryers Review.

- Advantages and disadvantages.
- Equipment available.

Fluid Bed Granulation Operation.

- Equipment selection.
- Fully automated systems.
- Rotary granulators.
- Comparison of methods.

Layering

- Solution, suspension and dry powder layering.

Spray Drying

- F.S.D. Spray Drying

Pellet Manufacture

- Techniques available
- Spray drying
- Drum granulation
- Comparison of methods.

Venue

Holiday Inn Oxford Circus, 57-59 Welbeck St, Marylebone, London W1G 9BL, United Kingdom

Website: <https://www.ihg.com>

Timing of the course

Registration will be at 8.45am on Monday 29 October and the Course will commence promptly at 9.00am. The Course will finish at about 17.00 on Wednesday 31 October. The Course will end at about 18.00 on each of the first two days

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Course Outline cont'd

Extrusion and Spheronisation

Extrusion theory. Basic rheological modelling/formulation indicators. Types of extruders. Commercial extruders. Development extruders. Melt Extrusion: Carriers for Melt Extrusion, Solid Dispersions, Examples of Extruders/Other Equipment, Parameters Affecting Melt Extrusion, Formulation and Process Design Problems. Laboratory modelling. Properties of extrudates. Moisture movement across extrudates. The role of microcrystalline cellulose. Spheronisation: spheronisation theory. Commercial equipment. Problems of spheronisation. Evaluation of pellets.

Hot Melt Extrusion

Review of process. Why hot melt extrusion. Types of solid dispersions. Types of carrier. Equipment. Case study

Roller Compaction

Review of the current state of roller compaction. Equipment available. Advantages and disadvantages.

Compression Theory Review

Why some materials compress satisfactorily whilst others compact poorly. Theory related to practice.

Compression Machinery

Review of the current state of press design. Removable turrets and cleaning of presses

Compaction Simulators Review and uses

Tabletting and Tooling Problems

A review of problems that arise in production and how to avoid producing poor quality tablets.

Oral Dispersion Tableting Technology

Review of methods. Advantages and disadvantages of the technology. Equipment required.

Scale-Up, Transfer Technology and Supac

Workshop A workshop will be arranged on hot melt extrusion processes.

Lecturers

Michael H. Rubinstein B.Pharm., Ph.D., M.R.Pharm.S., M.I.Chem.E., C.Eng., Q.P. (Course Director) Professor Rubinstein is Chairman and Co-Founder of Quay Pharmaceuticals Ltd., a contract pharmaceutical R & D and Clinical Trials Manufacturing company in North Wales. Previously he was Professor of Pharmaceutical Technology and Director of the School of Pharmacy and Chemistry at Liverpool John Moores University. His research interests include the examination of the granulation process and he has published and lectured widely in the field of tableting technology and the formulation of solid dosage forms. Professor Rubinstein has worked for AstraZeneca and GlaxoSmithKline in production technical support, pharmaceutical development and research.

He has published over 200 research papers and articles in the area of solid dosage form technology and in particular in tablet compression. He lead one of the only academic research teams using a high speed Compaction Simulator to fundamentally characterise powder compression.

Professor Rubinstein is both a Chemical Engineer and a Pharmacist with Q.P. Status, is the author of 5 books in pharmaceutical technology and two patents and is the series editor of the book series in Pharmaceutical Technology now published by Taylor & Francis Ltd.

Professor Rubinstein is a consultant to a number of pharmaceutical companies and governments and is the Conference Co-Ordinator for the annual Pharmaceutical Technology Conferences.

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Lecturers

Geert Verreck M.Eng., Ph.D.

Dr Verreck is a Scientist in the Pharmaceutical Sciences Department of Johnson and Johnson in Belgium. He is responsible for the evaluation of the solid dispersion approach for new active compounds, including hot melt extrusion and solubility techniques. He has published 37 papers and is the author of 6 patents in this area.

Ian Smales B.Sc.

Mr Smales is an Associate Scientist at Pfizer Central Research and has responsibilities for optimization, scale-up and technology transfer of pharmaceutical products. He has specialist expertise in wet and dry granulation and in particular roller compaction.

Paul Burton C.Chem, M.R.S.C.

Mr Burton has had extensive experience as a Formulation and Process Development Scientist with Beecham Products, Cyanamid UK and SmithKline Beecham Pharmaceuticals. He has been involved in new product introduction, scale-up of solid dosage forms and process validation. Currently he is Process Technology Manager for Glatt Protech where he has responsibility for applications of fluidised bed technology, high shear granulation and tablet coating technologies.

Terry Lewis

Mr Lewis is an independent Consultant and was formerly Operations Manager at I.Holland Ltd., UK. He is accountable for all technical activities of the company and has 28 years expertise in compression and tooling problems.

Harald Stahl Ph.D.

Dr Stahl is Senior Pharmaceutical Technologist with GEA Pharma Systems with world-wide process responsibility for the technologies supplied by GEA Pharma Systems. Previously he worked in the Pharmaceutical Development Division of Schering AG in Germany.

Jan Vogeleeer B.Sc.

Mr Vogeleeer is Managing Director of Courtoy N.V., manufacturers of tablet presses in Belgium. He has pioneered the design of new tablet machinery to enable tablets to be produced at faster speeds with minimal clean and down time and has a huge wealth of experience in novel design of compression machinery.

Ian Muir BSc., Ph.D.

Dr Muir is Vice-President of Zydis at Cardinal Health in the UK. He is responsible for product development for the fast dissolve Zydis technology. He has had previous experience in various aspects of product development from early compound selection to scale-up and commercialization.

Gordon Prudhoe BSc

Mr Prudhoe is Quality Assurance Technical Group Manager for Sanofi-Syhelabo. His responsibilities include technical support for production and co-ordination, planning and execution of all transfer activities both in and out of Sanofi-Syhelabo plants worldwide. Mr Prudhoe was previously Manager in charge of the formulation and analytical groups and has developed over 50 generic products. Mr Prudhoe has worked in the industry for over 20 years in a development/production support role.

Marina Levina MSc., Ph.D.

Dr Levina is a Lead Product Owner, OSD at GlaxoSmithKline responsible for Global Supply Oncology products. Previously, she worked as a Global Technical Manager, Excipients and Modified Release at Colorcon Ltd. Dr Levina has experience in the production of tablets by conventional and by ultrasound assisted compaction and with the development of various solid oral dose formulations for both immediate release and modified release applications. She has published over 70 research papers and communications in the area of Pharmaceutical Technology, including book chapters, peer-reviewed articles and poster abstracts presented at more than 20 national and international conferences and seminars. She is an Editorial Advisory Board member and reviewer for international pharmaceutical journals.

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REGISTRATION DETAILS:

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Early-bird fee: 23day course £1593.00 (+ VAT £318.60 if applicable, see notes on VAT)

For registering and paying before **3 September 2018**

Full Fee: 3 day course £1770.00 (+ VAT £354.00 if applicable, see VAT NOTES)

Academic rates are available, please enquire: info@pharma-training-courses.com

VAT NOTES:

UK: Under UK law all UK-based applications are subject to VAT at the prevailing rate however most UK VAT registered companies/organisations can reclaim this tax.

EU: With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT **PROVIDED THAT** valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.

OTHER: With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT, ie no VAT is charged or payable.

Methods of Payment available:

Cheque (**Please make payable to "PharmaCourses Ltd"**)

Bank transfer

Credit/Debit Card (Paying by Credit Card please register online)

Registration is available online:

www.pharma-training-courses.com

Data Protection

PharmaCourses Ltd gathers personal data in accordance with the UK Data Protection Act 1998 and we may use this to contact you by telephone, fax, post or email to tell you about other products and services. If you have any queries or want to update any of the data that we hold then please contact us.

Terms and Conditions:

Liability - PharmaCourses Ltd reserves the right to change the programme, speakers, date or venue without notice or cancel the event. If cancellation occurs delegates will be notified as soon as possible and will receive full refund of fees paid. PharmaCourses will not be responsible for any airfare, accommodation or other travel costs incurred.

Delegate fees - Fees for this programme are shown overleaf. Delegate fees are inclusive of course documentation, refreshments and lunch. Payment of the registration fee must be paid within 14 days of commencement of the course. Upon receipt of payment, a proof of payment will be sent to you.

Cancellation Policy - Full refunds less a handling fee of £100 will be made for cancellations received in writing within 28 days of the commencement of the course. Refunds of 50% will be made for cancellations received in writing between 28 and 7 days prior to the commencement of the course. Regrettably no refunds will be made after 7 days prior to commencement of the course. Substitutions can be made at any time.

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Course Programme 2018

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
13, 14 & 15 March 2018, **Croydon Greater London**

HPLC Analytical Method Development and Validation
10 & 11 May 2018 **Istanbul Turkey**

Stability Testing in Pharmaceutical Development and Manufacture
24 & 25 May 2018 **London**

Pharmaceutical Dissolution Testing – a 2 day course
21 & 22 May 2018 **London**

Pharmacokinetics in Drug Development - an integrated approach
18 & 19 June 2018 **London**

Pharmaceutical Packaging – an introductory course
25 June 2018 **London**

Powder Technology for Pharmaceutical Development and Manufacturing
26, 27 & 28 September 2018 **London**

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
13, 14 & 15 June, **Croydon Greater London**

Introduction to the Formulation and Stabilisation of Protein and Peptide Drugs
24 & 25 September 2018 **London**

Latest Advances in the Formulation & Stabilisation of Protein and Peptide Drugs
24 & 25 September 2018 **London**

Pharmaceutical Dissolution Testing – a Hands-on Course
23, 24, 25 & 26 October 2018 **London**

Pharmaceutical Granulation and Compression
29, 30 & 31 October 2018 **London**

GMP Auditor Training for Quality Systems
7, 8 & 9 November 2018 **London**

Parenteral Products
12, 13 & 14 November 2018 **London**

Pharmaceutical Aerosols, Dry Powder Inhalation Systems and Nasal Delivery Devices
19, 20 & 21 November 2018 **London**

Development of Stability-Indicating HPLC Methods
21 November 2018 **London**

HPLC Analytical Method Development and Validation
22 & 23 November 2018 **London**

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
5, 6 & 7 December 2018, **Croydon Greater London**
