Course overview

This unique 2 day course identifies the studies needed to characterise the physico-chemical properties of drug substances in the context of tablet development. Proper understanding of drug substance properties is essential for both candidate selection (during the Research process) and pharmaceutical development.

On Day 1 of the course we introduce the key elements of tablet development and the principles of Quality by Design (QbD), and the potential impact of drug substance properties on tablet development. On Day 2, we study some of the numerous recently developed techniques for rapid and scientific assessment of drug substances using techniques such as Atomic Force Microscopy (AFM), high stress stability testing (ASAP—Waterman), and Raman Spectroscopy. We include experimental, hands-on experience of material compaction using the new Gamlen Tablet Press.

Course content:

The Product Development Lifecycle
- Making sense of ICH Q8, 9 and 10
- Identifying the material properties at an early stage which will become Critical Quality Attributes of the product

Preformulation studies
- Material characterisation—chemical and physical
- Morphic form identification
- Salt selection
- Compressibility testing
- Excipient and Process compatibility testing

New Techniques and how to apply them
- Atomic Force Microscopy
- ASAP—short term high stress testing for accurate shelf life assessment
- Raman Spectroscopy and other mapping techniques
- Amorphous materials—uses and limitations
- Quantitative and Environmental XRPD
- Solid state NMR
- Evaluating drug substance compressibility

Course speakers:

Dr Michael Gamlen, Pharmaceutical Development Services
Michael is Managing Director of Pharmaceutical Development Services Ltd, a Guildford (UK)-based technical consultancy. He has over 35 years experience of tablet development. Awarded a First Class Honours degree in Pharmacy, specialising in Pharmaceutical Engineering, he studied for a PhD at Nottingham University. He was Head of Tablet Development at the The Wellcome Foundation for 15 years, and has since worked for Vanguard Medica Ltd and as a consultant. He specialises in managing product development, formulation, tablet and process development studies. He has been teaching professional tabletting courses for many years and his courses are highly rated, exceeding the expectation of the participants in many case.

Michael continually updates the content of his courses with the latest guidance and extracts of up-to-the minute scientific papers.

Dr Dipankar Dey, PharmaTraining Ltd
Dipankar Dey recently joined PharmaTraining Ltd as Training Manager. A graduate of Oxford University and with a PhD from Birmingham University, he was until recently Head of Process and Validation at OYSTAR Manesty, a well known tablet equipment manufacturer. Dipankar has experience in both sterile and solid dose pharmaceuticals, particularly in tablet coating and compression and is interested in PAT techniques to extract useful online information.
Who should attend?
The course is designed for people new to tablet development, and those requiring a refresher in the area. It will also benefit Process Development experts wishing to extend their understanding of the influence of material properties on processing behaviour, and regulatory and quality personnel who need to understand the development process.

Numbers are restricted for maximum benefit to participants

Course Programme:
This 2 day course will consist of:

Day 1: Introduction to preformulation
Morning
• Developing a Target Product Profile
• The product development process
• What are “Preformulation studies”
• Linking material properties to formulation and processing behaviour

Afternoon
• Identifying potential Critical Product Attributes related to the drug substance
• Established techniques for materials characterisation
• Linking material properties to formulation requirements
• Atomic Force Microscopy
• ASAP—short term high stress testing for accurate shelf life assessment

Day 2: Advanced preformulation techniques
Morning
• Raman Spectroscopy and other mapping techniques
• Amorphous materials—uses and limitations
• Quantitative and Environmental XRPD
• Solid state NMR

Afternoon
• Evaluating drug substance compressibility
• Case studies, workshops
• Participants open forum and Question and Answer session.
• Practical
• Effect of crystal form and particle size on compressibility using the Gamlen Tablet Press

NOTE
Wherever possible participants should bring practical problems and examples which can be reviewed on the course. The course will be highly participative and useful for people with or without formulation experience.