

# European Continuing Education College

## Pharmaceutical Coating Technology

### Three Day Intensive Course with the Emphasis on the Properties of Materials, Process Control and Optimisation, Avoidance of Coating Problems and Recent Developments

Holiday Inn Hotel, Oxford Circus, London, UK  
14th, 15th and 16th May 2012

#### Course Background and Objectives

The course will provide an extensive three-day review on all aspects of the film coating of pharmaceutical tablets and multiparticulates, focusing on:

- An examination of the fundamental science underpinning film coating
- A consideration of the properties of coating materials and formulations
- An understanding of coating processes, including process optimization and control
- An overview of some recent advances associated with film coating

#### Summary of Key Benefits of Attending

At the completion of the course participants will:

- Have a basic knowledge of the processes and materials used in tablet and multi-particulate coating and how these influence the formation and the properties of the coated product
- Have a knowledge of coating equipment, design, automation and qualification
- Be able to adopt a rational approach to solving practical film coating problems, taking into account problems arising from both the process and the coating/tablet formulation
- Appreciate current developments in pharmaceutical coating technology

#### Who Should Attend

The course will ideally suit a graduate working in pharmaceutical product development that needs to gain a good understanding of the film coating of pharmaceutical oral solid dosage forms; in addition, the course will be useful to those individuals responsible for technology transfer and for providing production technical support, as well as production personnel wishing to gain a better understanding of the fundamentals of film-coating technology. The course may also be suitable for providing background knowledge for someone engaged in product registration.

#### Course Outline

##### Course Introduction

An introduction to the material to be presented during the course.

##### Review of Materials Used in Film-Coating Formulations

Overview of the materials typically used in coating formulations, and will provide an understanding of the purpose of each class of ingredient used. Materials used in both immediate-release (IR) and modified-release (MR) coating formulations will be covered.

##### Design of Substrates for Film Coating

Review of what it takes to prepare robust materials for introduction to film-coating processes, with emphasis on both tablets and multiparticulates.

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## **Course Outline**

### **Review of Fundamental Issues That Impact Film Coating**

Film coating has long been considered an art-form, but there are many fundamental scientific principles that have to be considered, not least of which are surface chemistry, rheology, wetting and adhesion

### **Overview of Key Equipment Used in Film-Coating Processes**

Film coating is a process that can be accomplished using either pan-coating or fluid-bed processing equipment. A general overview of this type of equipment will be presented, as will information on other pieces of equipment critical to success in film coating.

### **Introduction to Film-Coating Processes**

General overview of the key elements of film-coating processes, and issues that have to be understood if a successful process is to be implemented.

### **Review of Critical Aspects of Film-Coating Processes**

The key elements of film coating are often poorly understood. This review will provide a basic understanding of the issues surrounding process thermodynamics, spray dynamics, and what is required to achieve acceptable uniformity of distribution of the coating and attain an acceptable process end point.

### **Design of Optimized Film-Coating Processes**

Pharmaceutical film-coating processes possess the largest number of potential process variables that can impact ultimate product quality. This presentation will provide an overview of what it means to achieve an optimal process, and provide some case studies illustrating effective approaches that have been used.

### **Understanding Process Control in Film-Coating Processes & the Implications of QbD**

In recent years, the importance of achieving effective control of film-coating processes, the implementation of Process Analytical Technologies (PAT), and the regulatory requirements surrounding Quality by Design (QbD) initiatives have all places challenges with respect to film-coating processes. This presentation will provide an introduction to how these challenges impact the film-coating process.

### **Scaling Up Film-Coating Processes**

Scaling up processes associated with pharmaceutical unit operations always presents many challenges, and never is this more true than when considering film coating. While many of the factors implicated in the scale-up process may be reasonably well understood, many critical factors receive scant attention. This presentation, illustrated by suitable case studies, will provide some important insight into the scale-up process, and the achievement of a successful production-scale process.

### **Introduction to Continuous Film-Coating Processes**

While the use of continuous processes in the modern pharmaceutical industry is not new (tableting process have always been continuous, for example), the use of continuous film-coating process is more recent. This section will provide an introduction to continuous film-coating processes, exploring the potential advantages and disadvantages of such processes.

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## **Course Outline**

### **Approaches to Consider for Measuring the Properties of Film Coatings and Assessing Film-Coated Products**

When designing coating formulations suitable for a given application, it is often useful to have access to a number of techniques that allow key attributes of the coating (such as mechanical strength, adhesion, and permeability properties) to be determined in order to ensure effective optimization of a given formulation. In addition, it is often useful to employ quantitative techniques that enable the quality and functional attributes of the final coated dosage form to be assessed. An overview of many such useful techniques will be provided.

### **Applications of Terahertz Pulsed Imaging in Analysis of Film-Coated Tablets**

In recent years, the utility of application of terahertz technology as an analytical tool to assess key aspects of applied film coatings (such as exact quantity of coating applied, coating uniformity around, for example, a tablet, and coating structure) has been expressed in a number of publications. This presentation will seek to review the utility of this new analytical tool, and will present numerous examples of its application to film-coating processes and film-coated products.

### **Approaches to Effective Troubleshooting of Film Coated Products & Processes**

Unfortunately, all-too-often the production of film-coated products is beset with numerous issues that impact ultimate product quality (in its broadest sense). The causes of many of these quality problems, and opportunities either to avoid, or correct them, will be presented.

## **Lecturers**

### **Stuart C. Porter Ph.D. (Course Director)**

Dr Porter is Senior Director, Global Pharma Applications R&D, Film Coatings and Excipients, International Specialty Products (ISP). Prior to joining ISP, Dr Porter was a consultant to the global pharmaceutical industry. He also spent more than 25 years with Colorcon, where he directed the development of the wide variety of coating systems for which that company is renowned. Before joining Colorcon, Dr Porter was involved in pharmaceutical product development with AstraZeneca in the UK. Dr Porter's technical interests relate to film coating, tableting, and fluid-bed technologies, with particular interest in modified-release drug-delivery systems, the application of statistical experiment design techniques to product and process optimization, and the design and implementation of continuous coating processes.

### **Phil Hadfield**

Mr. Hadfield is Senior Technical Specialist – Film Coatings, ISP, with responsibility for providing technical support for ISP's coating systems in the EMEA region. Previously, he spent 20 years with Colorcon in various technical roles, latterly as Global Technical Manager. Before joining Colorcon, he was engaged in pharmaceutical product development and production support with Wyeth Laboratories and May & Baker Ltd in the UK.

Mr. Hadfield's technical interests relate to film-coating technologies, colour science and a broad range of formulation and process design applications associated with oral drug delivery systems, with particular interest in film coating technology and the application of "new" polymers to film coating systems.

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## **Lecturers**

### **Linda Felton Ph.D.**

Dr. Felton is an Associate Professor of Pharmaceutics and the Chair of the Department of Pharmaceutical Sciences in the College of Pharmacy at the University of New Mexico. She earned a B.S. in Pharmacy and a Ph.D. in Pharmaceutics from the University of Texas at Austin. Her research interests are focused on polymeric film coating technology, modified release systems, and topical/transdermal drug delivery. She has presented her work at national and international conferences and has published extensively in peer-reviewed journals. Dr. Felton is an editorial board member of Drug Development and Industrial Pharmacy, the Manufacturing section editor of the 21st edition of "Remington: The Science and Practice of Pharmacy", and the co-editor of the 3rd edition of "Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms". Dr. Felton has a joint appointment with the Department of Veterans Affairs Cooperative Studies Program where she oversees the formulation development of clinical trials materials. She is a current member of the American Association of Pharmaceutical Scientists, the Controlled Release Society, and the International Society for Pharmaceutical Engineering.

### **Philip F. Taday PH.D.**

Dr. Taday earned his Bachelor of Science degree in physics (1986), and his Ph.D. in chemistry (1991) from the University of Reading in England. When working at the Central Laser Facility at the CLRC Rutherford Appleton Laboratory he developed a femtosecond tabletop laser system as well as worked on novel tunable sources. In August 2000 Dr Taday began working at Toshiba Research Europe Limited, of Cambridge, England, on terahertz spectroscopy. In April of 2001 this terahertz program was spun-out of Toshiba, becoming TeraView Limited.

Dr Taday is currently the Principal Scientist and Head of the Applications at TeraView Limited. He has authored and coauthored 90 published papers and presented at numerous scientific conferences. He is a co inventor of 5 patent applications.

## **Fees and Registration**

The participation fee is £1495.00 (exclusive of VAT). Places are strictly limited and therefore applications will be accepted on a first come basis. Under UK law all applications are subject to Value Added Tax (VAT) irrespective of the country of origin of participants. Most VAT registered companies/organisations can reclaim this tax. The fee includes full personal participation, extensive bound course notes, luncheons and light refreshments, on all days of the Course. Dinner at night is not included. Cancellations cannot be accepted less than 14 days prior to the start of the Course, but substitutions may be made at any time. The Course language will be English. An approved Certificate of Attendance will be given to each participant at the end of the Course.

## **Timing of the Course**

Registration will be at 8.45am on Monday 14th May and the Course will commence promptly at 9.00am. The Course will finish at about 16.30 on Wednesday 16th May. The Course will end at about 18.00 on each of the first two days.

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## **Timing of the Course**

Registration will be at 8.45am on Monday 11th June and the Course will commence promptly at 9.00am. The Course will finish at about 17.00 on Wednesday 13th June. The Course will end at about 18.00 on each of the first two days.

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## ECEC - Registration Form

### Course - Pharmaceutical Coating Technology

Please fill in the following details to apply for a place. No payment is necessary now. When filling in the form, fields marked with an asterix (\*) are compulsory. Your form will not be submitted if they are left blank.

#### Personal Details

First name: *	<input type="text"/>
Surname: *	<input type="text"/>
Organisation:	<input type="text"/>
Job title:	<input type="text"/>
Address: *	<input type="text"/>
Post/zip code:*	<input type="text"/>
Telephone no:	<input type="text"/>
Extension:	<input type="text"/>
Fax no:	<input type="text"/>
Email address: *	<input type="text"/>

I wish/do not wish to receive future mailings from ECEC about forthcoming courses.  
(Please note, we do not disclose your email address to any third party)

#### Accommodation

Accommodation will be at the: Holiday Inn Hotel, Oxford Circus, London, UK  
Room Rates: Single Room - Bed & Breakfast per person, per night £159.00  
Twin Room - Bed & Breakfast per person, per night £189.00  
Double Room - Bed & Breakfast per person, per night £189.00

Choose accommodation Type:

- I don't want accommodation
- I would like a Single Room - Bed & Breakfast
- I would like a Twin Room - Bed & Breakfast
- I would like a Double Room - Bed & Breakfast

Choose which days:

- Sunday 13th May 2012
- Monday 14th May 2012
- Tuesday 15th May 2012
- Wednesday 16th May 2012

Other nights (please specify): \_\_\_\_\_

\* Please note: Under UK law all applications are subject to Value Added Tax (VAT), irrespective of the country of origin of the Participant

**PLEASE FAX THIS COMPLETED FORM TO +44 (0)151 724 6343**