Course

ROYAL PHARMACEUTICAL SOCIETY

In association with

APS
www.apsgb.org

Dissolution testing for the pharmaceutical industry

Royal Pharmaceutical Society, London
Wednesday 20 – Friday 22 June 2012

ROYAL PHARMACEUTICAL SOCIETY

Do you work in formulation development or the testing of tablets? Do you require an intensive course of study on the relevance, development, validation and routine use of dissolution testing? This new three day residential course, organised by the Royal Pharmaceutical Society, provides the solution.

The course is an intensive introduction to dissolution testing and delegates will leave the course with knowledge they can apply to day-to-day problems in formulation evaluation & quality testing using dissolution testing.

The course offers delegates the unique opportunity to discuss real challenges faced in day-to-day work with expert lecturers. Delegates are encouraged to send in advance, or bring to the course, their own problems in dissolution test development & use, for discussion.

WHAT YOU WILL ACHIEVE FROM THE COURSE

By the end of the course you will have received an intensive course of study on the relevance of dissolution testing to the assessment of dosage forms (in particular oral dosage forms), dissolution method development, validation and solving day-to-day issues.

- You will understand:
  - the relevance of dissolution testing to industry & regulators
  - dissolution equipment
  - dissolution media
  - compendial requirements & testing
  - method development
  - method validation
- Learn about the current state of knowledge of the subject, both in terms of theoretical basis and practical experience.
- Acquire skills and knowledge you will be able to apply to day-to-day problems in dissolution testing, linked to a sound theoretical knowledge of the principles involved.
- Formed lasting contacts with colleagues in the field, as well as the expert course tutors.

COURSE FORMAT AND MATERIALS

The course is a blend of taught lectures and interactive problem-based workshops.

Delegates will be provided with a full set of course notes for use during and after the course.

Fees include two-night's accommodation (unless booking a non-residential place) catering and refreshments and a networking social programme.

A PROGRAMME PUT TOGETHER BY A TEAM OF EXPERTS

- James Butler, GSK
- Paul Dickinson, AstraZeneca
- Lee Dowden, MSD
- Nikoletta Fotaki, University of Bath
- David Holt, AstraZeneca
- Evangelos Kotzagiorgis, EMA
- James Mann, MSD
- Terry Way, Consultant

WHO SHOULD ATTEND

- Graduates or technical staff working in the field of formulation development, dissolution method development & validation, quality control;
- Those who have not previously worked in this field and who require an intensive introduction to dissolution testing and the associated procedures;
- Regulatory or Quality staff, and project or contract management personnel with responsibilities for dissolution test development or testing.

WEDNESDAY 20 JUNE

09.30 Registration
Tea and coffee

10.00 Introduction (interactive) & Overview
Terry Way, Consultant

10.45 Dissolution testing of oral dosage forms in context: a review of its physiological relevance
Paul Dickinson, AstraZeneca

11.30 Dissolution testing of non-oral dosage forms in context
Nikoletta Fotaki, University of Bath

12.15 Dissolution test methods and media for oral dosage forms – early development
James Butler, GSK

13.00 Lunch

13.45 Workshop 1
Selection of media and methods for oral dose forms, with an emphasis on early stage development
James Butler, GSK

15.45 Tea

16.00 Equipment for dissolution testing - oral dose & non-oral dose forms
Terry Way, Consultant

17.30 Close of day's programme

19.00 Dinner

THURSDAY 21 JUNE

08.15 Review of Day 1 with general discussion/Q&A
Terry Way, Consultant

08.45 Dissolution method development with an emphasis on late stage

- Product Critical Quality Attributes (CQA) and how they relate to method choice.
- Linkage of CQA's to dissolution method results.

Paul Dickinson, AstraZeneca and David Holt, AstraZeneca

10.30 Coffee break

10.45 Regulatory Requirements. How development data relate to Compendial Requirements (Ph.Eur.)
Evangelos Kotzagiorgis , EMA

11.30 Workshop 2
Method selection and development with an emphasis on late stage development
Paul Dickinson, Astra Zeneca

13.00 Lunch

13.45 Methods of Analysis
James Mann, MSD

14.30 Practical aspects of dissolution, including automation
Lee Dowden, MSD

15.15 Tea

15.30 Dissolution equipment qualification & method validation
Terry Way, Consultant

17.00 Close of day's programme

17. 10 Social programme followed by a free evening

DAY 3

FRIDAY 22 JUNE

08.30 **Review of Day 2 with general discussion/ Q&A**
Terry Way, Consultant

09.00 **Demonstrating in vitro/ in vivo relationships (IR & MR dose forms) using "In Vivo Simulators"**
James Mann, MSD

10.00 **Coffee break**

10.15 **Using dissolution testing to demonstrate dose form equivalence**
Nikoletta Fotaki, University of Bath

11.15 **Regulatory Examples of Biowaivers**
Evangelos Kotzagiogis, EMA

12.00 **Lunch**

13.00 **Workshop 3 Biowaivers**
David Holt, AstraZeneca

15.00 **Summary of course & immediate feedback**
Terry Way, Consultant

15.30 **Close of course**

For more information or to register, visit

www.rpharms.com/events

WHAT PREVIOUS DELEGATES SAID ABOUT OUR COURSES

"Excellent course, great to have such a varied background of participants and to be able to discuss ideas."

"I have definitely learned subjects and topics which I will use back at work."

"Very good course, good technical pitch and a very thorough overview. Very enjoyable."

"Extremely relevant and useful lectures"

VENUE AND ACCOMMODATION

The Royal Pharmaceutical Society is conveniently located in Central London with easy access from Waterloo, Vauxhall and Victoria rail and tube stations.

Address: 1 Lambeth High Street
London SE1 7JN

REGISTRATION FORM

Dissolution testing for the pharmaceutical industry

Wednesday 20 – Friday 22 June 2012

Two ways to register

- Visit **www.rpharms.com/events** and pay with credit/debit card or request an invoice.
- Complete this form and post, email or fax it back to us. You will be registered upon receipt of the completed form and payment must be made before the start of the course.

What's included in the fees?

- Course documentation
- Social programme
- Meals and refreshments throughout the day
- A three course evening meal

N.B. Please contact us if you haven't received an email confirmation of your booking within 5 working days of submitting your form.

MEMBER RPS	Early bird fee (before 20/04/12)	Full fee
Course only (without accommodation)	☐ £800	☐ £900
Course + accommodaiton (Wedn & Thurs nights)	☐ £1,180	☐ £1,280
NON-MEMBER	**Early bird fee (before 20/04/12)**	**Full fee**
Course (without accommodation)	☐ £960	☐ £1060
Course + accommodation (Wedn & Thurs nights)	☐ £1,340	☐ £1,440

PAYMENT AND DETAILS

Method of payment — Debit/credit card (someone will contact you to obtain your card details)

☐ Bank transfer (Sort code **60 60 04** Account number **45130574** National Westminster Bank, 91 Westminster Bridge Road, London SE1 7ZB) Quoting reference: **MMS EVT 439**

Title Firstname	Surname
Job title	Company
Address	
	Postcode
Telephone	Membership number
Email	
Dietary requirements	

PLEASE RETURN THIS FORM TO:

Events Coordinator, Royal Pharmaceutical Society, 1 Lambeth High Street, London SE1 7JN **Telephone:** 0845 257 2570 **Fax:** 020 7572 2506 **Email:** events@rpharms.com **Web:** www.rpharms.com/events

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Cancellations policy. For full details of terms and conditions please visit **www.rpharms.com/eventstc.** For cancellations, the following refunds will apply:
More than 30 working days before the event = 50% of the fee, 30 working days or less = no refund. In the unlikely event of the cancellation of the event, delegates will receive a full refund of the fees but we can not be held liable for other expenses incurred by delegates.