Course

ROYAL PHARMACEUTICAL SOCIETY

In association with

APS
www.apsgb.org

# Dissolution testing for the pharmaceutical industry

Møller Centre, Cambridge
Monday 12 – Wednesday 14 December 2011

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.

## 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.

## LEARN FROM A TEAM OF EXPERTS

**Course director**

Dr John M Hempenstall, Consultant

John has recently retired from GlaxoSmithKline after a 30 year career in product development, leading departments & teams of scientists in the development of a range of dosage forms, particularly oral dose forms. His primary research interests are in paediatric medicines, continuous processing, melt extrusion, modified release oral dose forms, dissolution testing (particularly using physiologically relevant media) and predictive models for oral drug delivery.

- James Butler, GSK
- Terry Way, USP
- Paul Dickinson, AstraZeneca
- James Mann, MSD

## MONDAY 12 DECEMBER

**09.30** **Registration**
Tea and coffee

**10.00** **Introductions (interactive) & Overview**
John Hempenstall, Consultant

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

**11.30** **Dissolution testing of non-oral dosage forms in context**
Paul Dickinson, Astra Zeneca

**12.15** **Dissolution test media for oral dose forms**
James Butler, GSK

**13.00** **Lunch**

**13.45** **Workshop 1**
**Selection of media 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, USP

**17.30** **Close of day's programme**

**19.00** **Dinner**

## TUESDAY 13 DECEMBER

**08.15** **Review of Day 1 with general discussion/Q&A**
John Hempenstall, 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, Astra Zeneca

**10.30** **Coffee break**

**10.45** **Regulatory requirements. How development data relate to compendial requirements (EP; JP; USP)**

**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**
Terry Way, USP

**15.15** **Tea**

**15.30** **Dissolution equipment qualification & method validation**
Terry Way, USP

**17.00** **Close of day's programme**

**17. 10** **Social programme**

**19.45** **Dinner**

# DAY 3

## WEDNESDAY 14 DECEMBER

**08.30** **Review of Day 2 with general discussion/ Q&A**
John Hempenstall, Consultant

**09.00** **In vitro/ in vivo relationships (IR & MR dose forms)**
James Mann, MSD

**10.15** **Coffee break**

**10.30** **Using dissolution tests to demonstrate dose form equivalence - F2 tests & biowaivers**
John Hempenstall, Consultant

**12.00** **Lunch**

**13.00** **Workshop 3 Biowaivers**
John Hempenstall, Consultant

**15.00** **Summary of course & immediate feedback**
John Hempenstall, Consultant

**15.30** **Close of meeting**

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 Møller Centre is a modern and purpose-built conference and training venue in the grounds of Churchill College – easily accessible by road, train and air. Car parking facilities are available.

The Møller Centre
Storey's Way
Cambridge
CB3 0DE

REGISTRATION FORM

# Dissolution testing for the pharmaceutical industry

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## 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
- Fees with accomodation include two nights at the Moller Centre and evening meals

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

| MEMBERS | Early bird fee (before 19.09.11) | Full fee |
|---|---|---|
| Course only | ☐ £1145 | ☐ £1305 |
| Course + accommodation + evening meals | ☐ £1435 | ☐ £1595 |
| **NON-MEMBERS** | **Early bird fee (before 19.09.11)** | **Full fee** |
| Course only | ☐ £1200 | ☐ £1360 |
| Course + accommodation + evening meals | ☐ £1490 | ☐ £1650 |

## 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 **70378193**
National Westminster Bank, 91 Westminster Bridge Road, London SE1 7ZB)
Quoting reference: **MMS EVT 439**

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|---|---|
| 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

The contact details you have provided may be used to keep you informed about future RPS Events, products and services. If you do not wish to receive such information by any of the methods listed, please indicate by ticking the corresponding box: Post ☐ Telephone ☐ Email ☐ All ☐

**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.