



Image: Bayer Schering Pharma

SPEAKERS

**DR CHRISTOPHER
BURGESS**

Burgess Analytical
Consultancy, UK

DR THOMAS FÜRST
Boehringer Ingelheim

DR KERSTIN PAULI
Bayer Schering Pharma

DR JOCHEN SCHER
Boehringer Ingelheim

Dissolution Testing

Visit the Dissolution Laboratories at Bayer Schering Pharma AG in Berlin

13 – 15 October 2010, Berlin, Germany

HIGHLIGHTS:

- Regulatory Requirements (Pharmacopoeias, etc.)
- Equipment Qualification (USP Requirements versus FDA Guidance)
- Development of Dissolution Methods
 - How to Set Specifications
 - Analytical Validation
 - Practical Recommendations
- OOS Results in Dissolution Testing
- The Role of Biowaivers During Drug Product Development
- Dissolution Profile Comparison
- Automation of Dissolution Methods

Objectives	<p>This conference on Dissolution Testing aims at providing delegates with a sound understanding of the principles and practices in dissolution testing, which has become increasingly important in pharmaceutical industry.</p> <p>A visit of the new dissolution laboratory at Bayer Schering Pharma is part of the course programme.</p>
Background	<p>Dissolution tests are a key tool in drug development and in quality control. In these fields they are used to assure batch-to-batch quality, to provide process control and to substitute in vivo studies under certain circumstances – mainly for solid dosage forms.</p> <p>The FDA has issued several guidances on this topic dealing with</p> <ul style="list-style-type: none"> ■ approaches for setting specifications ■ the relation to the biopharmaceutical characteristics of the drug substance ■ dissolution methodology, apparatus, and operating conditions, ■ validation of the dissolution methodology and ■ statistical methods for comparing dissolution profiles. <p>These items will be covered in this course. In addition, the questions and expectations of the European Medicines Agency (EMA) and of the pharmacopoeias (Ph.Eur. 2.9.3 and USP General Chapters <711> and <1092> including USP Reference Standard Tablets for the Performance Verification Test) will be discussed.</p> <p>The objective of this conference is to cover all aspects of dissolution testing with a focus on practical examples. Workshops are an essential part of the course in order to encourage the exchange of experience and to allow interactive and in depth discussions of the subject.</p>
Target Audience	<p>This conference is dedicated to scientists and managers in the pharmaceutical industry working in:</p> <ul style="list-style-type: none"> ■ Quality control ■ Quality assurance ■ Analytical development ■ Research and development ■ Regulatory Affairs <p>The course is also intended for participants from contract laboratories, regulatory authorities, and inspectorates.</p>
Moderator	DR CHRISTOPHER BURGESS , <i>Burgess Analytical Consultancy Ltd., UK</i>
Programme	<p>Dissolution Testing and Qualification from a Pharmacopoeial Perspective</p> <ul style="list-style-type: none"> ■ Requirements of the USP & EP ■ Qualification and calibration ■ Harmonisation of methods ■ Key differences between the USP and EP ■ FDA and ASTM activities ■ Related methodologies: disintegration and friability <p>DR CHRISTOPHER BURGESS, <i>Burgess Analytical Consultancy</i></p> <p>Regulatory Requirements for Dissolution Testing</p> <ul style="list-style-type: none"> ■ What guidelines tell us about <ul style="list-style-type: none"> – Biorelevant methods – In vivo – in vitro correlations – Profile Comparison – Setting of Specifications <p>DR THOMAS FÜRST, <i>Boehringer Ingelheim</i></p> <p>Automation in Dissolution Testing</p> <ul style="list-style-type: none"> ■ Presentation of different types of dissolution systems ■ Pros and cons of the various dissolution systems ■ When to use what type of equipment ■ Innovation in automation: the new RoboDis® <p>DR KERSTIN PAULI, <i>Bayer Schering Pharma</i></p>

Programme (cont'd)

Setting Specifications for Dissolution Methods

- Setting of specifications for various formulations (Immediate Release, Modified Release and Delayed Release)
- Requirements of Pharmacopoeias
- Presentation of relevant Guidelines
- Release- and Shelf life specification
- Special Dosage Forms (e.g. replacement of dissolution by disintegration)

DR KERSTIN PAULI, *Bayer Schering Pharma*

WORKSHOP I

Equipment Qualification including USP Performance Verification

- Control of mechanical, technical and dimensional tolerances
- Computerised system validation aspects
- Holistic testing of dissolution systems

Moderator: Dr Christopher Burgess

Development of Dissolution Methods with regard to Quality Control

- Points to Consider During Method Development
 - Dissolution Apparatus
 - Medium Selection and
 - Key Operating Parameters
- Discriminatory Capability of the Dissolution Method
- Dissolution methods for developing an IVIVC

DR JOCHEN SCHER, *Boehringer Ingelheim*

WORKSHOP II

Setting Specifications

The aim of the workshop is to demonstrate on certain case studies:

- How to adopt the requirements of the various Guidelines and Pharmacopoeias
- How to assign acceptance criteria for different types of formulations
- Replacement of dissolution by disintegration (decision tree 7 of the ICH Guideline Q6A)

Moderator: Dr Kerstin Pauli

Analytical Validation of Dissolution Testing Methods

- Pharmacopoeial and Regulatory Recommendations (e.g. ICH Q2 (R1) and USP <1092>)
- Validation characteristics:
 - Specificity, Linearity, Precision, Accuracy and Robustness,
 - Furthermore:
 - filter-validation
 - selecting the right deaeration method
 - validation of automated methods
- Some practical recommendations for performing the validation and recommended acceptance criteria
- Dissolution Method Transfer

DR JOCHEN SCHER, *Boehringer Ingelheim*

WORKSHOP III

Analytical Validation of Dissolution Methods

Putting theory to work (case studies):

- Develop Validation Protocol for Validation of Dissolution Methods for different solid oral dosage forms
- Pitfalls in performing the experiments

Moderator: Dr Jochen Scher

Programme (cont'd)

OOS Results in Dissolution Testing

- When is a result OOS and when is it not?
- Performance verification issues
- Failure investigations in dissolution testing
- Are statistical outlier tests useful as part of dissolution test failure investigations?
- Documenting the outcome of the failure investigation.

DR CHRISTOPHER BURGESS, *Burgess Analytical Consultancy*

The Importance of Biowaiving in Drug Product Development

- Overview of regulations
- Differences between US/EU and Japan
- The role of biowaivers during drug product development
- Types of biowaivers e.g. BCS based, proportional similar products
- What data are necessary
 - how to select batches
 - how many batches need to be compared
 - media selection

Case Studies (Phase III - commercial, additional strength, fixed dose combination)

DR THOMAS FÜRST, *Boehringer Ingelheim*

Dissolution Profile Comparison; Approaches and Issues

- Dissolution processes and data variability
- What are we trying to compare?
- What do the agencies specify?
- Model independent approaches
- Examples of approaches

DR CHRISTOPHER BURGESS, *Burgess Analytical Consultancy*

Application for a Marketing Authorisation: Data Required for the Justification and for the Submission of Dissolution Methods

- Required data and dissolution profiles
- Justification of discriminatory power and robustness of the dissolution method
- Selection of the analytical method
- Method transfer on automatic systems

DR KERSTIN PAULI, *Bayer Schering Pharma*

Visit of the Dissolution Laboratories at Bayer Schering Pharma AG, Berlin

In the afternoon of the second course day all participants and speakers are invited to a guided tour to the new dissolution laboratory at Bayer Schering Pharma AG in Berlin. The dissolution lab is equipped with various automated dissolution systems applicable to cover multiple aspects occurring during research and development:



- The new RoboDis: several fully automated robotic system (equipped with HPLC-, UV/ VIS- and fibre optics technology) developed in cooperation with ERWEKA
- Several semi-automated UV/VIS systems
- Semi-automated "Paddle-over disk" dissolution system



- Fully automated Sotax AT 70 smart dissolution systems



- Various semi-automated HPLC-systems

There will be a bus transfer to the laboratory and back to the hotel.

The number of participants for the lab visit is limited.

Speakers

DR CHRISTOPHER BURGESS



Burgess Analytical Consultancy Limited, UK

Dr Burgess is a Chartered Chemist and has more than 30 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" and a qualified ISO Guide Assessor and was a member of the PDA (US) Scientific Advisory Board on 'OOS Task Force'.

DR THOMAS FÜRST



Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany

Dr Fürst is Senior Principal Scientist at the Development Unit of Boehringer Ingelheim. He is responsible for the scientific quality of submissions and the QOS. Before joining Boehringer Ingelheim, Dr Fürst was with Schering AG, Berlin, where he worked in a production facility for oral dosage forms and the analytical development department before heading the Pharmaceutical Development Services group of Schering AG, Berlin.

DR KERSTIN PAULI



Bayer Schering Pharma AG, Berlin, Germany

Kerstin Pauli studied Food Chemistry and Pharmacy at the University of Bonn and received her PhD in Pharmaceutical Analytics. In her position as head of Dissolution Testing in Global Drug Development within Bayer Schering Pharma she is responsible for all aspects regarding dissolution testing of development projects (including development and validation of dissolution methods, submission of development projects and handling of post approval changes, life cycle management and patent protection of market products) and also for automation in dissolution testing (Robot Technology).

DR JOCHEN SCHER



Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany

Dr. J. Scher studied pharmacy and conducted his PhD at the University of Saarland at the Institute of Pharmacognosy and Analytical Phytochemistry and part time at the University of Otago. He is a specialised pharmacist for pharmaceutical analytics and since five years he is working at Boehringer Ingelheim GmbH & Co. KG in Biberach (Germany). He is laboratory head in the Analytical Development and responsible for a dissolution unit.

Social Event

We are looking forward to welcome all participants and speakers to a nice evening in a relaxed atmosphere after the first course day.



GMP Certification Programme

This course is recognised within the GMP Certification Programme Module "Pharmaceutical Quality Control Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

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Date

Wednesday, 13 October 2010, 9.00 h – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Thursday, 14 October 2010, 8.30 h – 18.30 h
Friday, 15 October 2010, 08.30 – 15.30 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Germany
Phone + 49 / (0) 30 / 2127 - 0
Fax + 49 / (0) 30 / 2127 - 799

Fees

Non-ECA Members € 1,990.- per delegate plus VAT
ECA Members € 1,791.- per delegate plus VAT
APIC Members € 1,890.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates € 995.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice
and includes conference documentation, dinner on the first day,
lunch on three days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in
the conference hotel. You will receive a room reservation form
when you have registered for the event. Please use this form for

your room reservation or be sure to mention "VA 6383 ECA Event"
to receive the specially negotiated rate for the duration of your
stay. Reservation should be made directly with the hotel not later
than 10 September 2010. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Conference language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG
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69007 Heidelberg, Germany
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For questions regarding content:

Dr Günter Brendelberger (Operations Director) at
+49-62 21 / 84 44 39, or per e-mail at
brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Susanne Ludwig (Organisation Manager) at +49-62 21 / 84 44 44, or
per e-mail at ludwig@concept-heidelberg.de.

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Dissolution Testing

13 – 15 October 2010, Berlin, Germany

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Department

Important: Please indicate your company's VAT ID Number

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