ECA
European Compliance Academy

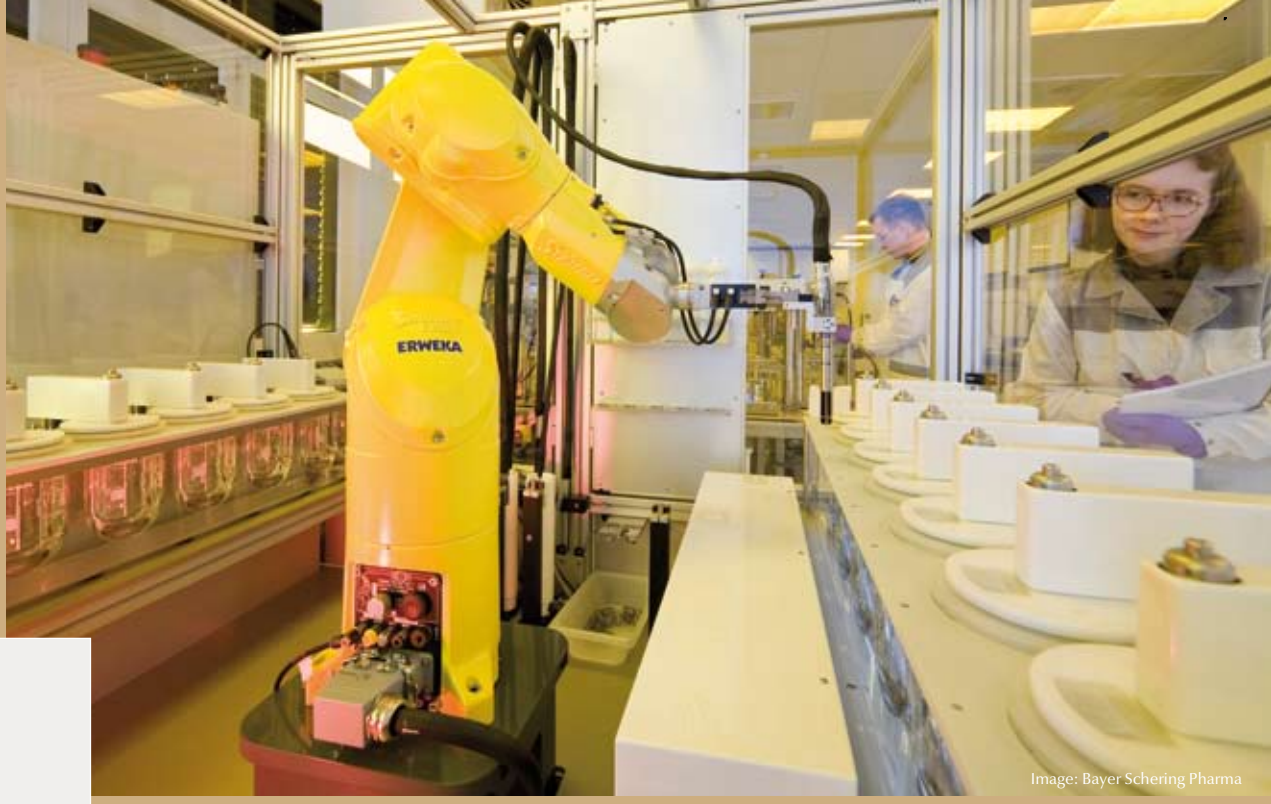


Image: Bayer Schering Pharma

Dissolution Testing

Visit the Dissolution Laboratories at Bayer HealthCare Pharmaceuticals in Berlin

2 - 4 November 2011, Berlin, Germany

SPEAKERS

DR CHRISTOPHER BURGESS
Burgess Analytical Consultancy, UK

DR THOMAS FÜRST
Boehringer Ingelheim

DR KERSTIN PAULI
Bayer HealthCare Pharmaceuticals

DR JOCHEN SCHER
Boehringer Ingelheim

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

This conference is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager“. Please find details at www.gmp-certification.eu

Dissolution Testing

2-4 November 2011, Berlin, Germany

Objectives

This GMP Education Course 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.

A visit of the new dissolution laboratory at Bayer HealthCare Pharmaceuticals is part of the course programme.

Background

The dissolution test is a key performance test of solid oral dosage forms in drug development and quality control. In these fields it is used to assure batch-to-batch quality, to provide process control and to substitute in vivo studies under certain circumstances – mainly for solid oral dosage forms.

Several authorities (e.g. FDA, EMA) issued guidances on this topic dealing with

- 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
- statistical methods for comparing dissolution profiles
- approaches for substitution of BE studies (biowaiver) and
- approaches to establish in vitro in vivo correlations (IVIVC).

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 Chapter <711> and General Information <1092> including USP Reference Standard Tablets for the Performance Verification Test will be discussed.

The objective of this course 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.

Target Audience

This conference is dedicated to scientists and managers in the pharmaceutical industry working in:

- Quality control
- Quality assurance
- Analytical development
- Pharmaceutical Development
- Research and development
- Regulatory Affairs

The course is also intended for participants from contract laboratories, regulatory authorities, and inspectorates.

Moderator

DR CHRISTOPHER BURGESS, *Burgess Analytical Consultancy Ltd., UK*

Programme

Dissolution Testing and Qualification from a Pharmacopoeial Perspective

- 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

DR CHRISTOPHER BURGESS, *Burgess Analytical Consultancy*

Regulatory Requirements and Beyond

- What guidelines tell us about
  - Biorelevant methods
  - In vivo – in vitro correlations
  - Profile Comparison
  - Setting of Specifications

and how this is put into practice

DR THOMAS FÜRST, *Boehringer Ingelheim*

Programme (cont'd)

Automation in Dissolution Testing

- Objectives of automation
- Presentation of different types of dissolution systems:
  - area of application
  - discussion about pros and cons
- Innovation in automation: the new RoboDis®

DR KERSTIN PAULI, *Bayer HealthCare Pharmaceuticals*

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

Setting Specifications for Dissolution Methods

- Setting specifications for various formulations:
  - Immediate Release Formulations
  - Modified Release Formulations
  - Delayed Release Formulations
  - Special Dosage Forms (e.g. replacement of dissolution by disintegration)
- Special needs in pharmaceutical industry
- Requirements of Pharmacopoeias
- Presentation of relevant Guidelines

DR KERSTIN PAULI, *Bayer HealthCare Pharmaceuticals*

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

Moderator: Dr Kerstin Pauli

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*

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

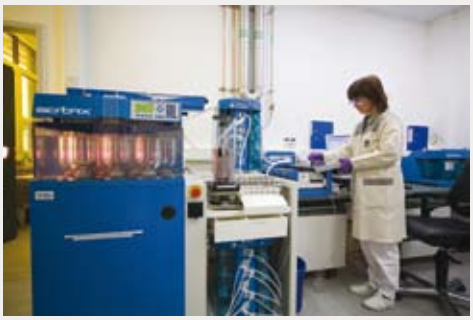
DR CHRISTOPHER BURGESS, Burgess Analytical Consultancy

Application for a Marketing Authorisation: Data Required for the Justification and for the Submission of Dissolution Methods
- Rationale for determining method parameters
- Justification of discriminatory power
- Proof of robustness of the dissolution method
- Selection of the analytical method
- Method transfer on automatic systems

DR KERSTIN PAULI, *Bayer HealthCare Pharmaceuticals*

Visit of the Dissolution Laboratories at Bayer HealthCare Pharmaceuticals, Berlin
In the afternoon of the first course day all participants and speakers are invited to a guided tour to the new dissolution laboratory at Bayer HealthCare Pharmaceuticals 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 36 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" and a member of the European QP Association advisory board. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and is a visiting professor of the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the chairman of the ECA Analytical Quality Control Group and a member of the Executive committee of European Compliance Academy.

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 HealthCare Pharmaceuticals, 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 a group of project laboratories in Global Drug Development within Bayer HealthCare Pharmaceuticals she is responsible for all aspects regarding the analytical part of product development. In her first position she was specialised in the area of dissolution testing (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).

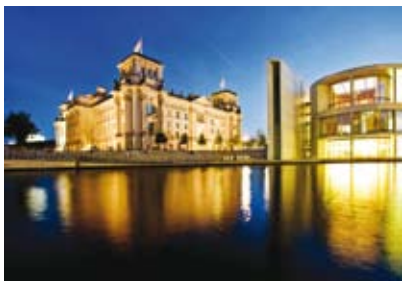
DR JOCHEN SCHER

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 for six 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:

- ECA Validation Manager
- ECA QA Manager
- ECA API Production Manager
- ECA Quality Control Manager
- ECA Technical Operations Manager
- ECA Computer Validation Manager
- ECA Regulatory Affairs Manager
- ECA Microbiological Laboratory Manager
- ECA Sterile Production Manager
- ECA Biotech Manager
- ECA Pharmaceutical Development Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Wednesday, 2 November 2011, 9.00 h – 18.00 h
(Registration and coffee 8.30 h – 9.00 h)
Thursday, 3 November 2011, 8.30 h – 18.30 h
Friday, 4 November 2011, 08.30 – 15.30 h

Venue
Esplanade Grand Hotel Berlin
Lützowufer 15
10785 Berlin
Germany
Phone: + 49 / (0) 30 / 25478 0
Fax: + 49 / (0) 30 / 25478 8617

Fees
ECA Members € 1,790.- per delegate plus VAT
APIC Members € 1,890.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,990.- per delegate plus VAT
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 6920 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 30 September 2011. 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
P.O. Box 10 17 64
69007 Heidelberg, Germany
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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
2 - 4 November 2011, Berlin, Germany

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If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
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Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!