BII WORLD
Engage • Enlighten • Empower

PHARMACEUTICAL DISSOLUTION TESTING

Solid Oral Dosage Forms Focus

Join our BII World global industry expert & instructor:
Mark Powell and transform your learning experience.

16 Hours In-person Learning Experience

12-13 May 2025 | Amsterdam, Netherlands

09:00 - 17:00 Central European Time (CET)

www.biiworld.com

INTRODUCTION:

Pharmaceutical dissolution test results are influenced by a large number of physical and chemical parameters. Regulators expect that dissolution tests will be robust, adequately precise and, for poorly-soluble drugs, discriminating. This two-day in- person course is aimed at those developing or performing dissolution tests for solid oral dosage forms. It would also be useful for regulatory professionals who would like to understand more about reviewers' expectations. The 16 hrs face to face course incorporates relevant guidance from the recent ICH Q14 (Analytical Procedure Development) and the updated ICH Q2 (Validation of Analytical Procedures).

LEARNING OBJECTIVES:

By attending this course, delegates will:

- Understand the theory behind drug dissolution
- Appreciate the potential and limitations of *in vitro* dissolution as a predictor of *in vivo* performance, including the uses of biorelevant dissolution media
- Learn when a dissolution test should be discriminating and how to demonstrate discriminating ability
- Be able to troubleshoot anomalous dissolution test results in a logical, scientifically sound manner and appreciate the importance of equipment qualification
- Understand how to approach dissolution method development and validation

WHO SHOULD ATTEND:

- Analytical development scientists
- Analytical development managers
- Quality control scientists
- Quality control managers
- Quality assurance professionals
- Formulation development scientists who perform dissolution testing
- Regulatory affairs professionals
- Consultants

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Instructor:

MARK POWELL

… your EXPERT TRAINER for this Course.

Mark Powell is a Fellow of the Royal Society of Chemistry (RSC) with over thirty years' experience as an analytical chemist. He is an expert in sampling and sample preparation, chromatography (liquid and gas), spectroscopy (atomic and molecular) and pharmaceutical dissolution testing. Mark was Honorary Treasurer of the RSC's Analytical Division and led a working group on continuing professional development until July 2016.

A PhD in analytical chemistry, he worked at a senior level in a number of industrial laboratories with responsibility for the development of analytical methods capable of quantifying very low levels of organic compounds in a wide range of different sample types. These included pharmaceutical rawmaterials, drinking water, industrial effluent and marine biota.

Mark joined Liverpool John Moores University's School of Pharmacy and Chemistry in 1997 as a Senior Lecturer, teaching chromatography, mass spectrometry and sample preparation. He was Programme Leader for the University's MSc in Instrumental Chemical Analysis and was also active in research and consultancy.

In 2003, he joined the newly-formed Quay Pharmaceuticals, a contract research and manufacturing organisation specialising in early-stage drug development, where he set up the analytical facility and managed the analytical development programme. The majority of projects involved novel small drug molecules presented in solid oral dosage forms, although nasal and transdermal products were also formulated. Mark and his team successfully tackled the job of developing suitable analytical methods for a number of challenging sample types, including low-dose drugs in oily or poorly-soluble matrices, and combination products with orders-of-magnitude differences between the highest-strength and lowest- strength active ingredients.

In 2010 Mark was appointed Quay's Scientific Manager, becoming involved more generally with drug development programmes and establishing collaborations with a number of UK universities and instrument manufacturers. His work at Quay has resulted in a number of published papers and presentations at international scientific conferences on topics as diverse as the adulteration of herbal medicines and novel methods of analysis for volatile impurities. In addition, he led GMP audits of contract analytical laboratories used by Quay and developed internal training programmes in analytical chemistry and technical report writing. Mark left Quay Pharmaceuticals in September 2013 to set up Mark Powell Scientific and has enjoyed working with companies of all sizes around the world on a variety of training, consultancy and expert witness assignments.

PRESENTATIONS:

Day 1:

09:00 - Introductions

09:15 -Session 1:

Challenges and Opportunities in Dissolution Testing

- Reason for dissolution testing
- Dissolution testing apparatus – characteristics, applications, and apparatus limitations
- Achieving adequate drug solubility
- Regulatory acceptability

10:15- Session 2:

Dissolution and Oral Bioavailability

- When could we expect a correlation between in vitro and in vivo performance?
- Biopharmaceutics Classification System (BCS)
- Developability Classification System (DCS)
- Factors affecting dissolution rate

Break

10:30- Session 3:

Regulatory expectations for Drug Release & Specification Limits

- Demonstrating discrimination
- Requirements for different dosage form types (including data interpretation)
- Immediate release
- Extended release
- Delayed release

12:00 - Lunch

12:45 – Session 4 -Dissolution Testing Apparatus for Solid Oral Drug Products

- Rotating basket (USP Apparatus 1)
- Rotating paddle (USP Apparatus 2)
- Reciprocating cylinder (USP Apparatus 3)
- Flow-through cell (USP Apparatus 4)
- Reciprocating holder (USP Apparatus 7)
- Non-compendial approaches (including small-volume apparatus and apex vessels)

13:15 – Case Study – basket/paddle comparison

13:30 – Session 5

Dissolution Method Development and Validation - I

- General requirements
- Selection of dissolution medium
- Biorelevant dissolution media
- Apparatus and agitation rate
- Approaches for suspensions and semi-solid dosage forms (including suppositories)

14:15 – Break

14:30 – Session 6

Dissolution Method Development and Validation - II

- Sampling (time points & filtration)
- Setting meaningful method validation acceptance criteria
- Specificity – UV vs. HPLC
- Robustness – risk-based approach
- Solution stability

15:30 – Case Study – Troubleshooting anomalous results

16:00 - Post - Session Q &A

16:30 – End of Day 1

Day 2:

09:00 – Session 7

Troubleshooting Dissolution Methods

- Equipment set-up and sample introduction errors
- Sample introduction
- Sampling and filtration
- Causes of result variability
- Calculation error

09:15 – Session 8

Qualifying Dissolution Apparatus

- USP vs. US FDA approach
- Relationship between mechanical parameters and result variability
- Requirements of the US FDA's enhanced mechanical approach

10:15 – Break

10:30 – Session 9

Biorelevant Dissolution & Problems with Oral Products

- Biorelevant media options
- Slowly-dissolving and low-dose products
- Dealing with labile drugs

12:00 – Lunch

12:45 – Session 10

Evaluating Bioavailability and Bioequivalence

- Definitions
- Methods for establishing bioavailability
- Methods for establishing bioequivalence

13:45 – Session 11

Case Study – developing a dissolution method for a poorly-soluble drug

14:15 – Break

14:30 – Session 12

Case Study/Workshop – Challenges in Dissolution Development

A selection of case studies illustrating regulatory expectations for dissolution methods and common deficiencies

Delegates will have an opportunity to discuss their own examples

16:00 - Post – Session/Course Q &A

16:30 – End of Day 2 and Course

FAQs

Does BII Online Virtual Training have the same value as traditional classroom training?

Yes, BII Online Virtual Training offers participants; same training system as in-person, i.e face-to-face engagement with instructors, course material, interactive participation of all delegates, and personal support that they would expect to find in a traditional classroom.

What are main features of your online courses? Are they on-demand? Is it different content from the in-person offering?

The content of the virtual training is similar to the in-person sessions and customized presentation makes it a richer online learning experience. As always, we will share presentation materials with attendees for later reference.

The online courses are not on-demand and recordings cannot be purchased. They are set on scheduled dates, live with an instructor and co-host via webinar software. While the day is shorter than an in-person session (4hrs vs 8hrs), timing are adjusted to accommodate attendees in different time zones and allow more time for one-on-one conversations via the Q & A.

What are the technical requirements for participation in a virtual course?

All you need to participate in virtual training are:

- Desktop or Laptop or Tablet Computer, and Internet connection
- Webcam
- Headset with built-in microphone

Can I attend an online training session if I have a Macintosh computer?

Yes, Our Online training systems does allow Macintosh computers, PCs, and computers running Linux to easily enter any of our online training sessions.

What type and version of browser will I need for online classes?

It is recommended that you use the latest version of Firefox, Chrome or Internet Explorer for Windows and Firefox or Safari for Mac. Each of these is available for free download and also suggested you have the PDF Reader

How do I have access to the trainer for questions?

As in the classroom, you will see the trainer in front of you and have the opportunity to ask questions at any time - all via audio and video transmission.

Is there a mute option within an online training session to minimize background noise from my audio connection?

Yes, the Mute button will display to the right of your name as you hover your mouse over your name shown in the Participants panel on the top, right side of the Web conferencing screen.

What if I miss few sessions of the online training program?

The training will be simultaneously recorded which will be provided to you as per request & requirement

Do I get a Certificate at the end?

Yes, you will get a PDF version of your certificate of completion

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Pharmaceutical Dissolution Testing

12 - 13 May, 2025 | Amsterdam

BII World Limited
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Northwest, Edmonton, AB
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Please complete this form and send it back to
mithun.siddartha@biiworld.com

Event Code: EU LS 04

Delegate Details

1. Name: Mr/Mrs/ Ms .....
   .....
   Job Title: .....
   Email: .....
2. Name: Mr/Mrs/ Ms .....
   .....
   Job Title: .....
   Email: .....
3. Name: Mr/Mrs/ Ms .....
   .....
   Job Title: .....
   Email: .....

Company/Organisation Detail

Name: .....
Person to Contact:.....
Email: .....
Address: .....
.....
City: .....
Country: .....
Contact No: .....
Type of Business: .....
Website: .....

PAYMENT METHOD:

CREDIT CARD OR ONLINE PAYMENT ☐
The secured payment link will be shared/sent

WIRE TRANSFER ☐

Authorization and Acceptance of Sales Contract & Terms & Conditions

I hereby declare I am authorised to sign this contract and terms & conditions in the name of the company/organisation:

Name:.....

Date:.....

Signature:.....

Delegate Fee ☐ **€ ~~2299~~ per delegate**
Delegate Fee ☐ **€ 2099 per delegate**

*(Early Bird until December 22nd, 2024)

20 USD administration charge and any applicable withholding or any other tax or fee will be applied

TERMS & CONDITIONS:

1. Payment terms: BII World LTD requires the full payment of the invoiced amount within 7 working days from the issue date of the invoice. BII World LTD reserves the right to refuse entry to any client who does not pay the invoice in full and on Ãme. The registraÃon fee includes: Training documentaÃon and admission to all training sessions.

2. CancellaÃon by client: The client has the right to cancel his/her parÃcipaÃon in the event. CancellaÃon must be received by BII World LTD in wriÃng either by mail or fax. If the client cancels the event, he/she will get two opÃons:

A. CREDIT NOTE: Choose 2-year credit note, BII World LTD will send all the schedule training event details throughout the year. Delegate has the right to choose and aÃend any of the training programs (valid 2 years).

B- NOMINATION: In this opÃon delegate can nominate/refer someone from his/her group/company to aÃend the parÃcular training program on behalf of the actual delegate.

3. CancellaÃon by BII World LTD : While every reasonable effort is made to adhere to the adverÃsed program, circumstances can arise which may cause changes in the program, including but not limited to changes in the content, date(s), or special features of the planned event. Such circumstances include but are not limited to acts of terrorism, war, extreme weather condiÃons, compliance with government requests, orders and legal requirements, failure of third-party suppliers to Ãmely deliver, and failure to register the minimum target number of aÃendees for a given event. BII World LTD reserves the right to change the content, date(s), and/ or special features of an event, to merge the event with another event, or to postpone it or cancel it enÃrely as appropriate under the circumstances. Client agrees that BII World LTD shall not be liable for any cost, damage or expense which may be incurred by client as a consequence of the event being so changed, merged, postponed or cancelled and client agrees to hold BII World LTD harmless and to indemnify BII World LTD in case of liability caused by any such changes, mergers, postponements or cancellaÃons.

4. CancellaÃon of the event: In case BII World LTD cancels an event, then client can choose any of the below menÃoned opÃons:

(a) BII World LTD will refund full payment to the client within 15 business days.
(b) Client can choose the credit opÃon for 2 years, for more details please read term no-2 part (a)

5. Postponement of the event : In case BII World Ltd postpones the event to a new date, then client can choose any of the below menÃoned opÃons.

(a) The client can aÃend the course on the postponed dates.
(b) Client can choose the credit opÃon for 2 years, for more details please read term no-2 part (a)

6. Client's idenÃficaÃon informaÃon. By signing of this sales contract and these terms and condiÃons the client gives full right to BII World LTD to share the client's idenÃficaÃon informaÃon, i.e. client's name, address, email addresses, phone numbers and names of representaÃves and website with other clients who parÃcipated in the same event. The client has the right to opt out of this clause by wriÃen noÃce to BII World LTD.

7. Governing law: This contract shall be governed by and construed in accordance with the laws of the Pr ovince of Alberta, Canada. Any disputes arising under or in connecÃon with this registr aÃon form shall be seÃled bef ore the competent court in Canada.

8. IndemnificaÃon: To the fullest extent permiÃed by the law, you agree to protect, indemnify, defend and hold harmless BII World LTD, its owners, managers, partners, subsidiaries, affiliates, officers, directors, employees and agents, from and against any and all claims, losses or damages to persons or property, governmental charges or fines, penalÃes, and costs (including reasonable aÃorney's fees) (collecÃvely "the Claims"), in any way arising out of or relaÃng to the event that is the subject of this contract, and regardless of negligence, included but not limited to, Claims arising out of the negligence, gross negligence or intenÃonal misconduct of BII World LTD employees, agents, contractors, and aÃendees; provided, however, that nothing in this indemnificaÃon shall require you to indemnify BII World LTD Indemnified parÃes for that porÃon of any Claim arising out of the sole negligence, gross negligence or intenÃonal misconduct of the BII World LTD parÃes.

9. Other currencies. In case that client requests payment in other than official currency (USD), BII World LTD reserves the right to apply 5% currency risk surcharge to the actual exchange rate.

10. Other CondiÃons: Any terms or condiÃons contained in the client's acceptance which contradict or are different from the terms and condiÃons of this registraÃon document shall not become part of the contract unless individually negoÃated with BII World LTD and expressly accepted by BII World LTD.