

Gain critical feedback from
Regulators to reduce costly
compliance risks

Comprehensive User Testing of the Patient Information Leaflet

Ensure your company has full confidence
in their User Testing strategy and help
maximise patient safety

Tuesday 15th - Wednesday 16th May 2007,
Danubius Hotel Gellert, Budapest, Hungary

Key Benefits:

- Learn best practice for bridging studies and hear how these can be used to demonstrate compliance with article 59(3)
- Interactive breakout sessions will allow you to practice setting up, conducting and maintaining the necessary standards of process for User Testing
- Gain access to regulatory, academic and consultancy advice, learning how and when to apply a User Test to PILs and who should be involved in the test process
- Hear case studies presented by three expert consulting companies and ensure the information you provide is legible, clear and easy to use

Your course leaders include:

- **Klaus Menges**, *Scientific Quality Assurance in the Unit Strategy and Plannings*, **BfArM, Germany**
- **Marion Schaefer**, *Professor and Lecturer at Charité University Medicine Berlin*, **Institute of Clinical Pharmacology, Germany**
- **Dave Trotter**, *Senior User Testing Consultant*, **Unicus, UK**
- **Angela Gisby**, *Director*, **Spectrum Regulatory Solutions, UK**
- **Diana Taylor**, *Medical Writer & In-house Instructor*, **PAREXEL, International GmbH, Germany**
- **Alison Turner**, *Product Information & User Testing Consultant*, **Unicus, UK**
- **Borislav Borissov**, *Managing Director*, **Prescriptia LLC, Bulgaria**

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Welcome to Informa's practical training course dedicated to comprehensive User Testing of the Patient Information Leaflet.

New legislation has recently been introduced requiring those responsible for the writing of Patient Information Leaflets to make sure that these have been drawn up to take into account the needs of the patients.

Are you confident that your PIL will receive approval first time?

Ensure your company has a robust User Testing strategy.

How many rounds of User Testing are appropriate?

What language should I use when submitting with the MRP and DCP?

Join us in Budapest, May 2007, and have all your questions answered. This two day practical training course will ensure you are adhering to the EU rules and helping your patients battle the jargon. You will leave feeling confident and prepared for your next regulatory challenge.

Here's what last year's delegates had to say . . .

“Very good conference – informative, useful and full of practical advice”

Sandoz, 2006

“Good experienced speakers with a good style of lecturing”

Agency for Medicinal Products and Medical Devices,
Croatia, 2006

Who should attend?

- Regulatory Affairs Managers and Executives with responsibilities for new Marketing Authorisation Applications
- Those who have a portfolio of currently marketed products which need to be brought into compliance
- Packaging and Labelling Managers
- Country Registration Managers
- User Testing Consultants

...and many more

Any Questions?

If you have any questions regarding the agenda or content, please contact:

Gemma Burns, Conference Producer, Tel: +44 (0)207 017 7134 or email: gemma.burns@informa.com

For information on press and PR please contact:

Shona Kelly, Marketing Manager, Tel: +44 (0)207 017 6782 or email: shona.kelly@informa.com

For group bookings of three or more delegates, excellent discounts are available, please contact:

Simon Lau, Tel: +44 (0)207 017 7165 or email: simon.lau@informa.com

Conference Day One Tuesday 15th May 2007

09:00 Registration and coffee

09:30 Introduction from the Chair
Angela Gisby, Director, Spectrum Regulatory Solutions, UK

09:40 Patient information and participation in decision making

- Examining information and e-health as a part of the new EU High Level Group on Health Technology Assessment
- Experience of providing information to special groups e.g. children and their parents in clinical research
- Technical opportunities for providing information to patients
- Suggestions for future developments

Borislav Borissov, Managing Director, Prescriptia LLC, Bulgaria

10:20 Readability testing report - Assessment from a Regulator's viewpoint

Regulatory
Perspective

- The revision of the Readability Guideline
- Different ways of testing
- Experience after the first 18 months
- Consequences from an Agency's perspective

Klaus Menges, Scientific Quality Assurance in the Unit Strategy and Plannings, BfArM, Germany

11:20 Coffee and networking break

11:50 Communicating with the patient across the lifecycle of a drug - from the clinical trial to the PIL

- How are the contents of a Subject Information and a PIL comparable?
- Differences between the participants in a clinical trial and patients using a drug
- User Testing and a subject's consent to participation in a clinical trial - differences and similarities of the two processes

Diana Taylor, Medical Writer & In-house Instructor, PAREXEL, International GmbH, Germany

12:30 Lunch

Case studies: Practical experiences with UT of the PIL

3 companies present detailed case studies on this topic.

13:40 Experiences of User Testing to date

- The need for User Testing of Patient Information Leaflets
- Basic assumptions for patient consultation and readability testing
- Order of events in a readability test
- Patient target groups and testing methods
- Experiences from readability tests in Germany

Marion Schaefer, Professor and Lecturer at Charité University Medicine Berlin, Institute of Clinical Pharmacology, Germany

14:40 Successful filing of User Tested PILs in the EU

- When is User Testing required during the product life cycle?
- Identifying key issues
- Points to consider for User Testing reports
- The review process and Regulatory Agency feedback

Alison Turner, Product Information & User Testing Consultant, Unicus, UK

15:40 Networking break

16:10 Lost in translation? Realities, practicalities and solutions in User Testing

- A User Testing consultant's experience in the UK
- PILs come in many shapes – how to apply User Testing to different forms of patient information
- A PIL's journey through User Testing: Use of case studies to demonstrate the challenges and solutions

Angela Gisby, Director, Spectrum Regulatory Solutions, UK

Our User Testing strategy wrong

17:10 Panel session

This is your opportunity to discuss areas of concern with our expert speaker panel. Ensure you come away with all your questions answered and take back successful User Testing strategies to your company.

[Marion Schaefer](#), *Professor and Lecturer at Charité University Medicine Berlin, Institute of Clinical Pharmacology, Germany*

[Angela Gisby](#), *Director, Spectrum Regulatory Solutions, UK*
[Borislav Borissov](#), *Managing Director, Prescriptia LLC, Bulgaria*

[Diana Taylor](#), *Medical Writer & In-house Instructor, PAREXEL, International GmbH, Germany*

[Alison Turner](#), *Product Information & User Testing Consultant, Unicus, UK*

17:40 Closing remarks from the Chair

17:50 End of day one

Conference Day Two Wednesday 16th May 2007

08.45 Morning coffee

09.00 Welcome back to day two and Chairman's comments

[Dave Trotter](#), *Senior User Testing Consultant, Unicus, UK*

09.15 Creating a "Parent PIL"

- The QRD template
- Writing styles
- Formatting
- Bridging reports
- Creating artwork

[Alison Turner](#), *Product Information & User Testing Consultant, Unicus, UK*

09.45 Breakout 1: Review of an existing document

[Dave Trotter](#), *Senior User Testing Consultant, Unicus, UK*

10.15 Group presentations and discussion

11.00 Coffee and networking break

11.30 Who does the testing and how?

- The skills sets required
- Methodology
- Who to test and where?
- What questions to ask
- Measuring the responses
- Checking for understanding
- Reporting the findings

[Dave Trotter](#), *Senior User Testing Consultant, Unicus, UK*

12.15 Breakout 2: Preparing a questionnaire

13.00 Lunch

14.00 Breakout 3: Introduction and preparation for role play

- Define roles
- Prepare

14.20 Conduct role plays

15.00 Role play feedback

15.20 Completing the process

15.45 Open forum for questions

16.00 End of training course

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ABPhM

The Association of Bulgarian Pharmaceutical Manufacturers is the only national branch organization, representing the 70 years old, local pharmaceutical industry through its active position on priority issues of pharmaceutical legislation and national drug policy development.

By its expert participation in the discussions on Human Medicines and Pharmacies Act amendment in 2002, the ABPhM contributed to the prospective harmonization of Bulgarian legislation with the European directives regulating the production and marketing of pharmaceutical products in the EU. Currently the Association of Bulgarian Pharmaceutical Manufacturers takes part in the vital final phase of the EU harmonization process in respect to its accession to the European Union in 2007.

ABPhM's main goal is to stimulate the manufacturing of high quality and affordable generic medicines, thus contributing to the highly restricted budget of the national healthcare system and ensuring a drug distribution system, which will provide access to drugs for all patient groups and healthcare providers.

ABPhM is a full member of the European Generic Medicines Association (EGA), which represents more than 500 pharmaceutical companies manufacturing generic products and active pharmaceutical ingredients.

For more information on the association visit: www.abphm.bg



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