

## Media Partners



### 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](http://www.abphm.bg)



Pharma Poland News is an English language information service covering the pharmaceutical sector in Poland. It includes weekly and monthly newsletters, both delivered by email in pdf format.

### Pharma Poland News: Weekly News Review contains:

- the latest pharmaceutical sector news
- news on the companies active on the Polish pharma market
- the most significant R&D and medical news
- news on world developments affecting the Polish pharmaceutical market.

### Pharma Poland News: Monthly Review and Analysis includes:

- the most recent statistics on the Polish pharmaceutical sector
- current trends and analyses of the climate on the market
- information on legislation governing the pharmaceutical sector in Poland
- information about conferences/trade shows.



Generics bulletin is the global generic industry's essential source of news and views on product launches, company deals, regulatory changes and patent pricing and reimbursement issues. Two formats: a weekly electronic newflash and a twice-monthly paper publication provide both immediacy and depth from a generics industry perspective. For further information please visit [www.generics-bulletin.com](http://www.generics-bulletin.com) or contact Val Davis at [val.davis@generics-bulletin.com](mailto:val.davis@generics-bulletin.com) or call +44 (0)1564 777550.

## EURALex

EURALex European Healthcare Law & Regulatory News (formerly ERA News)

EURALex provides a single source of broad spectrum European and national legal and regulatory news that affects the healthcare industries.

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EURALex's detailed analysis of European and national legal, IP decisions, and regulatory developments will guide you in planning your business strategy, keeping you ahead of your closest competitors.

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## Comprehensive User Testing of the Patient Information Leaflet

CQ5014C 11th-12th September 2006, Radisson SAS Grand, Sofia, Bulgaria  
Call Simon Lau for GROUP BOOKING DISCOUNTS +44 (0)20 7017 7165 or [simon.lau@uk.informa.com](mailto:simon.lau@uk.informa.com)

### FIVE EASY WAYS TO REGISTER Please remember to quote CQ5014C

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Web: [www.ibc-lifesci.com/readability](http://www.ibc-lifesci.com/readability)

### WHEN AND WHERE

11th – 12th September 2006  
Radisson SAS Grand  
4, Narodno Sabranie Square  
P.O.Box 549, 1000 Sofia, Bulgaria

Telephone: + 359 2 9334 334  
Fax: + 359 2 9334 335  
Web: [www.sofia.radissonsas.com](http://www.sofia.radissonsas.com)  
Email: [info.sofia@radissonsas.com](mailto:info.sofia@radissonsas.com)

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### PERSONAL DETAILS

Mr/Mrs/Ms \_\_\_\_\_

Job title \_\_\_\_\_ Department \_\_\_\_\_

Telephone \_\_\_\_\_ Fax \_\_\_\_\_

Email \_\_\_\_\_

### COMPANY DETAILS FOR INVOICING PURPOSES

Company name \_\_\_\_\_

Postal Address \_\_\_\_\_

Telephone \_\_\_\_\_ Fax \_\_\_\_\_

Nature of Business \_\_\_\_\_

Billing Address (if different from above) \_\_\_\_\_

### Documentation

Nothing compares to 'being there' but you need not miss out! Simply tick the box, send it with payment and your copy of the event documentation will be available 4 weeks after the event.

Documentation at £399 (no VAT)

Fax the form on +44 (0) 20 7915 5056. Alternatively, call Documentation on +44 (0) 20 7915 5055 or email: [documentation@iir-conferences.com](mailto:documentation@iir-conferences.com)

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Confirm your CANCELLATION in writing (letter or fax) before 25/08/06 and receive a refund less a 10% + VAT service charge. Should you cancel between this date and 04/09/06 then you will receive a refund less a 50% + VAT service charge. Regrettably, no refunds can be made for cancellations received less than one week prior to the conference. A substitute delegate is welcome at no extra charge.

Substantial discounts for new & candidate EU countries, as well as Small & Medium Sized Companies

Presenting IBC's inaugural course on...

# Comprehensive User Testing of the Patient Information Leaflet

Reduce the risk of PIL User Test report rejection and improve patient safety

11 & 12 September 2006

Radisson SAS Grand, Sofia, Bulgaria

## Your course checklist:

- ✓ In-depth guidance on User Testing regulation and what is expected of you
- ✓ Interactive breakout sessions to practice setting up, conducting and maintaining the necessary standards of process for User Testing
- ✓ Unique access to industry, regulatory and consultancy experts to help you work through areas of concern
- ✓ Full course notes and certificate of attendance

## Your course leaders:

- **Borislav Borissov**, *Managing Director, Prescriptia LLC, Bulgaria*
- **Peter Embley**, *Head of Regulatory Affairs, Ranbaxy, UK*
- **Dave Trotter**, *Head of User Testing, Unicus, UK*
- **Britta Ginnow**, *Head of National Authorisations, The German Pharmaceutical Industry Association (BPI), Germany*
- **Marion Schaefer**, *Institut für Klinische Pharmakologie, Germany*

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[www.ibc-lifesci.com/readability](http://www.ibc-lifesci.com/readability)

# With an average cost of £15,000 per product, can you afford to get your User Testing strategy wrong?

In the past, the PIL has been regarded as being of poor quality and too complicated. Research indicates that the public now demand clearer information about their medicines. In response to this, a new regulatory framework has been created for packaging and labelling. The New Medicines Legislation requires every PIL to:

- **Reflect the results of consultation with patient groups**
- **Be accessible, understandable and trustworthy**
- **Provide accurate information so that patients can use their medicines safely**
- **Take into account the needs of those with poor eyesight, poor basic skills and the elderly**

You must demonstrate that your patients can find, use and understand the safety messages in the PIL. As a regulatory affairs professional, your challenge is translating medical terminology into everyday language without loss of meaning. You will need to learn a new set of skills that allow you to commission a user test, approve questionnaires, oversee test interviews and manage your budget. Failure to do so will be a risk to public health. It is a massive task that needs proper project management.

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

This 2-day practical course will ensure that you are adhering to the new EU rules and that you are helping your patients battle the jargon. You will leave feeling confident and prepared for your next regulatory challenge.

### 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

## Day One: Monday 11th September 2006

- 09.15 Registration and morning coffee**
- 09.45 Welcome from the Chairman and introduction to User Testing**  
Borislav Borisov, *Managing Director, Prescriptia LLC, Bulgaria*
- 10.00 The history of the Directives relating to User Testing**  
Guidance on testing patient information leaflets has been available in Europe since 1999. From 1st July 2005 legal provisions were introduced in the UK to mandate "User Tested" PILs for new applications. The presentation reviews the key guidance documents shaping the format and success criteria for user testing. It also highlights the key challenges faced by applicants today from a pre and post-submission perspectives, based on several experiences with UK submissions.  
Peter Embley, *Head of Regulatory Affairs, Ranbaxy, UK*
- 11.00 Coffee and networking break**
- 11.30 The objectives and guidance of Competent Authorities – What do the Authorities look for?**
- Experiences with the package leaflet from the view of the patients
  - Requirements of Article 59 and 61 of Directive 2001/83 and the corresponding guidelines "Guidance concerning consultation with target patient groups for the package leaflet" and Readability Guideline
  - How have the Member States implemented the requirements of the Directive 2001/83 into national law
  - Methods for the readability test (Interview, written procedure)
  - How to file the readability test in the application for a marketing authorisation (national procedures, MRP, DCP).
  - Under which conditions is a readability test not necessary
- Britta Ginnow, *Head of National Authorisations, The German Pharmaceutical Industry Association (BPI), Germany*
- 12.30 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, *Institut für Klinische Pharmakologie, Germany*
- 13.15 Lunch**
- 14.15 Aims and progress of harmonising procedures throughout the EU**  
*Speaker to be confirmed*
- 16.15 What is a PIL Designed to do and does it Achieve this Aim?**
- A mandatory document
  - A legal disclaimer
  - Information for the patient
- Dave Trotter, *Head of User Testing, Unicus, UK*
- 17.15 End of Day One**
- 17.30 Cocktail reception for speakers and delegates**



## Day Two: Tuesday 12th September 2006

- 08.45 Morning coffee**
- 09.00 Welcome back to day two and Chairman's comments**  
Borislav Borisov, *Managing Director, Prescriptia LLC, Bulgaria*
- 09.15 Creating a style sheet 1**
- The QRD template
  - Writing Styles
  - Formatting
  - Creating artwork
- Dave Trotter, *Head of User Testing, Unicus, UK*
- 09.45 Breakout 1: Review of an existing document**
- 10.15 Group presentations and discussion**
- 11.00 Coffee and networking break**
- 11.30 Who does the testing and how?**
- The Key issues
  - The skills sets required
  - Who to test and where
  - What questions to ask
  - Measuring the responses
  - Checking for understanding
  - Reporting the findings
- Dave Trotter, *Head of User Testing, Unicus, UK*
- 12.15 Breakout 2: Preparing a questionnaire**
- 12.45 Lunch**
- 13.45 Group presentations and discussions**
- 14.30 Breakout 3: Prepare for role play**
- Define roles
  - Prepare
  - Role play
- 15.00 Completing the process**
- 15.30 Open forum for review and questions**
- 16.00 End of course**

### Any Questions?

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