innovationwell
Patient & Drug Safety
Community of Practice

Drug Safety Workshop

Oxford University, 3-5 July 2006

Interactive pragmatic workshops with world-leading medical faculty

- Saad Shakir, Director
  Drug Safety Research Unit, UK
- A. Leander Fontaine, President
  Pharmiceutics
- Peter Elkin, Professor of
  Medicine, Mayo Clinic

Work through and discuss issues that concern drug and patient safety and review complex case studies

Risk Management, Labeling Decision-Making, Personalised Medicine, Knowledge-based Decision Support ...

- Risk Management Planning
- Integrating Clinical Development & Pharmacovigilance Planning
- Communication of Drug Safety Issues
- Safety Evaluation and Outcomes
- Managing Spontaneous Reporting
- Responding to new US and EU Labeling Regulations & Guidelines
- Proactive Drug Safety Knowledge Management
- Decision Support for Research and Practice of Medicine
- Latest advances in Pharmacogenomics & Personalised Medicine

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Topics

Practical Strategies for Risk Characterisation, Assessment and Management of Medicinal Products
Professor Saad Shakir (Director, Drug Safety Research Unit, UK)

- Managing known risks at Product Launch
- Unknown risks discovered during clinical trials
- Characterising and quantifying risks from studies
- Optimising the risk/benefit balance of medicines
- Practical strategies for risk management
- Discussion of Case Studies

July 3

Safety Labeling Decision-Making and Regulatory Implementation
A. Leander Fontaine (President, Pharmiceutics)

- Decide which information to provide in product labeling
- Design a global regulatory implementation strategy
- Create a global publication strategy
- Negotiation scenarios with regulatory authorities
- Principles of safety labeling decision making
- Comparative review of safety regulations, guidelines and regulatory expectations

July 4

Latest Advances in Pharmacogenomics, Personalised Medicine and Decision Support for Research and Practice of Medicine
Professor Peter Elkin (Mayo Clinic)

- Personalised medicine & knowledge based practice
- Implications for drug safety and monitoring
- Incorporate personalized diagnosis & treatment into practice
- Develop clinical decision support in a practice setting
- Build computable rules to drive clinical decision support
- Demonstration of clinical decision support for patient safety
- Quality reporting, point-of-care, just-in-time case-based education

July 5

Faculty

About Saad Shakir

Professor Saad Shakir is the Director of the Drug Safety Research Unit (DSRU) in Southampton where he leads a research team with an active programme for monitoring and studying the safety of medicines. Originally a physician working in both hospitals and then general practice, he has been dedicated to pharmacovigilance & pharmacoepidemiology for many years, initially at the Medicines Control Agency (MCA) in the UK and then in the international pharmaceutical industry. As well as publishing extensively, Prof. Shakir has worked and advised on many drug safety issues including product withdrawals and major safety hazards, and serves on the editorial boards of *Pharmacoepidemiology* and *Drug Safety.*

About A. Leander Fontaine

Dr. A. Leander Fontaine is a leading labeling and regulatory expert and President of Pharmiceutics, LLC. He was Vice President and Head of the Global Labeling Division and Vice President, International Labeling Liaison, Wyeth, USA 1999 – 2005. He started his career in global labeling in 1991 and has served as head of global labeling functions for Hoechst Marion Roussel (USA) and Hoechst (Germany). He has also held positions in clinical development with Behringwerke (Germany), and before joining the pharmaceutical industry, he worked in internal medicine (German Army Hospital Ulm, Germany) as well as in anesthesiology, intensive care and emergency medicine (University Hospital Ulm, Germany).

About Peter Elkin

Dr. Peter L. Elkin is a Professor of Medicine at the Mayo Clinic College of Medicine, where he directs a laboratory of Biomedical Informatics and has been actively researching health data representation since 1987. He is currently the Chair of ASTM E31.01, the subcommittee focused on Controlled Health Vocabularies, the Chair of the OASIS International Healthcare Continuum (IHC) that focuses on creating and promoting standards for global health information, and a co-chair of the HL7 Clinical Genomics Special Interest Group. He has won a number of awards and is the primary author of the American National Standards Institute's (ANSI) national standard on Quality Indicators for Controlled Health Vocabularies ASTM E2087.

Join this international community of leading experts...

Founded in 2003, InnovationWell is a Community of Practice (CoP) of experts, researchers and executives with the common goal of improving innovation and knowledge management across the pharmaceutical, life sciences and healthcare sectors.

InnovationWell's activity format is designed to support different Communities of Practice and combines face-to-face and virtual meetings and workshops, supported by an online collaboration website.

The community is managed by Dr Barry Hardy, Douglas Connect, Switzerland, and is committed to the core value of outreach with diverse groups in the commercial, government and academic sectors for the sharing of best practices and the development of strategies, resources and common methodologies that address specific issues in knowledge-based innovation in healthcare.

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Drug Safety Journal

Drug Safety is the premier international journal covering the disciplines of pharmacovigilance, pharmacoepidemiology and benefit-risk assessment and risk management. Drug Safety's structured program of peer reviewed commissioned articles ensures comprehensive coverage of all topics. Scientific Citation Index Factor: 3.114

WEBLINK: http://pt.wkhealth.com/pt/re/drs/home.htm

Our special thanks go to Karl Harrison for images taken from his virtual tour of Oxford at www.seeoxford.com

Register now for InnovationWell's
Advanced Training Workshop on Drug Safety

5 ways to register...

- ✓ **Online** at innovationwell.net (Ticket Office is only visible after login)
- ✓ **Email** innovationwell at douglasconnect.com
- ✓ **Phone** Nicki Douglas on +41 61 851 04 61
- ✓ **Fax** +44 870 112 38 44 (eFax)
- ✓ **Post** Douglas Connect, Baermeggenweg 14 4314 Zeiningen, Switzerland

Please select

- ❑ I wish to register for the InnovationWell Drug Safety Training Workshop taking place at Oxford University (3-5 July, 2006). Registration Fee £1500.
- ❑ Please contact me over local accommodation options for staying in college during the training week (subject to availability)

For Registrations and payments made by bank transfer before May 15 we will include 3 nights bed and breakfast at one of the nearby colleges.

All registration payments must be received in advance of the Training Week.

Payments can be made by bank transfer, cheque or credit card: Amex, MasterCard, Visa

Name

Company/institute

Tel:

Email:

Billing Address

City Postcode

Country

Signed Date

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