Two meetings for the price of one...

Sessions & Chairs in Philadelphia, October 11 & 12

- Confidence in Safety
  Sidney Kahn (PvRM)

- Knowledge Management in R&D — optimizing productivity in knowledge creation, capture, retrieval and transfer
  Herschel J. Weintraub (CambridgeSoft)

- Drug Discovery Innovation
  David Mosenkis

- Personalized Medicine:
  Safety and Efficacy Concerns
  Discussed as a Case Study
  Donna Mendrick (Gene Logic)

- Drug Development Innovation
  Barry Hardy (Douglas Connect)

- Web-based Services in Drug Design
  Marc Nicklaus (National Institutes of Health)

- Protein Folding, Misfolding & Aggregation: Applications to Disease
  Nikolay V. Dokholyan
  (University of North Carolina)

Sessions & Chairs in Basel, Switzerland, November 9-10

- Drug Discovery Innovation
  Alan Gibbs (Johnson & Johnson Pharmaceutical R&D)

- Knowledge-based Intellectual Property Management
  Ronald Layden (Venture Valuation)

- Knowledge Management in R&D
  Robert Scoffin (CambridgeSoft)

- Improving Clinical Trial Effectiveness with Predictive Toxicology, Biomarkers and Pharmacogenomics
  Eric Kaldjian (Gene Logic)

- Combating Drug Counterfeiting & Trafficking
  Ulrich Meier (Sun Microsystems)

- Life Science Innovation Café — Confidence in Safety moderated by Victor Newman (KnowledgeWorks)

- Biosensors and Nanofluidics
  Nick Quirke (ICL)

- Complex Systems & Organisational Development Approaches
  Jim Cook (Volutio) & Barry Hardy (Douglas Connect)

- Knowledge Management in Manufacturing:
  Jim McKiernan (McKiernan Associates) & Mike Dey (Ipsen)

- Confidence in Safety
  James Averback (Life Science Integration Parters)

www.innovationwell.net
All participants are invited to join this executive forum to discuss the latest key advances in management practices, technology and informatics enabling the integrated advancement of the success, productivity, efficacy and safety of products moving through the drug development pipeline.

**New Technology Advances**

**Drug Development Productivity**

**Decision-Making in Development**

**Current Impact of New Advances in Chemistry and Biology (biomarkers, toxicology, proteomics, toxicogenomics, metabolomics etc) on Drug Development**

**Early Markers of Safety and Benefit**

**Make Drugs Safer and More Effective**

**Shape Signatures: a Tool for Rapid in silico Screening and Clustering**

**Computational Models are Needed to**

---

**Drug Development Innovation**

Barry Hardy (Douglas Connect)

---

**Drug Discovery Innovation**

David Mosenkis

---

**Roundtable Discussion on Confidence in Safety**

led by Sidney Kahn (Pharmacovigilance & Risk Management, Inc)

**Discussion Panel**

Sidney Kahn (PvRM)

A. Leander Fontaine (Pharmaceutics)

James Averback (Life Science Integration Partners)

Peter Elkin (Mayo Clinic)

**Part 1 – Sources of Drug Safety Knowledge**

Do we need to have a truly shared, comprehensive and global body of drug safety knowledge?

What is shared? And why? What is not shared? And why not?

What are the roles of clinicians, industry, regulators and other drug information providers in contributing to a common drug safety knowledge base? Do we have a common understanding of our roles? Should the roles change?

**Part 2 – Stakeholders in Drug Safety Evaluation**

Do we need multiple and largely independent drug safety evaluation systems serving the needs of distinct but collaborative stakeholders?

How do the needs of drug safety evaluation constituencies align or diverge? Do we speak the same language? Do we all evaluate risk in the same way?
Drug X has been approved for severe, debilitating migraines and is far more effective than other existing therapies. However, upon post-market use it has been observed that a small percentage of patients (1%) develop elevated serum transaminase levels and, if maintained on this treatment, develop fulminant liver failure leading to death or the need for liver transplantation. Additionally, it has been recognized that this drug is more efficacious in some patients than others.

Case Study
Drug X has been approved for severe, debilitating migraines and is far more effective than other existing therapies. However, upon post-market use it has been observed that a small percentage of patients (1%) develop elevated serum transaminase levels and, if maintained on this treatment, develop fulminant liver failure leading to death or the need for liver transplantation. Additionally, it has been recognized that this drug is more efficacious in some patients than others.

Interactive Discussion Points
Patient response reporting • Point of care assistance • Patient population for clinical trial • Regulatory acceptance of test
# Knowledge Management in R&D: Part I

**Herschel J. Weintraub**

- The ABCD Project: A Framework for Knowledge Management
  - Peter Gates (Johnson & Johnson)
- An Interactive Environment for Knowledge Management
  - James H. Wikel (Coalesix)
- Global Information Integration in R&D
  - Scott Starry (Symyx Intellichem)
- Enabling Collaboration in a Virtual and Global Drug Discovery R&D Environment
  - John Barrett (ITI Associates)
- Natural Language Processing for Knowledge Extraction in the Life Sciences
  - Rosemary Polsky-Newman (Exergen Biosciences)
- Analysis Based on Molecular Diversity
  - Steve Boyer (IBM)

# Knowledge Management in R&D: Part II

**Knowledge Management Case Study Analysis Of a Collaborative Life Science R&D Environment**
- Jeff Spitzner (Rescentris)
- Legal Issues in a Knowledge Sharing Environment
  - James M. Kanagy (GlaxoSmithKline)
- Measuring Knowledge Management via Social Network Analysis
  - Bonnie Montano (Georgetown University)
- Managing Knowledge in Breast Cancer: Converting Clinical, Molecular and Imaging Data into Knowledge
  - Michael Liebman (Windber Research Institute)
- Enterprise Electronic Lab Notebook Case Studies
  - Rudy Potenzone (CambridgeSoft)

---

**Knowledge Management in R&D**

**Robert Scoffin (CambridgeSoft)**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ontologies: Real Applications in Pharma</td>
<td>Steve Gardner (Biowisdom)</td>
</tr>
<tr>
<td>Assembly, Distribution and Retrieval of Biological Information in Drug Discovery</td>
<td>Kim Henrick (European Bioinformatics Institute)</td>
</tr>
<tr>
<td>Global Information Integration in R&amp;D</td>
<td>Pierre Allemand (Symyx)</td>
</tr>
<tr>
<td>Aggregation, Filtering and Alerting of Scientific Information from Multiple Sources</td>
<td>Mark Sharp (Corpora)</td>
</tr>
<tr>
<td>ABCD and Combinatorial Library Design</td>
<td>Alan Gibbs (Johnson &amp; Johnson Pharmaceutical R&amp;D)</td>
</tr>
<tr>
<td>Molecular Architecture to Prepare Structures with Desired Properties</td>
<td>Ulrich Jordis (Vienna Univ. Technology)</td>
</tr>
<tr>
<td>Pharmaceutical Development and the Use of Electronic Lab Notebooks</td>
<td>Michael Swartz (CambridgeSoft)</td>
</tr>
<tr>
<td>Strategic Knowledge Management in Life Science Research</td>
<td>Victor Newman (Knowledgeworks)</td>
</tr>
<tr>
<td>Global Roll-Out of an Electronic Notebook at Schering</td>
<td>Rolf Jautelat (Schering)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Life Science Innovation Café — Confidence in Safety
moderated by Victor Newman (KnowledgeWorks)

Innovation Café workshops demonstrate a new kind of conversation that quickly leads to documented, usable tactics in authentic language.

Supported by experts in drug safety and development, Victor will involve participants in two types of innovation thinking about Confidence in Safety:

- Inviting participants to visualize a scenario where optimum confidence in safety has been realized, and then work backwards to define and prioritize the necessary capabilities that need to be constructed to make it happen
- Using reversal-thinking to pose questions about innovation failure to identify what we know intuitively works now, and turn it into usable knowledge to make the capabilities developed in the success visualization a reality.

*The Innovation Café may also be booked separately from the conference.*

Roundtable Discussion on Confidence in Safety
led by James Averback (Life Science Integration Partners)

Discussion Panel
Saad Shakir  
(Drug Safety Research Unit, UK)
James Averback  
(Life Science Integration Partners)
Sidney Kahn (PvRM)
A. Leander Fontaine (Pharmiceutics)
Peter Elkin (Mayo Clinic)

Part 1 – Sources of Drug Safety Knowledge
Do we need to have a truly shared, comprehensive and global body of drug safety knowledge? What is shared? And why? What is not shared? And why not? What are the roles of clinicians, industry, regulators and other drug information providers in contributing to a common drug safety knowledge base? Do we have a common understanding of our roles? Should the roles change?

Part 2 – Stakeholders in Drug Safety Evaluation
Do we need multiple and largely independent drug safety evaluation systems serving the needs of distinct but collaborative stakeholders? How do the needs of drug safety evaluation constituencies align or diverge? Do we speak the same language? Do we all evaluate risk in the same way?

Knowledge Management in Manufacturing
Jim McKiernan (McKiernan Associates) & Mike Dey (Ipsen)

During this session Jim McKiernan and Mike Dey will each present case studies from pharmaceutical companies where knowledge management issues in the transfer from R&D to manufacturing have been successfully addressed.

They will then facilitate an interactive workshop with the participants in order to identify key concerns and the steps to be taken to achieve excellent knowledge management in technical development and manufacturing.
Drug Discovery Innovation

Alan Gibbs (Johnson & Johnson Product Research and Development)

Pattern Recognition and Grid Computing in Drug Discovery
Graham Richards (University of Oxford)

A New Clustering Algorithm for General Metric Spaces
Alan Gibbs (Johnson & Johnson PRD)

Metabolomics for White Biotechnology
Lars M. Blank (Univ. Dortmund & Institute For Analytical Sciences)

Investigating and Manipulating the Dynamics of NF-κappa B Signalling:
Novel temporal complexity uncovered by real-time single cell imaging
Michael White (University of Liverpool, School of Biological Sciences)

Combating Drug Counterfeiting, Trafficking
Panel Discussion led by Ulrich Meier (Sun Microsystems)

Hellmuth Broda
(Sun Microsystems)
Dietrich Heinicke
(CADAC)
Saad Shakir
(Drug Safety Research Unit, UK)

The panel will discuss current issues and solutions in the introduction of new technologies and processes for ensuring the legality and safety of drugs obtained by patients.

We examine the use of electronic labeling, SPL, RFID-tagging, barcoding and automatic product checking to track product throughout the supply chain.

We see how IT–based approaches to security and privacy protection such as federated identity management can be integrated to secure consumer–related information.

Applying Complex Systems & Organisational Development Approaches to Life Science Product Development & Drug Safety Decisions
Jim Cook (Volutio) and Barry Hardy (Douglas Connect)

Discussion Panel
David Snowden
(The Cynefin Centre)
Adam Filler
(Denison Europe)
Thomas Kell
(Heidrich & Struggles)

A panel discussion examining and discussing approaches that offer potential contributions to organisational development in the context of key product development and safety decision making:

- Sense making
- Complex systems analysis
- Organisational Culture and Assessment
- Executive leadership and Competency Assessment
Knowledge-based IP Management, Auditing & Investment Panel Discussion, led by Ronald Layden (Venture Valuation)

Rudolf Gygax (Novartis Venture Fund)
Gerald Farmer (Alfomec International Regulatory Consultants)
Ronald Layden (Venture Valuation)
Antonino Cattaneo (Lay Line Genomics)
Stefan Odenthal (Arthur D. Little)

Topics for Discussion
- Company and IP valuation
- Managing IP and knowledge in licencing situations
- Intellectual property creation, protection and utilisation
- Knowledge audits, inventories and maps
- Knowledge management strategies and planning
- Weighting of risks
- Life science & healthcare industry and regulatory factors
- Impact of safety issues
- Pharma and biotech viewpoints

Biosensors and Nanofluids
Nick Quirke (Imperial College London)

Thermophoresis Between Solids: A Molecular Dynamics Study of Gold Nanoparticles Confined and Thermally Driven through Carbon Nanotubes
Jens Walther (ETH–Zürich)

Computational Modeling for Biosensor Devices
Richard Gilbert (e2v Technologies)

Simulating Nanoflows
Nick Quirke (Imperial College London)

Continuous–Flow Electrophoresis
Joachim Franzke (Institute for Analytical Sciences, Dortmund & Berlin)

Microfluidic Systems for Controlled Production of Small Molecules & Nanoparticles
Andrew De Mello (Imperial College London)

Improving Clinical Trial Effectiveness with Predictive Toxicology, Biomarkers and Pharmacogenomics
Eric Kaldjian (Gene Logic)

In this session we explore how predictive toxicology and pharmacogenomics (eg. As envisioned by the FDA’s pharmacogenomics guidelines) are impacting drug safety from pre-clinical to downstream phases. In an effort to pre-identify populations at risk of adverse reactions to drugs being tested, predictive models for pharmacovigilance are now being developed. At the same time, clinical scientists are evaluating biomarkers to determine which ones are the best indicators of disease and treatment response. We will discuss how the efficacy of the prediction varies with the data provided as well as introduce new solutions for ensuring the quality and integrity of the drug being administered to the patient.
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 (web/conference calls), supported by an online collaboration website, http://innovationwell.net

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.

innovationwell.net

Register now for InnovationWell’s InterAction Meetings on Knowledge-based Innovation in Life Science Product Development

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’m already a member of InnovationWell and I want to participate in this InterAction Meeting: $900 / SFr. 1080
☐ I’m an academic member of InnovationWell and I want to participate in this InterAction Meeting: $500 / SFr. 600
☐ Conference-only registration for non-members: $1100 / SFr. 1320
☐ Conference-only registration, academic non-members: $600 / SFr. 720
☐ I want to become a member: $400 / SFr. 480
☐ I’m an academic and want to become a member: $300 / SFr 360
☐ Life Science Innovation Café as separate item: Members SFr 400 / non-members SFr 500

☐ Philadelphia ☐ Basel

Name ____________________________________________
Company/institute ____________________________________________
Tel: ____________________________________________
Email: ____________________________________________
Billing Address ____________________________________________
City __________________________ Postcode __________
Country ____________________________________________
Signed __________________________ Date __________

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

We thank the following for their support...

Johnson & Johnson Pharmaceutical R&D
Gene Logic
Symyx Intellichem