

Community of Practice
Integrating Knowledge in the
Life Science Product Life Cycle

InterAction Meetings US & Europe
Knowledge-based
Innovation
Life Science

Product Development

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 Development Innovation Barry Hardy (Douglas Connect)

Web-based Services in Drug Design Marc Nicklaus (National Institutes of Health) Drug Discovery Innovation David Mosenkis

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

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

Come to any sessions in person, and access any others virtually!

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

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

Knowledge Management in R&D Robert Scoffin (CambridgeSoft)

Combating Drug Counterfeiting & Trafficking Ulrich Meier (Sun Microsystems)

Biosensors and Nanofluidics Nick Quirke (ICL)

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

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

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

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

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

Confidence in Safety James Averback (Life Science Integration Parters)

DouglasConnect

www.innovationwell.net

Drug Development Innovation Barry Hardy (Douglas Connect)

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

Early Markers of Safety and Benefit

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

October 11

Drug Discovery Innovation David Mosenkis

ABCD Chemoinformatics: Integrating Chemoinformatics Tools into Everyday Drug Discovery Victor Lobanov (Johnson & Johnson Pharmaceutical Research and Development)

Structure-based Design of Allosteric Protein Kinase Inhibitors Jeff Wiseman (Locus Pharmaceuticals)

An Interactive Environment for Multiparameter Optimization James H. Wikel (Coalesix) Computational Models are Needed to Make Drugs Safer and More Effective G. Scott Lett (Bioanalytics Group)

Shape Signatures: a Tool for Rapid in silico Screening and Clustering Randy J. Zauhar (University of the Sciences in Philadelphia)

Bryn Mawr College 101 N. Merion Ave. Bryn Mawr, PA

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?

Philadelphia

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

Web-Enabling Technology for the Design, Enumeration, Optimization and Tracking of Compound Libraries Brad Feuston (Merck) Pubchem Steve Bryant NCBI

ZINC Web Services

Providing 3D Structures
 of Purchasable Compounds

for Virtual Screening to Humans and Machines John Irwin (UCSF) A Web-based Chemoinformatics System for Drug Discovery Brett Tounge (Johnson & Johnson Pharmaceutical R & D)

Web-based Services of the National Cancer Institute's CADD Group Marc Nicklaus (NIH) Search-and-Query Information System for the Study and Discovery of Novel Agents in the Treatment of Cancer David Covell (NCI)

High Performance Applications Based on Web Services: It's Not an Oxymoron.

The Use of Web Services in the ABCD Drug Discovery Platform

Dmitrii Rassokhin (Johnson & Johnson Pharmaceutical Research and Development)

October 11

Personalized Medicine: Safety & Efficacy Concerns - Case Study Donna Mendrick (Gene Logic)

Sidney Gilman Gene Logic Derek Janszen Wyeth Matt Cooper Biogen Idec

Donna Mendrick Gene Logic Steven Arnold Queens-Long Island Medical

Group

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

Bryn Mawr College 101 N. Merion Ave. Bryn Mawr, PA

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

Amyloid beta-protein Oligomerization and Alzheimer's Disease David Teplow (David Geffen School of Medicine at UCLA)

The Assembly and Structure of Amyloid-Like Polyglutamine Aggregates Associated with Huntingdon's Disease Ron Wetzel (University of Tennessee Medical Center)

Protein Misfolding in End-Stage Renal Failure Andrew Mirankar (Yale University)

Catalytic Origins of

Direct Observation of Protein Folding, Misfolding and Prion-Like Conformational Infectivity Feng Ding (University of North Carolina)

> Detection of Intermediate States of Cell Adhesion Proteins Richard Dixon (Univ. North Carolina)

Flexibility and Mobility in Biomolecules Michael Thorpe (Arizona State University)

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Philadelphia

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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)

October 12

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)

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Basel

Knowledge Management in R&D Robert Scoffin (CambridgeSoft)

Ontologies: Real Applications in Pharma Steve Gardner (Biowisdom) ABCD and Combinatorial Library Design Alan Gibbs (Johnson & Johnson Pharmaceutical R&D)

Assembly, Distribution and Retrieval of Biological Information in Drug Discovery

Kim Henrick (European Bioinformatics Institute)

Molecular Architecture to Prepare Structures with Desired Properties Ulrich Jordis (Vienna Univ. Technology)

Global Information Integration in R&D Pierre Allemand (Symyx)

Pharmaceutical Development and the Use of Electronic Lab Notebooks Michael Swartz (CambridgeSoft)

Aggregation, Filtering and Alerting of Scientific Information from Multiple Sources Mark Sharp (Corpora)

Global Roll-Out of an Electronic Notebook at Schering Rolf Jautelat (Schering) Strategic Knowledge Management in Life Science Research Victor Newman (Knowledgeworks)

November 9

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.

Basel

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

Swissôtel L'Entrée Convention Center Riehenring 118 4005 Basel

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Discussion Panel

Saad Shakir (Drug Safety Research Unit, UK) James Averback (Life Science Integration Partners)

Virtual Panel

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?

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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.

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

Hellmuth Broda (Sun Microsystems)

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.

Dietrich Heinicke (CADAC)

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

Saad Shakir (Drug Safety Research Unit, UK)

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

Basel

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Drug Discovery Innovation Alan Gibbs (Johnson & Johnson Product Research and Development)

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

Metabolomics for White Biotechnology Lars M. Blank (Univ. Dortmund & Institute For Analytical Sciences) A New Clustering Algorithm for General Metric Spaces Alan Gibbs (Johnson & Johnson PRD)

vember 1

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

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)

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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

Basel

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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)

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

Computational Modeling for Biosensor Devices Richard Gilbert (e2v Technologies)

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

Simulating Nanoflows Nick Quirke (Imperial College London)

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

Discussion Panel

Christoph Helma (in silico Toxicology)

Eric Kaldjjan (Gene Logic)

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Gérard Hopfgartner (University of Geneva) 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.

lovember 10

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.

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We thank the following for their support...

Johnson & Johnson Pharmaceutical R&D

Gene Logic

Symyx Intellichem

DouglasConnect

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

5 ways to register... □ Philadelphia □ Basel ✓ 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) Company/institute ✓ Post Douglas Connect, Baermeggenweg 14 4314 Zeiningen, Switzerland Please select ☐ I'm already a member of InnovationWell and Email: I want to participate in this InterAction Meeting: \$900 / SFr. 1080 **Billing Address** ☐ 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 Postcode ☐ I want to become a member: \$400 / SFr. 480 ☐ I'm an academic and want to become a member: Country \$300 / SFr 360 ☐ Life Science Innovation Café as separate item: Members SFr 400 / non-members SFr 500 Signed