Pharmacovigilance

Developing Successful Risk Management Strategies to Increase Drug Safety

Dec 6-7, Senate House, City of London UK

Key Speakers

- Dr Steve Bentley, Managing Director, Medgenesis
- Dr Andrew Rut, VP Global Safety, GSK
- Dr Jan Patracek, CEO, Pharminvest Services
- Prof Thomas Steadter, Managing Consultant, EXTEDO
- Dr Katba Achor, Case Medical Evaluator Leader, Sanofi-Aventis
- Dr Ellen Evelaar, Assistant Director Pharmacovigilance, Astellas
- Dr Will Maier, VP Epidemiology, Registrat-Mapi
- Dr Barbara Leichman, Head of Quality Risk Management for Safety Science, Roche
- Dr Karen Jaffre, Regulatory Research, Alfred E Mann Foundation

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Dear Colleague,

In recent years the focus on developing effective pharmacovigilance systems has been driven by an increased concern with drug safety and ever-changing regulatory environment.

Join us at Appel Consulting’s Pharmacovigilance Conference, where our expert panel of speakers will share insights on ‘exploring innovation’, pivotal to achieve success in the global pharmacovigilance field.

Our Pharmacovigilance Conference will focus on six scientific areas:
- Compliance with clinical and post marketing pharmacovigilance
- New strategies in risk management, risk communication, labeling & packaging
- Addressing drug counterfeiting issues & evaluating possible measures to combat & protect consumers
- Recent trends within pharmacovigilance within the EU
- The economics of pharmacovigilance
- Preparing for product specific inspections & compliance monitoring by authorities

Our programme is driven by an advisory board who have already started working on the event and have identified these strategic areas to be addressed in the programme:
- Challenges of Benefit-Risk Management Systems
- Understanding the financial impact of pharmacovigilance
- Pharmacovigilance pre-approval planning and research
- Current difficulties and challenges facing the pharmacovigilance industry

I look forward to meeting you at the conference
Best regards
I look forward to meeting you at the conference

Sabrina Daw
CEO

Who will be there?

Presidents, Chief Executives, VPs, Global Heads, Scientific Advisors, Therapeutic Area Heads, in:

- Pharmacovigilance
- Pharmacoeconomics
- Pharmacogenomics
- Drug/Product Safety
- Drug development
- Information and Clinical Data Management
- Clinical Pharmacology
- Clinical Safety
- Periodical safety update report
- Risk Management
- Research & Development
- Quality Assurance
- Patient Safety
- Signal Detection
- Safety Surveillance
- Outcomes Research
- Data Analysis
- Epidemiology
- Medical Affairs
- Regulatory Affairs and Compliance
- Information technology
- Sales and Marketing

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For more information please e-mail sabrina.daw@appelconsulting.co.uk

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Tara has been designed from the outset for pharmacovigilance professionals, supported by a team of software developers, drawn from both academia and the Information Technology Industry. The development of TARA has allowed dramatic improvements to the quality and speed of case processing.

For further information please visit: www.tarapv.com
09:30 Registration and refreshments

10:00 Opening address from the chair

10:10 The thought planning and data collected during clinical development is fundamental to rigorous post-market risk management
- Design & delivery of a safety plan from inception of development through to early post-marketing
- Participate in design of the clinical studies followed by analysis and interpretation of all safety data (AEs, SAEs, outcomes and labs)
- Derive conclusions, decisions and next steps including risk management planning

Dr Andrew Rut
Vice President – Global Safety
GSK

10:50 Pharmacovigilance in biopharmaceuticals
- The importance of pharmacovigilance in biopharmaceuticals
- Unique aspects of safety concerns
- To be prepared for the unexpected

Representative
Pharmacovigilance Manager
Sanofi Pasteur MSD

11:30 Morning refreshments

11:50 Benefit Risk-Management Systems
- Use of evidence based toolbox for risk minimisation
- PASS and PAES
- Examples of benefit risk management plans

Dr Jan Petracek
CEO, Pharminvest Services

12:10 Standardised MedDRA Queries (SMQs) in Pharmacovigilance
- Description of characteristics of SMQs
- Development, maintenance and practical applications
- Modified SMQs and customized queries

Dr Judy Harrisson
New Venture Development Director
Clinical Consulting LLC

12:50 Networking lunch

13.50 Understanding the financial impact of pharmacovigilance
- The costs of ongoing pharmacovigilance
- The costs of a failure in pharmacovigilance
- Positive impact of pharmacovigilance in product life cycle

Karen Jaffe
Alfred E Mann Foundation

14:10 Benefit/Risk assessments and striking the right balance
- Developing systems in harmony with regulatory developments
- Pre and Post marketing safety judgements
- Making accurate determinations on product safety

Representative
Director, Pfizer

14:50 Afternoon refreshments

15:10 The impact of EMAs announcement to make submission of EVMPD data mandatory
- Data requirements and timelines
- Impact assessment
- Technology and process options for market authorization options

Dr Andrew Marr
Managing Director
Marr Consultancy

15:50 Regulatory pharmacovigilance in Europe: recent developments
- Overview
- Current pharmacovigilance in Europe
- Improving pharmacovigilance in Europe

Representative
Research Fellow
Drug Safety Research Unit

16:30 Closing remarks from the chair

16:40 Networking drinks
Take your discussions further and build new relationships in a relaxed and informal setting.
<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>09:30</td>
<td>Registration and refreshments</td>
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<tr>
<td>10:00</td>
<td>Opening address from the chair</td>
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<td>Quality Risk Management: Principle and Practice</td>
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<td>• Meeting the challenge of risk based assessment</td>
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<td>• Quality risk management in practice</td>
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<td>Dr Barbara Leishman</td>
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<td>Head of Quality Risk Management for Safety Science</td>
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<td>Drug Safety Business Solution via Cloud Computing</td>
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<td>• Search, query and reports: Get what you need out of your data</td>
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<td>Prof. Dr. Thomas Staedter</td>
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<td>11:30</td>
<td>Morning refreshments</td>
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<td>Case Study: Customer experience and risk orientation in case management</td>
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<td>The case study will feature new approaches to improve efficiency in</td>
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<td>case management creating real time visibility and context for case data</td>
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<td>Dr Katba Achor</td>
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<td>Risk Management of Drug Safety: Pre-approval planning and Research will</td>
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<td>Ensure Success</td>
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<td>• Update on latest EU and US regulations</td>
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<td>• New Regulatory Committees to review risk management plans</td>
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<td>• Why companies need to be more proactive</td>
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<td>• Additional research needed for drug approval</td>
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<td>Dr Will Maier</td>
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<td>Vice President Epidemiology</td>
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<td>13:10</td>
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<td>Case study: Current difficulties facing the pharmacovigilance industry</td>
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<td>case study will explore whether non-commercial entities successfully</td>
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<td>Steve Bentley</td>
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<td>14:50</td>
<td>Risk Management &amp; economics: how pharmacovigilance can save lives &amp; money</td>
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<td>Dr Ellen Evelaar</td>
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<td>Assistant Director Pharmacovigilance</td>
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<td>Manufacturing: Managing Clinical Safety</td>
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<td>Vice President Drug Safety</td>
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<td>Chair’s closing remarks</td>
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Pharmacovigilance Registration

DEC 6\textsuperscript{th} - 7\textsuperscript{th}  
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