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, **Pharminvent Services**
- Prof Thomas Steadter, Managing Consultant , **EXTEDO**
- Dr Katba Achor, Case Medical Evaluator Leader, **Sanofi-Aventis**
- Dr Ellen Evelaar, Manager PV/QPPV, **Sanquin**
- 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**
- Dr Andrew Marr, Managing Director, **Marr Consultancy**
- Dr Steve Mott, Managing Director, **DrugLogic Inc**
- Dr Ashok Srivastava, CEO, **Global Pharma Tek**
- Dr Suzanne Mouton, CEO, **Mouton's Safety Consultancy**

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Conference Introduction

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, rick 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

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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

Who will be there?

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

- Pharmacovigilance
- Pharmacoepidemiology
- 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

Pharmacovigilance Dec 6

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 the age of real world data

- The need for real World Data
- Demonstrating how FDA AERS data and the GPRD can be analyzed from the desk top to support drug safety
- The future potential for electronic patient records in pharmacovigilance

Steve Mott
Managing Director
DrugLogic Inc

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, Pharminvent Services

12.10 'Toesting online' an outcome or disastrous tool?

- Intro the Dutch HA (CCMO) procedures
- Pharmaceutical companies and SAEs
- More vigilance or confusion?

Dr Suzanne Mouton
CEO
Mouton's Safety Consultancy

12:50 Networking lunch

13.50 Challenges in Drug Safety and Pharmacovigilance

- Why Drug safety and PV are required
- What is medical relevance in global setting
- PV an effect of chronic diseases and drugs in market place (e.g Cancer drugs and Cardiology drugs)

Dr Ashok Srivastava
CEO Global Pharma Tek

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

Dr Ute Hoeffner
EU QPPV
Novartis

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 pharmacoviglance in Europe: recent developments

- Overview
- Current pharmacovigilance in Europe
- Improving pharmacovigilance in Europe

Represenative
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.

Pharmacovigilance Dec 7

09:30 Registration and refreshments

10:00 Opening address from the chair

10:10 Quality Risk Management: Principle and Practice

- Overview Quality Management Systems
- Regulators expectations and requirements
- Meeting the challenge of risk based assessment
- Quality risk management in practice

Dr Barbara Leishman
Head of Quality Risk Management for Safety Science
Roche

10:50 Drug Safety Business Solution via Cloud Computing

- Architecture and Design Aspects
- Deployment and Validation Process
- Submission: Paper or electric, US-EU be prepared for all filling requirements
- Search, query and reports: Get what you need out of your data

Prof. Dr. Thomas Staedter
Managing Consultant
EXTEDO

11:30 Morning refreshments

11:50 Case Study: Customer experience and risk orientation in case management.

CASE STUDY

The case study will feature new approaches to improve efficiency in case management creating real time visibility and context for case data

Dr Katba Achor
Case Medical Evaluator Leader
Case management and medical evaluation /GPE
Sanofi-Aventis

12:30 Risk Management of Drug Safety: Pre-approval planning and Research will Ensure Success

- Update on latest EU and US regulations
- New Regulatory Committees to review risk management plans
- Why companies need to be more proactive
- Additional research needed for drug approval

Dr Will Maier
Vice President Epidemiology
Drug Safety and Risk Management
Registrat-Mapi

13:10 Networking lunch

14:10 Case study: Current difficulties facing the pharmacovigilance industry

CASE STUDY

The case study will operational aspects of small companies, the role of outsourcing and software solutions for the smaller user. The case study will explore whether non-commercial entities successfully manage phamacovigilance activities.

Steve Bentley
MD
Medgenesis

14:50 Risk Management & economics: how pharmacovigilance can save lives & money

- PV involvement in early development
- Contribution to fast track development
- Safety task force teams

Dr Ellen Evelaar
Manager PV/QPPV
Sanquin

15:30 Afternoon refreshments

15:50 Manufacturing: Managing Clinical Safety

- Safety monitoring of medicines
- Implementing an effective response action plan
- Case Studies

Represenative
Vice President Drug Safety
Biogen Idec

16:30 Chair's closing remarks

16:40 End of Conference

Pharmacovigilance Registration

DEC 6th-7th LONDON UK

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