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PHARAMACOVIGILANCE EUROPE CONGRESS



**3rd Annual International Conference
& Exhibition in Pharmacovigilance,
Regulatory Affairs and Risk Management**
24th - 25th May 2017, London, UK



www.pveurope.com

info@gravitonevents.org





WELCOME

Dear Members,

We welcome you to attend the 3rd Annual International Conference & Exhibition - Pharmacovigilance Europe 2017 during May 24-25, 2017, London, UK.

Our agendas are tailor-made to precisely suit the industry profile of our attendees. After a comprehensive research study, we categorize the end user giving exclusive opportunities relevant to their business needs and requirements. Moreover, our finest speakers share the same industry background as our delegates. They hold the distinguished position of senior-level decision makers and influential leaders in their field.

Join us for brainstorming sessions filled with innovative ideas and share tete a tete moments with the experts for exclusive advice. Our Networking expertise will ensure with their innovation products/services.

Regards,

Pharmacovigilance Europe 2017 Committee



KEY FEATURES



A Global Event in Pharmacovigilance



Ensuring Pharmacovigilance for Global Public Health



20+ Expert Speakers from around the world



100's Pharma/ Biotech Professionals from over 50 countries



Bringing together the key decision makers under one roof



Over 10 hours of dedicated Networking and Interactive sessions



ABOUT

PHARMACOVIGILANCE EUROPE 2017

On the road to striving towards globalizing and strengthening pharmacovigilance, the Pharmacovigilance Europe 2017 conference is being held as a platform to share experiences and knowledge on the many concerns and advancements in the field. Together with likeminded individuals having the conviction to spread awareness, we shall hope to gain insights on public safety and risk management, focusing mainly on drugs, biologics and medical devices and the future of PV in the globalization era.

The extensive group of experts at the conference will discuss on advancements and trends in EU legislation, operational challenges of changes propounded, implementing global risk management plans, impact of IT and social media on PV and harmonization of different regulatory bodies.

Witnessing the success of Pharmacovigilance Europe 2016 which witnessed more than 70 companies, we are inspired to make this year's conference a larger gathering of people with keen intentions to better the sustenance of drugs and improve their impact on people through strong pharmacovigilance. we welcome you to Pharmacovigilance Europe 2017 for networking and knowledge sharing.

TARGET INDUSTRY



Pharma



CRO's



Biotechnology



Software Providers

KEY THEMES

- ✓ Review of the new EU legislation on pharmacovigilance
- ✓ Good Pharmacovigilance and Clinical Practice
- ✓ Signal Management - revised GVP guidance
- ✓ Current Regulatory Guidelines employed in Pharmacovigilance in Europe and USA
- ✓ EU revised and new guidelines on biological drugs
- ✓ Managing pharmacovigilance compliance locally: perspectives from a local affiliate
- ✓ Digital media: websites and social media and their impact on pharmacovigilance
- ✓ Medical Literature Monitoring (MLM) and PSUR repository, PASS, DSUR
- ✓ Finding new methods to promote harmonization of regulatory framework- developed and emerging markets Pharmacovigilance Audit and Inspections
- ✓ Post-Marketing Authorisation Studies in Drug Risk Surveillance
- ✓ How will Brexit affect Pharmacovigilance at present and in the future?
- ✓ Role of Biologics in PV
- ✓ Patient Support Program

WHO WILL YOU MEET?

Vps, Directors, Heads, Managers, Scientific Advisors, Consultants, Research Scholars and professionals with intermediate to advance knowledge and experience in the following:

- ✓ Pharmacovigilance
- ✓ Clinical Trials & CRO's
- ✓ Pharma Recruitment
- ✓ Drug safety
- ✓ Pharmacoepidemiology
- ✓ Clinical Pharmacology
- ✓ Clinical Safety
- ✓ Clinical research & safety
- ✓ Information technology
- ✓ Medical Information
- ✓ Health Outcomes
- ✓ Sales and Marketing
- ✓ Contract Manufacturing
- ✓ Drug Research & Development
- ✓ Information and Clinical Data Management
- ✓ Data analysis



Disparities: Access

Racial and ethnic differences in the use of health services

Health disparities are differences in the quality of health care among different groups of people. These differences can be based on race, ethnicity, social class, and other factors.

Health disparities can be caused by a variety of factors, including:

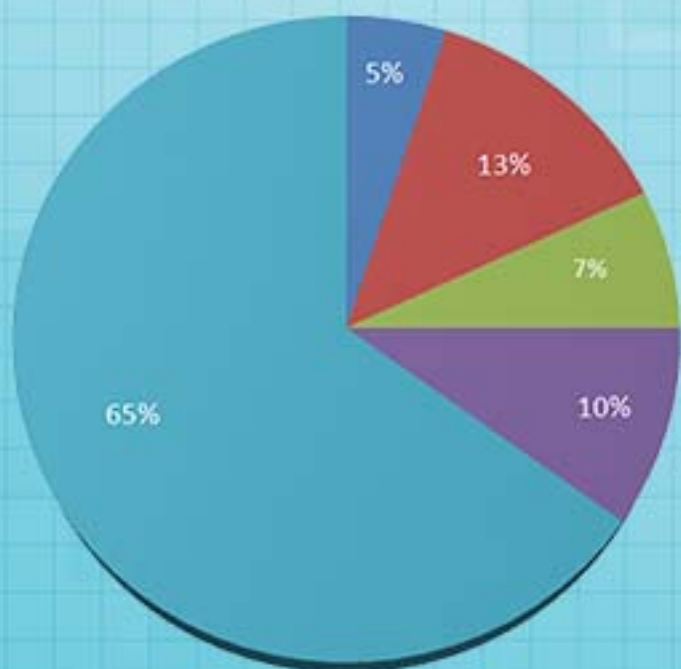
- Differences in access to health care
- Differences in the quality of health care
- Differences in the social determinants of health

Health disparities can have a significant impact on the health of individuals and communities. Addressing these disparities is a key goal of public health and health care reform.

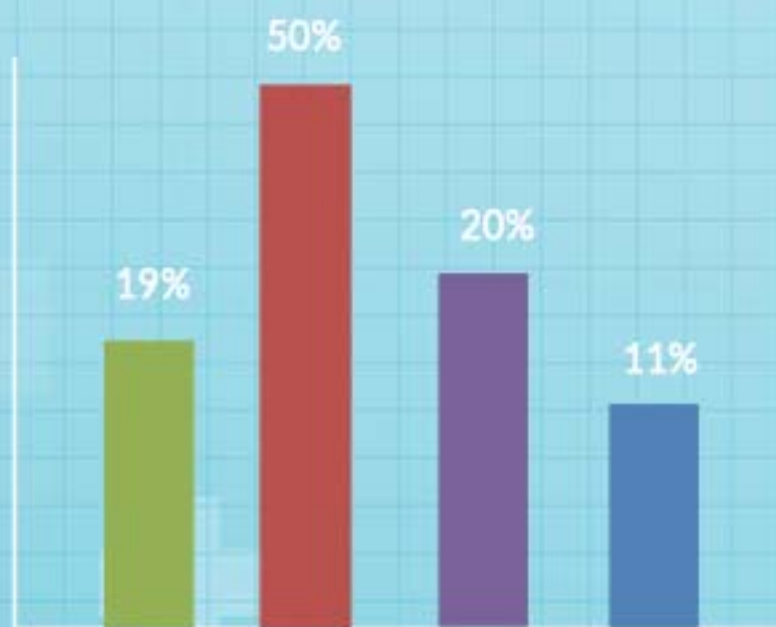
WHO ATTENDS



COMPANY TYPE



JOB FUNCTION



- Pharma & Biotech
- Regulators
- Consultancy
- Vice President
- Director
- Technology Provider
- CRO
- Global Head
- Manager

OUR FIRST ROUND OF EXPERT SPEAKERS

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About

Dr. Heike Schoepper
Head Global Drug Safety Regions,
Merck Serono



Dr. Jackie Roberts
Executive Director – Regulatory, PHV and Medical,
Actavis



Speakers

Dr. Mircea Ciuca
Head of Medical and Clinical Drug Safety
Vifor Pharma Switzerland



Attendees

Dr. Emanuel Lohrmann
Lead Safety Physician
Boehringer Ingelheim



Dr. Bert P Van Leeuwen
Global Pharmacovigilance Department
Astellas Pharma



Testimonials

Dr. Shelley Gandhi
Director Pharmacovigilance and
Drug safety, NDA Group AB, UK



Explore

Dr. Tatjana Ajhler Duretek
Head Of Medical Affairs and
Pharmacovigilance,
Belupo Pharmaceuticals



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OUR FIRST ROUND OF EXPERT SPEAKERS

Dr. Anita Rakic
LQPPV, Global Drug Safety-Regions, Global Medical Affairs and Drug Safety, Global R&D Merck Biopharma



Dr Giovanni Furlan
Helsinn Birex Pharmaceuticals Ireland



Ashok Srivastava
Medical Oncologist & Chief Medical Officer ARKAYA PHARMA, USA



Vaska Tone
President & CEO LaVaPharm Consulting, USA



DAY 1 AGENDA

08:30	Registration & Refreshments
09:30 - 9:45	Chairperson's opening remarks Shelley Gandhi Director, NDA
09:45 - 10:30	Monitoring of Safety Data to Management of the Benefit-Risk Profile <ul style="list-style-type: none"> - Do we have a good understanding of Risks in the context of benefit? - Benefit-Risk: Does one size fit all? - Can we manage the Benefit-Risk profile of a product? Dr Heike Schoepper, Head Global Drug Safety Regions, Merck Serono, Germany
10:30 - 11:00	Power Networking – An Ice Breaker Session
11:00 - 11:30	Morning Coffee/Tea & Networking RISK MANAGEMENT
11:30 - 12:00	Implementation of additional risk management measures Dr Emanuel Lohrmann Lead Safety Physician Boehringer Ingelheim, Germany



DAY 1 AGENDA

- 12:00 – 12:30 Pharmacovigilance (PV) outsourcing standard
Can Pharmacovigilance learn from the oil and gas industry?
**Bert P van Leeuwen, MD Global Pharmacovigilance
Astellas Pharma, Netherlands**
- 12:30 – 13:30 Networking luncheon
- 13:30 – 14:00 **Proposed Good PV outsourcing standards**
- Failure is a likely to occur if cost saving is the only goal of the pharmaceutical company outsourcing its pharmacovigilance activities
 - Clients and service providers should understand and openly discuss each other's needs, avoiding unrealistic expectations
 - Clients should always have in house a pharmacovigilance expert to provide constant feedback to the service provider
- Dr. Giovanni Furlan
EU QPPV Helsinn Birex Pharmaceuticals Ireland**
- 14:00 – 15:00 **Panel Discussion:**
- 14:30 – 15:00 **PRAC Strategy on measuring the impact of
Pharmacovigilance activities**
- 15:00 - 15:30 Afternoon Tea/Coffee
- 15:30 - 16:00 TBC
Vaska Tone
President & CEO
LaVaPharm Consulting, USA
- 16:00 - 16:30 Sponsor Session
- 16:30 - 17:00 Sponsor Session
- 17:00 Chairperson's closing remarks
- 17:10 - 18:30 Networking Drinks Reception



DAY 2 AGENDA

08:30 - 09:30

Registration & Refreshments

09:30 - 09:45

Chairperson's opening remarks

Shelley Gandhi, Director, NDA

09:45 - 10:30

Opening Keynote Address

SIGNAL MANAGEMENT

10:30 - 11:00

Signal Management - revised GVP guidance

Dr Mircea Ciuca, Head of Medical and Clinical Drug Safety, Vifor Pharma, Switzerland

11:00 - 11:30

Morning Coffee/Tea & Networking

CHALLENGES & OPPORTUNITIES

11:30 - 12:00

GVPs, challenges to the generic industry and how to overcome them

- Is there difference in interpretation of GVP modules between generic and
- Benefit-risk assessment for great number of drugs
- What does signal management mean for generic industry
- Challenges of risk minimization measures and safety communication for generic drugs

Dr. Tatjana Ajhler Duretek, Head Of Medical Affairs and Pharmacovigilance, Belupo Pharmaceuticals

12:00 - 12:30

Managing Pharmacovigilance Compliance locally: perspectives from a local affiliate

- Change and Ensuring compliance
- Organizational structures – what is best done locally vs globally?
- Risks and benefits of a local PV function

Dr Jackie Roberts, Director of Regulatory, Pharmacovigilance and Medical, Actavis

12:30 - 13:30

Networking luncheon



DAY 2 AGENDA

13:30 – 14:30

Panel Discussion - Patient Support Programme

14:30 - 15:00

Post-Marketing Authorisation Studies in Drug Risk Surveillance

'PASS studies: Options and practicalities'

- Regulatory aspects
- Safety issues, designs and data sources
- Risk minimisation evaluation studies
- Data Integration

Dr Nawab Qizilbash OXON Epidemiology

15:00 - 15:30

PV Audit and Inspections

- Internal audit programmes – expectations for scheduling, conduct and follow-up
- Regulatory inspections – thoughts on maintaining inspection-readiness, and preparing staff and documentation for inspection

Dr Miranda Dollen, Vice President, MAPI Group, UK

15:30 - 16:00

Afternoon Tea/Coffee

16:00 - 16:30

Good Pharmacovigilance and Clinical Practice"; "Challenges in Drug safety in Cancer Patients and Treatment

**Ashok Srivastava
Medical Oncologist & Chief Medical Officer,
ARKAYA PHARMA, USA**

16:30 - 17:00

Pharmacovigilance legislation in the non-EU Balkan countries

Dr Anita Rakic, Global Medical R&D, Merck Biopharma.

17:00 - 17:10

Chairperson's closing remarks and end of conference



PAST ATTENDEES TESTIMONIAL



Graviton did an excellent job by bringing so many busy Pharmacovigilance professionals together in a room who stayed throughout the day is a testimony to how interesting the event was, also it has been very educational and informative

Senior Vice President,
Global Pharmacovigilance,
Ipsen BioPharma



Attending an event like this makes me complete more than 50 client meetings in one place and a short span of time, rather than going out to meet clients across the country

Exhibitor,
Wolters Kluwer



PV Europe 2016 was an excellent platform for communication

Head of Global
Drug Safety, Merck



Explore
LONDON
 UNITED KINGDOM

London, the capital city of England set on the river Thames, is a 21st Century city with histories stretching back to Roman times. At its centre stand the imposing houses of parliament, the iconic "Big Ben" Clock Tower and Westminster Abbey, site of British Monarch Coronations. Across the Thames, the London Eye observation wheel provides panoramic views of the South Bank cultural complex, and the entire city.

London is a leading global city with strengths in the arts, commerce, education, entertainment, fashion, finance, health care, media, professional services, research and development, tourism & transports all contributing to its prominence. It is one of the World's Leading Financial Centers. London has a diverse range of peoples and cultures, and more than 300 languages are spoken within Greater London.

London is a world cultural capital is the world's most-visited city as measured by international arrivals London is the world's leading investment destination and best place for International Brand Promotion and Conferences.



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Important Dates:

Abstract Submission last date: 26th February 2017



Super Early Bird offer ends 26th February 2017

Early Bird Offer ends 30th March 2017



Conference Venue

Hilton London Olympia,
380 Kensington High St,
Kensington, London W14 8NL

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Conference Secretariat



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