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# Pharmacovigilance 2010

"Overseeing risks & Optimizing drug safety in today's pharma market"

January 21<sup>st</sup> - 22<sup>nd</sup> 2010, ITC Maratha, Mumbai, India

## Key Speakers:

- Veena Rajan, Head - Patient Safety, **AstraZeneca**
- Viraj Rajadhyaksha, Senior Manager, Operations, Planning & Management Clinical Research, **Pfizer**
- Simrat Sohal, Head - Pharmacovigilance, **Eli Lilly**
- Bhaswat S. Chakraborty, Senior VP, R&D, **Cadila Pharmaceuticals**
- Prashanth BSB, Medical & Safety expert (Regulatory Affairs), **Cipla**
- Deven Parmar MD, Vice President - Clinical Research & Pharmacovigilance, **Wockhardt**
- Milind Antani, Head-Pharma LifeSciences group, **Nishith Desai Associates**
- Arani Chatterjee, Vice President, Clinical Research, **Panacea Biotec**
- Siddarth S. Chachad, Medical & Safety Expert (Regulatory Affairs), **Cipla**
- Dipti Kadam, Consultant - Clinical Technology & System, **DBMS**
- Vishwas Sovani, MD, Vice President, Pharma Delivery, **TCS**
- Arun Bhatt, President, **Clininvent Research**
- Arunima Sen, Manager Medical Team, **MMS Holdings Incorporation**
- Krathish Bopanna, Senior Vice President, **Acunova**
- Sanjay Zodpey, Director, **Public Health Foundation of India**
- Gopal Pande, Scientist, **Center for Cellular & Molecular Biology**

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January 21<sup>st</sup>, 22<sup>nd</sup> 2010, Hotel ITC Maratha, Mumbai, India.

## Conference Intro:

Pharmacovigilance is the science and actions relating to detection, evaluation, understanding and prevention of adverse effects or any other likely medicine related problems. The main aim of pharmacovigilance is to improve patient care and safety in relation to the use of medicines and other interventions. Despite all the benefits of medicines in disease management, there continues to be problems related to adverse reactions which are important cause for morbidity and mortality in many countries. Significant harm to even a few patients not only destroys the credibility of the medicine, the patients also tend to lose trust on health system. A good Pharmacovigilance system will identify the risks in the shortest possible time, so that any harm can be avoided or minimized. The most frightening thought for any pharma company is the prospect of a drug withdrawal. As the costs associated with product withdrawals escalate, the importance of pharmacovigilance increases.

Pharmacovigilance 2010 conference will discuss the on-going pressing concerns faced in drug safety, addressing the risks, timeline and budget constraints, whilst effectively tackling key challenges in overcoming trials agreement and site contract negotiation hurdles. This conference brings together top pharmaceutical, biotechnology and regulatory representatives in a forum that addresses the key issues of the industry. The in-depth program covers discussion on the detection, analysis and prevention of adverse drug reactions with case studies and industry experiences. Understand and learn the latest insights, tools and knowledge to ensure that you and your firm catch up with the current and future market. Analyze along with the market leaders, the latest developments in pharmacovigilance which would shape your organization-wide risk management strategy.

## Reasons to Register:

- Reviewing the best revenue generating models suitable for current and future PV market.
- Grabbing the opportunity: learning about the challenges & complexities in the role
- Best practices, service offerings & deployment
- Global marketing strategies in order to engage with regulatory centres of excellence on pharmacovigilance and to understand their perspectives on best practice & future trends
- Improving patient care and safety in relation to use of medicines and all medical and paramedical interventions
- Exploiting the role of electronic data standards and controlled vocabularies in pharmacovigilance
- Positioning yourself in light of new market entries
- Analyzing the worldwide trends in PV & lessons for India.
- Discover approaches for collecting, integrating and analyzing all of the safety data generated from preclinical models
- Updating yourself with legislations, policies, systems, technology, communication strategies and best practice in PV
- Dwell ahead of regulatory developments & improving your risk management strategies in a cost effective way

## Who Should Attend:

VP's, Directors, CRO's, Heads and Managers of:

- Pharmacovigilance Strategy
- Drug Safety/Risk Management
- Information and Clinical Data Management
- Clinical Research & Development
- Product Safety/Assurance Assessment
- Patient Safety, Outcomes Research & Data Analysis
- Epidemiology project management
- Regulatory Affairs and Compliance
- Sales & Marketing
- Biotech manufacturers

## Target Audience:

- Pharmaceutical and Biotechnological Companies
- Contract Research Organisations (CROs),
- Contract Manufacturing Organisations (CMOs),
- Drug Regulators,
- Intellectual Property/Law Firms,
- Academia,
- Government Bodies, Regulatory Affairs, Clinical Research Scientists
- Pharmaceutical manufacturing and distributing companies
- Wholesalers
- Pharmaceutical packaging and labelling companies
- Service suppliers
- Pharmaceutical specialist couriers
- Public health and regulatory bodies,
- Anti-counterfeiting organisations
- Non-governmental healthcare organisations
- Patient Recruitment Companies
- Non-profit Organisations/Association, Consultants

## Why should you attend:

Pharmacovigilance 2010 - "Overseeing risks & Optimizing drug safety in today's pharma market"  
Get more from the event, with a broader scope bringing the whole communications value chain together. Enjoy and make the best out of our dedicated networking drinks time, meet the leading international vendors showcasing the products of tomorrow in the co-located exhibition. Expand your knowledge of the latest business models and strategies in the high-level conference.

## Delegate Registration:

To register and to book your seats at the conference - please email your interest to [delegate@virtueinsight.com](mailto:delegate@virtueinsight.com)

## Sponsorship & Exhibition Opportunities:

If you would like to benefit by promoting your organization at one of our events then exhibit is perfect for you.

- Hosting a networking drinks reception
- Increase and maintain brand awareness
- Taking an exhibition space at the conference
- Target your marketing campaign
- Advertising in the delegate documentation pack
- Providing branded bags, pens, gifts, etc.
- Network with industry decision-makers
- Meet potential clients & Present your products and ideas

Any questions on Sponsorships or Exhibition – Email your queries to [sarika.sareen@virtueinsight.com](mailto:sarika.sareen@virtueinsight.com)

## About Virtue Insight:

Virtue Insight equips business professionals around the world with the latest in-depth industry knowledge and provides networking opportunities in the telecom and pharmaceutical industry. Our aim is to provide a platform to share knowledge and insights and provide our event attendees to network effectively and deliver maximum ROI by making new business alliances. We strive to produce high quality conferences which include the latest topics which are delivered by world class leaders of the industry.

Our motto is to offer our customers the expertise and connections for a profitable business. Our events encompass an optimum chance to gain maximum value in terms of networking and an opportunity to sponsor and exhibit to attract new business alliances.

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A part of the Tata Group, India's largest industrial conglomerate, TCS has over 140,000 of the world's best trained IT consultants in 42 countries. The company generated consolidated revenues of US \$6 billion for fiscal year ended 31 March 2009. For the H1 FY 2010 quarter, BPO revenues were close to 12% of TCS revenues. TCS is listed on the National Stock Exchange and Bombay Stock Exchange in India. For more information, visit [www.tcs.com](http://www.tcs.com).

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# Pharmacovigilance 2010

Day One, 21<sup>st</sup> January 2010

**08:45 - Coffee and registration - An opportunity to meet and to network with your conference colleagues.**

**09:30 - Chair's opening remarks**

**Arani Chatterjee, Vice President, Clinical Research Panacea Biotech**

**09:40 - Observe the current & future market of Pharmacovigilance**

- Analysing the current market situation and revealing the key revenue drivers for the future markets.
- What are the steps to be taken if the industry is to achieve full potential?
- Challenges and Opportunities in 21st Century Safety Testing
- Determine the key considerations in implementing a progressive pharmacovigilance strategy

**10:20 - Topic TBC**

**Speaker TBC, Oracle Life Sciences**

**11:00 - Morning coffee & Discussion**

**11:20 - Pre-Approval periodic safety reporting using DSUR & post marketing reporting using PSUR - Understanding the essentials**

**Sanish Davis, Clinical Research Manager, PGRD, Pfizer**

**12:00- Panel discussion: Challenges in upcoming markets**

- Successful strategies to face the future challenges in pharmacovigilance
- Analyzing the changing business environment
- Evaluating where are the opportunities and threats in emerging markets

**Moderator:**

**Gopal Pande, Scientist, Center for Cellular & Molecular Biology**

**Panellists:**

**Arunima Sen, Manager Medical Team, MMS Holdings Incorporation**

**Veena Rajan, Head - Patient Safety, AstraZeneca**

**12:30 - Role of Therapeutic alliance in PV**

**13:00 - Networking luncheon**

**14:10 - Signal detection with Oracle Product**

**Dipti Kadam, Consultant - Clinical Technology & System, DBMS**

**14:40 - Growth of pharmacovigilance systems - India**

- Benefits of developing PV in India
- Analyzing the current and the future of PV in India
- Demand for efficient PV by middle class Indians

**Deven Parmar MD, Vice President - Clinical Research & Pharmacovigilance, Wockhardt**

**15:20 - Afternoon tea**

**15:40 - Emerging technologies & strategies for drug safety evaluation**

**Vishwas Sovani, MD, Vice President, Pharma Delivery, TCS**

**16:10 - Panel Discussion - Regulator's perspective**

- Pharmacovigilance from the Regulator's Perspective - Latest Updates
- Understanding how companies can work more successfully with regulators
- What can the regulators do to help industry?
- Determining the best strategy to secure approval.
- An overview of the Global Regulatory Safety Information Database

**Moderator:**

**Milind Antani, Head-Pharma LifeSciences group, Nishith Desai Associates**

**Panellists:**

**Arun Bhatt, President, Clininvent Research**

**16:50 - Chairperson's closing remarks and End of Conference**

**17:20 - Networking Drinks - Take your discussions further & build new relationships in a relaxed & informal setting...**



# Pharmacovigilance 2010

Day Two, 22<sup>nd</sup> January 2010

**08:45 – Coffee and registration – An opportunity to meet and to network with your conference colleagues.**

**09:30 – Morning Chair's opening remarks**

**TBC**

**09:40 – Data mining & signal detection in Pharmacovigilance**

**Bhaswat S. Chakraborty, Senior VP, R&D, Cadila Pharmaceuticals**

**10:20 – Pharmacovigilance in focus**

- Economic impact of ADR
- Thalidomide status through PV
- Real lessons from Vioxx
- Best-selling drugs & adv through PV for these drugs
- Practical problems & Challenges in PV
- Penalties on non-compliance to PV

**Prashanth BSB, Medical & Safety expert (Regulatory Affairs), Cipla**

**11:00 – Morning coffee & Discussion**

**11:20 – Panel Discussion - Working towards patient subject safety from early development**

- Advanced Pharmacology Techniques and Methodologies to Improve Safety
- Putting the patient first – The importance of developing a comprehensive post-marketing surveillance strategy

**Moderator:**

**Panellists:**

**S.K. Kulkarni, Emeritus Scientist & Emeritus Professor of Pharmacology**

**Siddarth S. Chachad, Medical & Safety Expert (Regulatory Affairs), Cipla**

**12:00 – Challenges in the local regulations for pharmacovigilance**

**Simrat Sohal, Head - Pharmacovigilance, Eli Lilly**

**12:40 – Networking luncheon**

**13:50 – Afternoon Chair's opening remarks**

**Sanjay Zodpey, Director, Public Health Foundation of India**

**14:00 – Topic TBC**

**Speaker TBC, Oracle Life Sciences**

**14:40 – Risk management -**

- Lessons to be learned from extensive drug safety research
- Cutting-edge risk management, how to prepare for the worst
- Managing developments and adapting to changing information
- Constant improvement in risk management strategies
- Developing and maintaining exemplary drug safety standards

**15:20 – Afternoon tea**

**15:40 – Challenges in Pharmacovigilance: Different Sponsors, Same Drug**

- What are current "best practices" in this challenging area?
- How can "continuous safety monitoring" be achieved?
- What are issues in signal detection across sponsors and trans-nationally?
- Best methods for pharmacovigilance, signal detection, risk management in this setting

**16:20 – Panel Discussion – SWOT analysis**

Strength, Weakness, Opportunities & Threats of Pharmacovigilance in India (Overall review of this Pharmacovigilance 2010 conference)

**Moderator:**

**Sanjay Zodpey, Director, Public Health Foundation of India**

**Panellists:**

**Krathish Bopanna, Senior Vice President, Acunova**

**Viraj Rajadhyaksha, Senior Manager, Operations, Planning & Management Clinical Research, Pfizer, India**

**17:00 – Chairperson's closing remarks and End of Conference**

# Registration Form

## Pharmacovigilance 2010

### 21<sup>st</sup> - 22<sup>nd</sup> January, 2010

#### For Multiple Bookings

Photocopy this form...

#### Price INR (Please Tick)

2 Day conference                      Fee: INR 12,000 + Tax                        
1 Day conference                      Fee: INR 7,000 + Tax                     

#### Academic Price (Students)

2 Day conference                      Fee: INR 5,000 + Tax                        
1 Day conference                      Fee: INR 3,000 + Tax                     

#### Registration Form Details:

Forename .....Surname .....

Job Title .....Company .....

Official Contact Number .....

Address .....

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Country .....Postcode.....

Phone .....Fax .....

Email .....

I confirm that I have read & agree to the terms and conditions of booking..... (Please Tick)                     

Signature .....

#### Methods of Payments:

**By Cheque** - Complete and return the above registration form via post or email, together with your cheque payable to Virtue Insight.

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#### Queries:

Should you have any questions on bookings, Please feel free to contact us.

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#### Payment terms:

Virtue Insight requires the full amount to be paid before the conference. Virtue Insight may refuse entry to delegates who have not paid their invoice in full.

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#### Fee:

The conference fee includes lunch, refreshments and conference papers provided on the day. This fee does not include travel or hotel accommodation.

#### How we will contact you:

Virtue Insight's preferred method of communication is by email and phone. Please ensure that you complete the registration form in full so that we can contact you.

#### News Updates:

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