14th Pharmacovigilance 2017 #VIphv

"Ensuring safer drugs to market by analyzing latest developments in pharmacovigilance, drug safety and risk management"

9th November 2017, Kohinoor Continental Hotel, Mumbai, India

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Key Speakers Include

O S SADHWANI, FDA,
Drug controller of Maharashtra and Jt.Commissioner Drug

K. BANGARURAJAN, CDSCO,
Deputy Drugs Controller, DDC(I)

MUZAFFAR AHMAD, Member, Strategic Advisory Board on Health Millenium Alliance (Govt of India) and Member Council of India

DAARA B. PATEL, Indian Drug Manufacturers' Association,
Secretary General

DEEPA ARORA, Lupin,
Vice President - Pharmacovigilance & Global Head - Drug Safety & Risk Management

JEAN-CHRISTOPHE DELUMEAU, Bayer HealthCare (Singapore),
Head of Pharmacovigilance Asia-Pacific

MANISH VERMA, Sanofi,
Director and Head of Medical Affairs, South Asia Zone

SARABJEET KAUR, APCER Life Sciences,
Associate Vice President- Pharmacovigilance

AMBRISH SRIVASTAVA, Alkem Laboratories,
Vice President: Medial Affairs, Clinical Research & Regulatory

VIKRAM GOTA, ACTREC, Tata Memorial Centre,
Associate Professor

BHASWAT CHAKRABORTY, Cadila,
Senior VP & Chair, Research and Development Core Committee

AVINASH R. KAKADE, Cipla,
Senior Director and Head of Pharmacovigilance

SHUBHADEEP SINHA, Hetero Labs,
Vice-President & Head (Global) - Clinical Development, Medical Affairs & Pharmacovigilance

RAHUL GUPTA, USV,
Vice President, Regulatory Affairs

SUJAY SURESH KULKARNI, GSK,
Senior Manager, Medical and Regulatory Affairs

MILIND ANTANI, Nishith Desai Associates,
Partner In-Charge - Pharma LifeSciences

DEEPTI SANGHAVI, Tata Consultancy Services,
Assistant Manager-Medical Writing

SRIDHAR YESHAMAINA, Wockhardt,
GM - Global Clinical Development & PV

RUCHIKA SINGHAL, AstraZeneca,
Business Unit Head

GURPREET SINGH, Novartis,
Head of Vendor Management in PV

NIDHI VAISH DAS, Roche Pharmaceuticals,
Drug Safety

MANOJ SWAMINATHAN, Piramal,
Chief Manager / Head - Global Pharmacovigilance

PRANJAL BORDOLOI, Veeda Clinical Research,
AVP - Medical Affairs and Pharmacovigilance

RAJANI ROKADE, PharmaSoulz,
Founder-Director

PRASHANT BODHE, CliniSearch,
Director

Plus many more COMING SOON.....

Special Reasons To Attend

- PV legislation: Next steps? Commission's Reflections, IMA and the industry.
- Creating a PV-focused culture
- Achieve pragmatism environment in today's PV?
- Enabling technologies: Successful business models
- Opportunity & Challenges
- Pharmacovigilance Inspection Readiness & RMP
- Research Based PV and exchange of safety data
- A digital app for reporting ADRs
- PV automation for data processing - Can Artificial Intelligence be trusted?
- Impact of social media
- Barriers to adopting AI and automation
- Patient view:
- Drug safety through patient engagement
- The challenges of the Indian Regulation – How to adapt and when?
- Required undergo registration process with CDSCO & DCGI
- Accelerating new medicine introduction in developing world
- Be part of a major networking opportunity

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Our potent conference agenda delivering the latest information and the world class leaders as speakers attract delegates to attend from around the world. We aim for our attendees to be equipped with knowledge of latest developments & enable them to network with the industry key personnel.

Delegate Registration - delegate@virtueinsight.com

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9th November 2017, Kohinoor Continental Hotel, Mumbai, India

CONFERENCE INTRODUCTION:-

The Pharmacovigilance conference, organised yearly by Virtue Insight, is a unique event where key stakeholders gather with the aim of promoting patient safety and undertaking to continue work towards a more efficient pharmacovigilance system. In the spirit of constructive cooperation, this event brings together representatives from the industry and regulators as well as healthcare professionals and patient organisations.

In order to succeed in this new environment, it is critical to be up to date on legislation globally and be transparent in all PV process. We need to have effective systems in place to empower patients, physicians, drug manufacturers and consumers to make the best drug safety decisions.

14th Pharmacovigilance 2017 will bring together key thought leaders and experts to explore these worldwide challenges. This is your opportunity to engage and sit alongside the pioneers who are driving forward innovation in pharmacovigilance. Explore benefit-risk management strategies and patient-centric approaches; discuss how you can tackle the challenges of social media and drug safety legislation globally.

Morning sessions reflect on achievements so far and focus on the milestones ahead. An open dialogue between key stakeholders has proven to be the right approach for making significant progress towards better pharmacovigilance for better public protection. Traditional afternoon brainstorming sessions stimulate a lively, engaging debate incorporating all perspectives. Hot topics are debated to identify the best possible processes and tools leading to better access to high quality medicines in India.

It gives us immense pleasure in welcoming you to the 14th Pharmacovigilance 2017

KEY THEMES DISCUSSED AT THIS CONFERENCE:-

- PV legislation: What are the next steps? Reflections from the commission, IMA and the industry.
- How to improve pharmacovigilance activities?
- Creating a PV-focused culture
- How can you achieve pragmatism environment in today's PV?
- Pharmacovigilance and enabling technologies: which business model in a fast changing world?
- Opportunity that can reduce financial risk and increase effectiveness
- Pharmacovigilance Inspection Readiness
- Risk Minimization and effectiveness evaluation
- Business partners and exchange of safety data
- Optimising Drug Safety through Research Based Pharmacovigilance
- Launching a digital app in India for reporting ADRs: first results
- PV automation for data processing - Can Artificial Intelligence be trusted
- How social media can be used for pharmacovigilance syste
- Barriers to adopting AI and automation
- Patient view: the influence of real-time patient ratings and reviews of medicines and healthcare, and how this will shape the future of pharmacovigilance
- Proactively accomplish drug safety through patient engagement
- The challenges of the Indian Regulation – How to adapt and when?
- Required undergo registration process with CDSCO & DCGI
- Accelerating new medicine introduction in developing world & overcoming challenges
- Be part of a major networking opportunity

WHO WILL YOU MEET:-

Vice Presidents, Directors, CRO's, Heads and Managers of:

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

From the following:

Pharmaceutical organizations, Generic pharmaceutical companies, Contract research organizations, Patient recruitment companies, Government- Department of health, Non-profit organizations/ Association, Consultants

WHY SHOULD YOU ATTEND?

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.

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08:30 – Coffee and registration – An opportunity to meet and to network with your conference colleagues.

09:20 – Chairperson opening remarks

MARKET OVERVIEW & ANALYSIS

09:30 – Topic TBC

O S SADHWANI, Drug controller of Maharashtra and Jt. Commissioner Drug, **FDA**

10:00 – Pharmacovigilance System Master File: Prime indicator of a robust pharmacovigilance system

- Expectations in EU from PV system master file (PSMF)
- Importance of effective Key Performance Indicators (KPIs): Measurement of PV processes
- Adoption of PSMF outside EU

SARABJEET KAUR, Associate Vice President-Pharmacovigilance, **APCER Life Sciences**

10:30 – Morning Coffee/Tea & Discussion

CHALLENGES & OPPORTUNITIES

10:50 – DISCUSSION WITH EXPERTS: Creating a PV-focused culture

- How digital health initiatives altered the monetization and accuracy of PV?
- Merging global PV system into the company corporate quality system
- How can you achieve pragmatism environment in today's PV?
- Challenges and solutions – function of PV in scientific literature
- Required legislation to screen scientific literature – how to regularly identify adverse drug reactions and other safety relevant information using software solutions? Can it contribute to solving these challenges?
- What are the challenges for dealing large amount of data, developing search strings and integrating IMA MLM results
- Implementation of additional risk management measures
- Mobile technologies and social media in pharmacovigilance
- GVP guidelines and how it can change your organizational performance and reporting.
- Discussing how the latest Pharmacoepidemiological approaches support risk management
- Discussing pharmacovigilance in vaccine development is in general using the same methods as in development of usual drugs

Moderator:

PRANJAL BORDOLOI, AVP - Medical Affairs and Pharmacovigilance, **Veeda Clinical Research**

Panellists:

SRIDHAR YESHAMAINA, GM - Global Clinical Development & PV, **Wockhardt**

DAARA B. PATEL, Secretary General, **IDMA**

MANISH VERMA, Director and Head of Medical Affairs, South Asia Zone, **Sanofi**

SUJAY SURESH KULKARNI, Senior Manager, Medical and Regulatory Affairs, **GSK**

ADDING VALUE TO THE GLOBAL PHARMA INDUSTRY

11:30 – DISCUSSION WITH EXPERTS: Pharmacovigilance and enabling technologies: which business model in a fast changing world?

- Fast changing business environment - Pushing the stakeholders in the life science industry to look for different way to face business challenges
- Add substantial value to the pharmaceutical industry beyond its cooperation to be the custodian of patient safety
- Pharmacovigilance business, shrunk budgets, increasing data sources. How fast changing regulations are rising and what are the needs in the operators
- Challenges while expanding business expansion, raising corporate images, insuring financial security and envisioning scientific challenges
- How technology and information technology can enable the need to be compliant with the business changes? Are there “new or different” approaches to deal with pharmacovigilance services?
- Unbundling of PV services and PV platform management, Software as a Service vs. Hosting
- Opportunity that can reduce financial risk and increase effectiveness
- PV automation for data processing - Can Artificial Intelligence be trusted
- How social media can be used for pharmacovigilance system

Moderator:

PRASHANT BODHE, Director, **CliniSearch**

Panellists:

SHUBHADEEP SINHA, Vice-President & Head (Global) - Clinical Development, Medical Affairs & Pharmacovigilance, **Hetero Labs**

BHASWAT CHAKRABORTY, Senior VP & Chair, Research and Development Core Committee, **Cadila**

MANOJ SWAMINATHAN, Chief Manager / Head - Global Pharmacovigilance, **Piramal**

DEEPA ARORA, Vice President - Pharmacovigilance & Global Head - Drug Safety & Risk Management, **Lupin**

RUCHIKA SINGHAL, Business Unit Head, **AstraZeneca**

NIDHI VAISH DAS, Drug Safety, **Roche Pharmaceuticals**

12:10 – Business partners and exchange of safety data

- Organising and developing, sales, marketing, safety handling, regulatory matters, phone centres and manufacturing for vendors to handle development.
- Safety exchange agreement – Necessary act to cooperate with health authority demands
- Direction and instructions to all involved organizations with regard to their responsibilities for drug safety.
- Ensuring all associates receive the safety documents they need to remain in full compliance with all regulatory and legal requirements in their jurisdictions of sale or study.
- Adequate signalling and benefit to risk analysis
- Is the data ready for a corporate audit or health authority inspection?

12:40 – Networking luncheon

Afternoon Chair Person

13:40 – Self-inspections in Pharmacovigilance

- Relevant regulations & Expectation of authorities
- Strategic planning to meet regulatory requirements
- Selecting auditors- ensuring compliance
- Risk based approach- Developing the most appropriate check list

DEEPA ARORA, Vice President - Pharmacovigilance & Global Head - Drug Safety & Risk Management, **Lupin**

14:10 – PANEL DISCUSSION WITH EXPERTS: Risk Minimization and effectiveness evaluation

- Risk management plan – Challenges and Opportunities
- Detailed practices in risk minimization
- Insights to effectiveness evaluation from both regulator and industry perspective
- The guidelines for risk management plans (RMPs) and how to develop it?
- What are the expectations of the PRAC? How it is assessed by the authorities?
- What are the main weaknesses of the RMPs provided by the license holders and how to improve them?
- Benefit-Risk Assessment in PSUR: Discussion on Practices
- What are the current regulatory and practical challenges of the Risk Management Plan and can potential improvements be identified?
- Pharmacovigilance Inspection Readiness
- PV Outsourcing Landscape - Changing dimensions from Service Provider to Partner

Moderator:

RAJANI ROKADE, Founder-Director, **PharmaSoulz**

Panellists:

VIKRAM GOTA, Associate Professor, **ACTREC, Tata Memorial Centre**

GURPREET SINGH, Head of Vendor Management in PV, **Novartis**

AVINASH R. KAKADE, Senior Director and Head of Pharmacovigilance, **Cipla**

DEEPTI SANGHAVI, Assistant Manager-Medical Writing, **Tata Consultancy Services**

14:50 – Topic TBC

MUZAFFAR AHMAD, Member, Strategic Advisory Board on Health Millenium Alliance (Govt. of India) and Member Council of India

15:20 – Topic TBC

JEAN-CHRISTOPHE DELUMEAU, Head of Pharmacovigilance Asia-Pacific, **Bayer HealthCare (Singapore)**

15:50 – Afternoon Tea/Coffee

REGULATORY

16:20 – The challenges of the Indian Regulation – How to adapt and when?

- Challenges faced in Indian market as compared to the global market
- How to work with regulators to optimise timelines for drug approvals?
- Regulatory updates on submission, approval, harmonization, new policy and speed in licensing
- Overview on how to educate for the future regulatory surroundings/outlining the result obligations for the manufacturer, including: Classification/ PSURs/ Post-market surveillance system/ Clinical evaluation report.

- Signal detecting and management – New process and overview
- Is the legislation on new Indian Medical Devices Regulation (MDR) are in final phase?
- Required undergo registration process with CDSCO & DCGI

Moderator:

MILIND ANTANI, Partner In-Charge - Pharma LifeSciences, **Nishith Desai Associates**

Panellists:

AMBRISH SRIVASTAVA, Vice President: Medial Affairs, Clinical Research & Regulatory, **Alkem Laboratories**

K. BANGARURAJAN, Deputy Drugs Controller, DDC(I), **CDSCO**

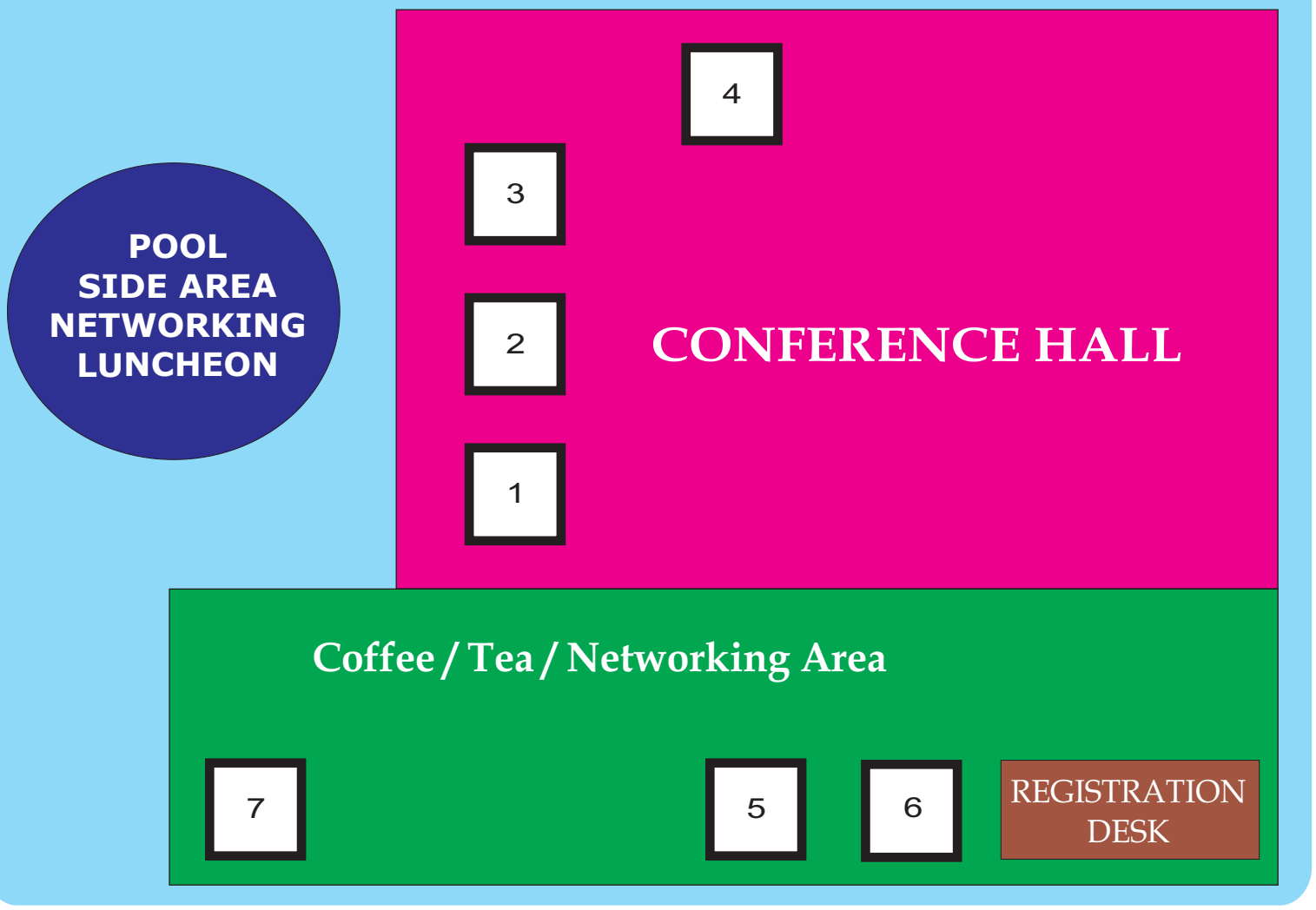
RAHUL GUPTA, Vice President, Regulatory Affairs, **USV**

17:00 – Chairperson's closing remarks and end of conference

17:10 - 18:00 - Networking Drinks - Take your discussions further & build new relationships in a relaxed & informal setting

14th Pharmacovigilance 2017

FLOOR PLAN - Book your stalls now before they run out !!!



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4C Drug Safety Services LLP
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Abbott
Abbott India
Abbott Healthcare
Abbvie
Abiogenesis Clinpharm
Accenture Services
Accutest Research Laboratories
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Dr Lal Path Labs
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Drug Safety Research Unit (DSRU)
Drug Safety Solutions
DSRU
Ecron Acunova
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Early Bird Discount Rate Till 26th September 2017

1 day conference per delegate - Fee: INR 6,000 + GST(18%) ☐

Standard Rate (27th September 2017 Onwards)

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GST No (If Applicable) .....

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Address .....

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

Signature .....

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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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Bank Address - 2/8 LAMBERT NAGAR, 1st cross street, Virugambakkam, Chennai - 600 092
Branch Name - Virugambakkam, Chennai
Swift Code - AXISINBB211
NEFT / IFSC Code - UTIB0000211
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Queries:

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

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Virtue Insight reserves the right to make alterations to the conference/executive briefing content, timing, speakers or venue without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of Virtue Insight. If such a situation arises, we will refund your registration fee and we will try to reschedule the event.

Fee:

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

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UPCOMING CONFERENCES:

- **6th Annual Pharma AntiCounterfeiting & Serialisation 2017 - 19th - 20th September 2017, London, UK**
- **13th Pharmacovigilance 2017 - 27th - 28th September 2017, Chicago, USA**
- **14th Pharmacovigilance 2017 - 09th November 2017, Mumbai, India**
- **11th Biosimilars Congregation 2017 - 06th December 2017, Mumbai, India**
- **12th Biosimilars Congregation 2018 - 27th - 28th February 2018, London, UK**
- **15th Pharmacovigilance 2018 - 07th - 08th March 2018, London, UK**
- **Pharma Regulatory Summit 2018 - 15th March 2018, Mumbai, India**
- **11th Annual Cloud & Big Data Analytics 2018 - 5th April 2018, Bangalore, India**
- **9th Annual Clinical Trials Summit 2018 - 24th May 2018, Mumbai, India**
- **Pharma IoT & AI 2018 - 13th - 14th June 2018, London, UK**
- **5th IoT Summit 2018 - 05th July 2018, Bangalore, India**
- **7th Annual Pharma AntiCounterfeiting & Serialisation 2018 - 12th - 13th September 2018, London, UK**
- **Pharma Packaging and Labelling - 19th September 2018, Mumbai, India**
- **16th Pharmacovigilance 2018 - 27th - 28th September 2018, Chicago, USA**
- **3rd Annual Pharma Pricing, Reimbursement & Market Access 2018 - 14th - 15th November 2018, London, UK**
- **17th Pharmacovigilance 2018 - 15th November 2018, Mumbai, India**
- **13th Biosimilars Congregation 2018 - 13th December 2018, Mumbai, India**

For more info on these summits - Kindly contact us at -

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Virtue Insight:-

Virtue Insight equips business professionals around the world with the latest indepth industry knowledge and provides networking opportunities in the telecom, infrastructure 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 make 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.