3rd Edition

Pharma Risk and Compliance Summit 2018

9th Feb 2018, Westin Garden City, Mumbai

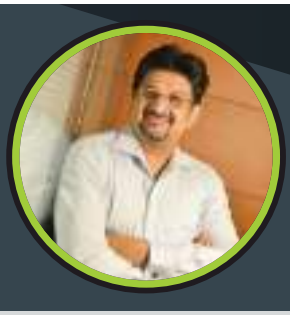
New regulations bring new risks to life sciences firms

Shantanu Mukherjee
Legal Head, Asia Pacific and Japan
Lupin Limited

Rashmi Hegde
Director - Medical
Abbott Products

Pradnya Deshmukh
VP & Head of Corporate Quality Audit
Sun Pharma

Satyajit Mallick
Head - Controls & Assurance
GSK Pharma



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Sanjay Kumar
Head of Legal, Ethics & Compliance
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Director and Head, Medical Affairs
Sanofi

Seema Manku
General Counsel India
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Nishith Desai Associates (NDA) is a research based international law firm with offices in Mumbai, Bangalore, Palo Alto (Silicon Valley), Singapore, New Delhi, Munich and New York. NDA provide strategic legal, regulatory, and tax advice coupled with industry expertise in an integrated manner. NDA's forte includes innovation and strategic advice in futuristic areas of law such as those relating to Bitcoins (block chain), Internet of Things (IOT), Aviation, Artificial Intelligence, Privatization of Outer Space, Drones, Robotics, Virtual Reality, Med-Tech, Ed-Tech and

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Pharmaceutical and Life sciences industry across the globe is among the most heavily regulated industry.
In this dynamically changing clinical, regulatory and business landscape there is a need of a common forum where the Industry experts can share the issues and challenges faced and can take a consolidated view on way forward.

The Pharma Risk & Compliance Summit intends to provide a common platform to Pharma Quality, Marketing, Business, Legal, Compliance, Risk, Regulatory fraternity, both in India as well as the Globe, to discuss and debate various Risk & Compliance issues and challenges related to the industry as well as explore new Strategies and Opportunities for growth.

This event will give professionals, whether they are new entrants in the field or Middle Management or Senior Management to interact with the leading minds in the Industry about the current state of Laws and Regulations and Government oversight and more.

Who Should Attend
You will benefit from attending this event if you are a Chief Compliance Officer, Chief Risk Officer, General Counsel or senior-level professional or team member at a pharmaceutical or biotechnology company with responsibilities or involvement in the following areas:

- *Compliance*
- *Ethics*
- *Transparency & reporting*
- *Legal/ Regulatory Affairs*
- *Risk Management*
- *Medical Affairs*
- *Regulatory Affairs*
- *General Counsel*

Why you should attend:
The summit focuses on introducing new ideas, proven strategies and practical techniques that you can take away and implement within your company's compliance and regulatory challenges. This also prepares your company to equip itself against audit exposure and facilitate audit readiness.
This year's group of speakers and presentations will help your organization better align learning strategies with its quality and compliance objectives.

Key Highlights
- *Quality & Compliance Trends and Best practices*
- *Discover the roadmap to create a compliance culture*
- *What You Need to Know about Risk and Compliance to the NEW PHARMA POLICY*
- *Understanding the Data Protection and Privacy*
- *Managing Supply Chain Risk and Interruptions*
- *Business challenges in Multi regulatory environment*

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08:30 **Registration and morning refreshments**

09:15 **Chairpersons Opening Remarks**

09:30 **Keynote Address:**
Emerging trends in Pharma Risk & Compliance - What to expect in next decade

- Pharma vision 2020.
- Dealing with various Regulators (US FDA, eMEA, TGA, MMC) for global Quality Requirement.
- Compliance with regulatory requirement of US FDA, EMEA, MHRA, MCC for export
- What lies ahead for Pharma Risk & Compliance?

Satyajit Mallick, Head - Controls & Assurance,
GSK Pharma

09:50 **Panel Discussion:**
Global Regulatory and Quality Compliance

Focus One: Regulatory expectations
Focus Two: Data integrity challenges
Focus Three: Culture and capability Building in Pharma Quality/Regulatory

Learning Outcomes and Objectives for Participants

- The new wave of Pharma Quality/Regulatory failure risks and its impact on company business and market reputation.
- Overcoming data integrity and other technical challenges.
- Ideas to improve Compliance Culture and capability in Quality

Panel Moderator:

Shantanu Mukherjee, Legal Head, Asia Pacific and Japan
Lupin Limited

Panel Members:

Dr Manish Verma, Director and Head of Medical Affairs, South Asia Zone
Sanofi

10:30 **Keynote Presentation:**
Roadmap to create a Compliance Culture

Need: While the "Culture of Compliance" concept has been around for more than a decade, compliance and ethics scandals continue to demonstrate that such cultures are still lacking in many organizations.

Without organizational commitment to compliance, policies and procedures are merely documents.

- Compliance: High priority for the organization
- The Three C's of Compliance
- Practical examples and Ideas to improve Compliance Culture
- Need to align compliance with enterprise risk management

Sandeep Seth, Director Corporate Compliance
Pfizer India

10:50 **Deep Dive Session:**

- Participant's Share their Key Learning outcomes and take back from the morning Session
- Q&A with the Speaker

11:10 **Networking and Refreshment Break**

11.40 **Strategic Insight:**
Compliance to Regulatory Audit

- Multi regulatory global challenge-
- Holistic approach to non-compliance - Journey from Burden to benefit
- Robust Quality management - 6 M Concept- Harmonization.

Pradnya Deshmukh, VP & Head of Corporate Quality Audit
Sun Pharma

12:00 **Strategic Insight:**
Cyber security and Data Privacy: Be future ready

- Internal and external Cyber security threats
- Increasing automation and related Security considerations
- Ransom ware and other emerging Cyber risks
- Data Privacy

Learning Outcomes and key take back Objectives

- Vulnerable areas in Pharma Operations.
- Options available to manage risks
- Data-Privacy hotspots
- Key considerations for a cyber-security setup.

Sanjay Kumar, Head of Legal , Ethics & Compliance
GSK Consumer Healthcare India

12:20 **Deep Dive: From mid-day session**

- Participant's share their key learning outcomes and take back from the mid-day session
- Q&A with the speaker

12:50 **Networking Lunch**

14:00 **Keynote Presentation:**
Managing Supply Chain Risk and Disruption

Need: Supply Chain Division is considered as the back bone of the Pharma Industry. Starting with procurement of the raw material for the manufacturing till supply of the products in local as well as international market is dependent on supply chain.

The current session will assist the relevant processes and mechanism to ensure efficient supply of the products.

- Identify the process gaps and weak inter department communication leading to various non-compliances.
- Strong reliance on third parties leads to mischief
- Effective Vendor Qualification process, due diligence and approval mechanism to ensure compliance from third parties
- Well defined contractual terms and flow down of obligations
- Review mechanism and surprise onsite visits.

Anand Sampath, Finance and Risk Management professional
Insynergy Consulting LLP

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14:20 **Keynote Address:**
Corruption risk in Pharma: Diagnosing the challenges

Need: Within the health sector, pharmaceuticals stands out as sub-sector that is particularly prone to corruption. There are abundant examples globally that display how corruption in the pharmaceutical sector endangers positive health outcomes

- Anti-corruption measures.
- How to ensure a strong legislative and regulatory framework.
- Ensuring accountability through increased monitoring and sanctions.
- Enforcement of Policies.
- Employee best practices.

Dr Manish Verma, Director and Head of Medical Affairs, South Asia Zone
Sanofi

14:40 **Case Study:**
Engaging with Indian Regulators: Lessons and Challenges

15:00 **Technological Insight:**
Preparing for the Future Threat: Data Protection and Privacy

Need: Managing Privacy and Data Protection requirements in the Pharmaceutical and Biotech world can be a highly complicated matter.

- Strategies for Data protection and Assessment
- Key strategies to Prevent Privacy Violations.
- Setting up a trustworthy platforms

Seema Manku, General Counsel India
Apotex India *(Tentative)*

15:20 **Deep Dive Session**

- Participant's Share their Key Learning outcomes and take back from the morning Session
- Q&A with the Speaker

15:40 **Networking and Refreshment Break**

16:10 **Strategic Insight:**
Compliance with Environmental Laws

- Environmental Laws & Risk Management initiatives.
- Sustainability and CSR initiatives as a tool to de risking the business model.

Learning outcomes and key take back objectives for participants

- Key environmental risk and compliance hotspots
- Overcoming longer term risks through safety and sustainability initiatives including CSR.

16:30 **Strategic Insight:**
Price Regulation and the Pharma Industry: Analyzing Global Trends

- Frequent changes in Drug pricing by the regulators.
- Industry specific measures.
- Volatile environment:
- Difficulty to cope up with huge cost involved in R&D versus profit margins.

Shantanu Mukherjee, Legal Head, Asia Pacific and Japan
Lupin Limited

16:50 **Panel Discussion:**
Business challenges in Multi regulatory environment

Need: One of the major challenge for Pharma Companies is to comply with Multi Regulatory Environment. The Regulatory requirements specified by each regulatory body i.e. local FDA, US FDA, EMEA, MHRA are unique and this results into huge R&D cost, more time for getting approvals, which impacts on profitability and revenue generation.

The Panelists here are invited to discuss how to minimize business impact due to multi regulatory requirement, ensure compliance and suggest way forward.

Focus of the discussion:

Focus 1. Need for synergy of requirements and approval process between various regulatory authorities.

Focus 2: Cost implication versus profit margins.

Focus 3: Effective Inter department communication

Focus 4: Robust Compliance Mechanism to avoid non compliances / penalties.

Focus 5: Way forward

Jignesh Mehta, Associate Director, Enterprise Risk Management
Dr. Reddy's Laboratories

Sandeep Seth, Director Corporate Compliance
Pfizer India

Rashmi Hegde, Director – Medical,
Abbott

17:30 **Close of Conference**

REGISTRATION FORM

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LOCATION AND DATE

Pharma Risk and Compliance Summit 2018

Friday 9th February 2018

Westin Garden City, Mumbai

CONTACT INFORMATION

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Mail this completed form together with payment to
UBS TRANSFORMANCE

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Indian Delegates:

Early Bird Rates	Till 11th December	Till 15th January	Standard Rate
Amount in INR	☐ 10,000	☐ 12,500	☐ 15,000
Group discounts available (The group discounts compound on top of the early-bird discounts) *Prices are in INR. *Additional tax of 18% GST is applicable.*			Your GST No

International Delegates:

Early Bird Rates	Till 11th December	Till 15th January	Standard Rate
Amount in USD	☐ $200	☐ $300	☐ $500
Group discounts available (The group discounts compound on top of the early-bird discounts) *Prices are in USD. *Additional tax of 18% GST is applicable.*			Your GST No

All payments must be received prior to the event date
Attire: Formal Business Attire
Date: 9th February, 2018
Time: 08:30 am - 05:30pm

General Information: The fees cover participation at the event, lunch, tea breaks and certificate of participation.

Confirmation Details: Joining details confirming your participation and invoice will be sent, once registration form has been received. Payments to be made within 5 working days of receiving the invoice

Hotel Bookings: For hotel bookings, please contact the Reservations department directly and quote UBS Transformance to take advantage of the corporate rate.

Cancellations: Once registration form is received; participation can't be cancelled. Cancellations carry a 100% liability and course materials will be emailed to you. However substitutions of delegates are welcome any time before the conference date

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