6th Annual Edition®

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Pharma Legal & Compliance Summit 2017

in association with SILF Society of Indian Law Firms

6th October 2017 | NOVOTEL Juhu Beach, Mumbai

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INVITED AND CONFIRMED SPEAKERS

Debolina Partap, Vice President – Legal & General Counsel, Wockhardt Group – Summit Chair

Dr. Kalyan Chakravarthy, Head-Regulatory Affairs (India Operations), Dr. Reddy's Laboratories
Akshat Pande, Partner, Alpha Partners
Garima Sahney, Associate Partner, Saikrishna & Associates
Gautam Rohidekar, General Counsel, Cipla
Ghanashyam Hegde, Director Legal, Abbott India
J Sai Deepak, Founder, Law Chamber of J Sai Deepak
Kaizad Hazari, Head, Legal and Corporate Affairs (South Asia), Legal Operations International
Lalit Ambastha, Founder and Patent Attorney, PatentWire Consultants
Mahalaxmi Andheria, Vice President- Intellectual Property Cell, Panacea Biotec
Meera Vanjari, Sr. Vice President and General Counsel, Glenmark Pharmaceuticals
Rahul Gupta, Vice President – Regulatory Affairs, USV
Rakesh Chandra Sinha, Head Legal – Sun Pharmaceutical Industries
Samir Kazi, Director Legal, Pfizer
Sanjay Kumar, Head of Legal , Ethics & Compliance, GSK Consumer Healthcare India
Sanjaykumar Patel, Head-IPR (Intellectual Property Rights) |B&S Group, UK
Shantanu Mukherjee, Legal Head, Asia Pacific and Japan, Lupin
Shujath Bin Ali, Senior Director- Legal & Risk Management, PAREXEL International
Siva Gopinatham, Partner, Dhir & Dhir Associates
Subodh P Deo, Partner, Saikrishna & Associates
Sudeep Sanyal – Regional Vice President, Apttus
Tapan Pati, Director & Senior Counsel Legal, Johnson & Johnson
Taranpreet Singh Lamba, Vice-President; Intellectual Property and Global Product Portfolio, Glenmark Pharmaceuticals
Vinod Kumar. B, Head Legal, Strides Shasun
Vivek Mittal, Legal Counsel, Lupin

AGENDA

08:30 AM	SUMMIT REGISTRATION & MORNING REFRESHMENTS
09:30 AM	OPENING REMARKS BY LEX WITNESS
09:45 AM	THE SUMMIT CHAIR'S ADDRESS – DEBOLINA PARTAP, VP & GENERAL COUNSEL, WOCKHARDT GROUP
10:00 AM	THE INDIAN PHARMA REGULATORY RIDES – ARE WE READY FOR 2020?

THE FDC SAGAS

- The 344 FDC Ban – Lessons & Learnings – Managing FDC related litigation & court matters
- India as an FDC Market – Getting Future Ready – Overlaps between FSSAI & CDSCO Reins – The Classic Case of ORS

PRICING OF DRUGS – WHOSE CAP IS IT ANYWAY?

- The NPPA Whips on Drugs & Medical Devices – Impact on R&D and Manufacturing
- The Medical Devices Rules, 2017 Industry Implications And Action Required

CREATING A 100% COMPLIANT BUSINESS ENVIRON

- USFCPA – Impact Assessment
- Importance of e-Discovery as a Tool, Litigation Risks wrt e-Discovery Preparedness
- Global Employment related Compliance Challenges – Are You Prepared Enough?
- Whistle Blower Protection | Managing Forensic Investigations | Enterprise Risk Management | Audit Lifecycle Management
- Good Manufacturing Practices – Quality Control vs. Business Margins
- Alliance for Integrity – A Self-Regulatory Drive

UCPMP & MCI GUIDELINES

- Prescription Guidelines – Capping on Sampling of Drugs
- Power to Pharmacists – Salts Vs. Drug Names – UCPMP Code – on its way to become Mandatory?

AGENDA

COMPETITION LAW

- CCI Warning to Druggists & Chemists Associations
- Interplay between Regulatory and Competition for pricing of products – Merger Notifications to CCI

DEMYSTIFYING THE BIOSIMILARS

- Defining Number of Trials in case of Biosimilars – Lack Legislative Clarity for Biosimilars
- The 180-Day Post-Licensure Notice for Biosimilar Litigation – CDSCO Revised Guidelines On Similar Biologics

CLINICAL TRIALS

- Demand for Compensations for the Affected – Justified Enough?
- Recent Regulatory Changes – A leg up to the Indian Clinical Trials Industry?

THE TOUGH INDIAN PHARMA TURF 2017

- GST impact on domestic business and its normalisation – Update on USFDA issues plaguing several companies
- Continued pricing erosion in US business with consolidation of buyers
- Increased competition and growth in emerging markets after stabilisation of currencies

THE GLOBAL GAMES

- Combating USFDA Pressures
- FDI Fevers in Brownfield Projects – Standard Operating Procedure (SOP) for processing the FDI proposals by DIPP
- Setting up Globally Compatible Regulatory Standards – Challenges facing seamless exports of Indian Drugs
- Facilitating Import of Foreign Drugs – Concept of GDUFA – Disallowance of Reverse Engineering

& MORE – NICE TO KNOW

- Fair Remuneration for Compulsory Licensing – Amendments to The Legal Metrology (Packaged Commodities) Rules, 2011
- Industry's Concern Over issue of Growing expired drugs with no set rules – Indian Health Care Payment Rates – Assessment

AGENDA

11:30 AM	NETWORKING AND REFRESHMENT BREAK
12:00 NOON	THE DIGITAL WAVE – TECHNOLOGICAL ADVANCEMENTS & PREPAREDNESS

- The Growing Role of Automation in the Pharmaceutical Industry
- Use of Artificial Intelligence for Drug Discovery
- Cyber Security – Proactive Measures for Ransomware Attacks
- Need to strengthen know-how in regulations including cyber security & anti-bribery
- Data Driven Insights – Criticality for Drug Value Assessment & Decision Making
- Developing Integrated Clinical Research Frameworks & Big Data Analysis
- Devising a Growth Strategy by Big Data Analysis – Data Protection & Privacy – Eliminating Chances of Breach of Confidentiality
- Securing Patient Data – Leakage of e-prescription information
- FDI in Pharma Tech and e-Pharma
- e-Pharmacy – Dire Need to Cover the Black Hole of Legislation & Regulatory Affairs?
- e-Pharma Liabilities – Intermediary Vs. Aggregator – Probable e-Pharmacy Models – Inventory & Marketplace
- Cloud Computing – Legal & Regulatory Challenges w.r.t Indian Pharma Sector
- Driving ROI & Risk Mitigation through effective Contract Lifecycle Management
- Can Enterprise Businesses outperform rivals by leveraging Artificial Intelligence in their Contracting processes?
- Can AI+Intelligent Bot enabled Contract Management be the best ally of a GC today?

01:15 PM	NETWORKING LUNCH
02:15 PM	IPR & THE INDIAN PHARMA REGIME

- Combating Counterfeiting Efforts
- Demand for Anti-Counterfeiting Service Agencies
- Anti-Counterfeiting Advisory
- Patent Issues – Indian Standpoint Vs. Global Benchmarks
- Patent Wars – Opposition & Litigation
- Survival of the Generics
- ANDA Licenses – Blindspot for India
- Role of IPR in ANDA Litigations
- Trade Secret Policies Vs. Patents – Pros & Cons
- Injunction Vs. Licenses – How would R&D Furnish?

AGENDA

- Critical e-Discovery Mandates in IPR
- WIPO Alternative Dispute Resolution (ADR) for Life Sciences
- Need of Incentivization for Research to Foster IPR Environ
- Patents & Data Exclusivity
- Combating Trademark Litigation
- Bolar Exemption in Indian Patent Law
- Patent Term Extension & Non-Patent Exclusivities for Pharmaceuticals – Much Needed?
- Setting up of The IP Exchange in India
- Drug Re-purposing & Associated Patentability Scope

03:45 PM	NETWORKING AND REFRESHMENT BREAK
04:15 PM	THE INDIAN PHARMA MARATHON – 3 POWER PACKED DISCUSSION GROUPS TO CHOOSE FROM

A 60 minute power packed set of deliberations and discussions where the audience would be segregated into 3 roundtables led by respective roundtable leaders who will share their respective discussion insights individually. To conclude the marathon, a session chair will draw key learnings and takeaways basis all 3 roundtable discussion insights. The 3 roundtable discussion topics that the audience may choose to be a part of are as follows;

- Creating Value through Smart Contracts
- Global Bestpractices to Combat Counterfeiting
- Streamlining Strategies & Creating a Roadmap – Pharmaceutical Pricing in India

05:15 PM	GALA LUCKY DRAW FOLLOWED BY SUMMIT CLOSING REMARKS