14th Annual Global Pharma Regulatory Summit

6th – 8th May 2025

Novotel Mumbai International Airport

COUNTRY'S LARGEST GLOBAL PHARMA REGULATORY CONFERENCE

Day 1 Tuesday, 6th May 2025 – USA REGULATORY LANDSCAPE

09:00 – 10:00	**Registration & Networking**
10:00 – 10:15	**Opening Remarks from Informa Markets in India**
10:15 – 11:15	**Leadership Panel Discussion: Adapting to Regulatory Shifts: Navigating Volatility & Change in the Evolving Landscape** • Overview of regulatory changes & potential impact on the pharma and healthcare • Strategies for maintaining compliance in a dynamic regulatory landscape • Anticipating changes in FDA and CMS • Assessing the impact of U.S. regulatory changes on global markets, including international drug approvals, pricing, and compliance • Regulatory evolution in biosimilars: Approval pathways, interchangeability, and market access challenges **Moderator: Kumar Gaurav,** General Manager - Regulatory Affairs**, Panacea Biotec** **Panellist:** **Abhishek Sinha,** Vice President & Head Global Regulatory Affairs, **Advanz Pharma** **Raja Sekhar Reddy Vanga,** Vice President - Global Regulatory Affairs**, Biocon Biologics** **Dr. Akshaya S. Odak,** Head Regulatory Affairs (Biotech)**, Lupin Limited**
11:15 – 11:45	**Networking Coffee Break**
11:45 – 12:25	**GDUFA III Reauthorization and Its Implications** • GDUFA III Reauthorization: What's New? • GDUFA III and its impact on submission timelines • Opportunities and challenges **Anand Saxena**, Director Regulatory Affairs, **Cipla Ltd**
12:25 – 12:45	**Emerging Threats to Emerging Solutions: Vaccines, Regulations, And Technology** • Breaking Barriers: Regulatory strategies for expedited vaccine access in emerging market • From Bench to Border: Driving equitable vaccine innovation and delivery • Strong Links, Stronger Health: Future-proofing vaccine supply chains **Kumar Gaurav,** General Manager - Regulatory Affairs**, Panacea Biotec**
12:45 – 14:00	**Networking Lunch Break**

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14:00 – 14:45	**Panel Discussion: Audits & Inspections: Streamlining Regulatory Submissions and Document Management** • Best practices for preparing for FDA audits • Streamlining regulatory submission processes • Managing regulatory documents and ensuring compliance • Use of technology for effective & faster submissions **Moderator: Anand Saxena**, Director Regulatory Affairs, **Cipla Ltd** **Panellist:** **Yogananda Reddy Gotluru,** General Manager- Global Regulatory Affairs**, Biocon Biologics** **Shyam Butte,** Deputy General Manager, **Glenmark Pharmaceuticals** **Suhas Katare,** Global Regulatory Affairs Head, **Umedica Laboratories Private Limited**
14:45 – 15:25	**Real-World Evidence (RWE) & Real-World Data (RWD) in Regulatory Decision-Making** • Supporting drug approvals, label expansions, and safety monitoring • Global approaches to incorporating RWE/RWD in decision-making • Ensuring reliability, standardization, and interoperability • Role of AI and big data analytics in advancing RWE/RWD utilization **Juliet Rebello,** Director – Clinical Research**, Cipla Ltd**
15:25 – 15:55	**Networking Coffee Break**
15:55 – 16:35	**PDE Analysis in Cleaning and Validation** • Overview of PDE principles • Insights into addressing PDE analysis challenges in the US market • Best practices for aligning PDE analysis with regulatory requirements **Shubhadeep Sinha**, Senior Vice President, Head - Clinical Development & Medical Affairs, **Hetero**
16:35 – 17:15	**Nitrosamine Risk Assessments: Regulatory Expectations and Industry Insights** • FDA's Guidance on Nitrosamine Contamination • Risk assessment and control measures for nitrosamines • Implications for manufacturers and regulatory compliance **Ramana Kumar. K**, Director- Head Regulatory Affairs API, **Cipla**
Networking Coffee Break & End of Day 1	

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Day 2 Wednesday, 7th May 2025 – UK & EUROPE REGULATORY LANDSCAPE

09:00 – 10:00	**Registration & Networking**
10:00 – 10:45	**Panel Discussion: Navigating the Evolving Regulatory Landscape in Europe** • EU pharmaceutical legislation updates • Understanding the EU Variation Guidelines: Practical Insights for Manufacturers • Recent developments in EMA guidelines for the regulatory requirements of biosimilars • Highlights of the proposed tailored clinical approach in biosimilar development **Moderator: Pooja Thakur**, Associate Director, Regulatory Intelligence & Reporting, **Advanz Pharma** **Panellist:** **Dr Shuvankar Ballav,** Head, Regulatory Affairs - Advanced Biotech Lab (ABL)**, IPCA Laboratories Ltd** **Meheka Kotwal**, Senior Manager Regulatory Affairs, **Advanz Pharma** **Vishal Bankar**, Sr. Manager- RA CMC, **TevaPharm India Private Limited**
10:45 – 11:25	**NABL Accreditation and it's Benefits** The purpose of this session is to educate the Pharma industries, laboratories, and other stakeholders about the significance of NABL accreditation and how it aligns with the institution's goals of excellence in their respective fields. Through interactive session and presentation, this session aims to: • Explain the importance and relevance of NABL accreditation. • Outline the process of obtaining NABL accreditation and the criteria involved. • Highlight the benefits and advantages of being NABL accredited, such as improved quality assurance, increased customer confidence, and international recognition. • Address any queries regarding the accreditation process and its implementation within an institution. **Dr Bhumi Rajyaguru**, Joint Director, **NABL-Quality Council of India QCI**
11:25 – 11:55	**Networking Coffee Break**
11:55 – 12:25	**Fireside Chat: Good Pharmacovigilance Practices- GVP Annex 1 in Europe for Better Human Health Protection** • Key updates and scope of Annex 1 in pharmacovigilance practices • Leveraging digital platforms for proactive pharmacovigilance • Risk Analysis for Drugs, Biologics & Combination Products • Evolution of clinical efficacy and safety study waivers for biosimilars **Moderator:** **Shubhadeep Sinha**, Senior Vice President, Head - Clinical Development & Medical Affairs, **Hetero** **Speaker: Rahul Gupta,** VP- Regulatory Affairs**, USV** **Dr Priyanka Das,** Head Pharmacovigilance**, CuraTeQ Biologics Pvt. Ltd**

12:25 – 13:05	**Regulatory Intelligence - Proactive Approach Towards Regulatory Strategy** • Harnessing tools and technologies to predict regulatory shifts and streamline compliance planning • Discussing strategies to adapt to diverse and evolving international regulatory frameworks • Integrating regulatory intelligence into product lifecycles **Pooja Thakur**, Associate Director, Regulatory Intelligence & Reporting, **Advanz Pharma**
13:05 – 14:05	**Networking Lunch Break** 
14:05 – 14:45	**Regulatory insights into Artificial Intelligence Integration on Drug Lifecycle** • Understanding regulatory requirements for AI-driven drug discovery tools • Guidelines for using AI in patient recruitment, monitoring, and trial optimization • Managing risk and ensuring compliance with GMP **Harimohan Gupta**, General Manager – EU & UK Regulatory Affairs, **Indoco Remedies**
14:45 - 15:25	**Aligning with Evolving Standards: Navigating the Expectations of Revised EU Regulations.** • Interpreting and navigating the revised EU regulatory framework • Meeting Industry expectations amid the complexities of global regulatory alignment **Vishal Bankar,** Sr. Manager- RA CMC**, TevaPharm India Private Limited**
15:25 – 16:05	**Knowledge - Aided Assessment and Structured Application** • KASA is A data-based (Health Authority Cloud Server) IT system for regulatory review and knowledge management by using structured submission of data. • It establishes rules and algorithms to the risk identification, mitigation & communication for drug product, manufacturing process and facilities. • Improves overall efficiency and excels regulatory decision making by assuring drugs dependably meet high quality standards. **Durga Prasad Erukulla**, Manager – Regulatory Generics Development, **Sandoz Development Center**
Networking Coffee Break & End of Day 2	

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Day 3 Thursday, 8th May 2025 – INDIA & APAC REGULATORY LANDSCAPE

09:00 – 10:00	**Registration & Networking**
10:00 – 10:45	**Leadership Panel Discussion: India's Evolving Pharma Regulatory Framework: Driving Industry Growth and Compliance** • Progress in pharma regulatory evolution • Updates on CGT & Biosimilars approvals & guidelines • Medical Devices - Rules, risk classification, mandatory QMS and GMP adherence • Impact of revised Schedule M compliance **Moderator**: **Martina Gomes,** Head Regulatory Affairs – CH South Asia**, Bayer** **Panellist:** **Sudheendra Kulkarni,** Associate Vice President**, Biocon Biologics** **Dr Atharva Karulkar,** Co-Founder and Head - Scientific Affairs, **ImmunoACT**
10:45 – 11:25	**Advancing CAR-T Therapy in India: Regulatory Milestones and Future Directions** • Examination of CDSCO's approval process for CAR-T products • Lessons learned from the approval of two CAR-T therapies in India • Opportunities and challenges in fostering innovation and commercialization of CAR-T therapies **Dr Atharva Karulkar,** Co-Founder and Head - Scientific Affairs, **ImmunoACT**
11:25 – 12:00	**Networking Coffee Break**
12:00 – 12:40	**Bridging Regulatory Gaps: A Deep Dive into Japan, China, and ASEAN Countries** • Regulatory frameworks in Japan's PMDC, China's evolving pharma regulations, and the ASEAN market dynamics • Strategies for global pharma companies to align with diverse regulatory standards • Future trends in cross-border regulatory cooperation and challenges in harmonizing policies **Ramana Kumar. K**, Director- Head Regulatory Affairs API, **Cipla**
12:40 – 13:20	**Exploring the Evolving Pharmaceutical Regulatory Landscape in Africa - Recent Updates in Ethiopia's National Regulatory Procedures** **Abebe Alamneh,** Senior Medicine Registration Expert, **Ethiopian Food and Drug Authority** Vice chairman, **East Africa Regulatory Affairs Professionals Association**
13:20 – 14:00	**RoundTable 1: Navigating Global Regulatory Complexity: Aligning Strategies Across Multiple Markets** **RoundTable 2: Leveraging Digital Transformation in Regulatory Affairs**
14:00 – 15:00	**Networking Lunch Break and End of the Conference**

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