ISPE India Affiliate

ISPE India Conference 2025

Manufacturing and Quality Compliance Conference

Advances in Pharmaceuticals and Biopharmaceuticals Technologies

AGENDA

- **Annex 1 & Containment requirements**
  Mr. Richard Denk , SKAN AG
- **Advanced Therapies and Biotechnology Products – Regulatory updates**
  Mr. Mark Birse, Vice President Technical, Strategic Compliance Consulting, Parexel International
- **Annex 1 in Practice: The Role of RTP Transfer Systems and Stopper and Cap Treatment Equipment in Meeting GMP Standards in Pharmaceutical Production**
  Mr. Andreas Mayer, Chief Technical Officer & Mr. Julian Schwendele, Process Engineering Specialist, Castus Germany
- **Antibody drug conjugate: challenges & solutions**
  Dr. Subhasis Banerjee ,Merck Life Science
- **Fill finish operations for high-potent products – with a case study for an ADC facility**
  Mr. Lukas Munzinger, Syntegon Germany
- **Design of Facility / Engineering Considerations for Contamination Control**
  Ms. Jo Sherriff, Seer Pharma
- **Plastic Waste Quantitation in Biopharmaceutical Manufacturing**
  Mr. Adam Goldstein, Sr Director R+D Innovation, Thermo Fisher Scientific USA
- **Sustainability in Digitalisation and Automation**
  Dr Vipul Doshi, Chief Quality & Compliance Officer, Zydus Lifescience Ltd
- **Current status of lyophilization for Pharmaceuticals :challenges and achievements**
  Dr. Madhav Kamat, Kamat pharma, USA
- **Closed Processing (CP): A Key Enabler for Next Generation Biomanufacturing**
  Mr. Somasundaram, Merck Life Science
- **Comparison of Open / Closed / Automated Systems for ATMP Manufacturing**
  Ms. Shanshan Liu, Technical Director, No Deviation, Singapore
- **Containment for high potent products**
  Mr. Richard Denk, Skan, AG
- **Contamination Control Strategy**
  Mr. Sanjaya Nanjundaiah. Quality Tech Lead, No deviation , Singapore

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- **How to Achieve & Maintain OEB-7 Containment**
  Mr. Andrew Lemaire, Director, DEC Group, Switzerland

- **Biologics manufacturing : Scale up, process intensification & cogs optimization**
  Mr. Sandeep Majumdar, Intas Biotech

- **OPEX and CAPEX Optimization for Biopharma Plants**
  Mr. Magesh Ramadoss, Zeta Biosystems

- **Digital Safeguards: Leveraging Digitisation to Reduce FDA Recall Risks**
  Mr. Rohan Bhatia, Director & Software Products and Services Manager, SeerPharma , Australia

- **Airflow Visualization techniques and technology: How to avoid common mistakes and misunderstandings related to smoke studies**
  Mr. Morgan Polen, Microrite Inc., USA

- **Exploring the Relationship Between Contamination Control Strategies and Quality Risk Management**
  Ms Amanda McFarland, Seer Pharma

- **Panel discussion on PHARMA 4.0 Implementation**
  Chair by Mr Sekhar Surabhi, President, Caliber

- **Digitalization for Data Analysis and Trending/Pattern Recognition for Annex 1 Contamination Control Strategy**
  Ms. Susan Cleary, Director of Product Development, Novatek International, Canada

- **Digital Transformation with Asset Administration Shell for Efficiency Improvement**
  Mr. Sadiq Khan, Burkert

Register Now

27th and 28th February 2025 **The Forum, Ahmedabad**

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