Injectables X (IJX26)

29 Jan 2026 - 30 Jan 2026

CONFERENCE PROGRAMME

Thursday, 29th January 2026

09:00	**Inauguration**
09:05	**Introduction to Glostem**
09:10	**Introduction to Exhibitors**
09:15	**Welcome Address** **Sanjay Bajaj** , CEO & MD , Glostem Private Limited , India
09:30	**Injectable Horizons: Synchronizing Portfolio Strategy with High-Efficiency Growth**
09:35	**The Complex Injectable Horizon: Strategic Selection and the Pursuit of Low, Moderate or Highly Complex Pipeline with Low Competition in the Global Market** **Avijit Kelkar** , Co-founder & Principal Strategist , Aharav Consultants , United Kingdom The seminar shows a unique way to select products and portfolio strategy, that helps you for a faster easier and very efficient way of identifying opportunities, using some of the examples obtained from our flagship Portfolio ideation platform - HORIZONS
10:05	**Efficiency in Action: How Startups and Small Pharma Fuel Global Pharma Growth — A Stakeholder Perspective** **Deepak Murpani** , Chief Scientific Officer (CSO) & Chief Operational Officer (COO) , Andersen Pharma Global , Poland This presentation highlights how generic pharma startups complement established players, drive efficiency, and create long-term value for healthcare systems, regulators, and investors, positioning them as critical enablers of growth and innovation in the global generic pharmaceutical ecosystem.
10:35	***Tea/Coffee Break***
11:05	**Multi-Dimensional Characterization: Bridging the Gap Between API, Excipient, and Complex Formulations**

11:10	**Characterization of Complex Products with Specific Reference to API, Excipients & Formulations** **Hari Raghuram Desu** , Director and Head, Complex Products , Aizant Drug Research Solutions Private Limited , India The purpose of this session is to discuss the scientific principles and practical considerations that inform current FDA thinking about the characterization of complex products to support product development and assessments. Approximately 110 NDAs are approved each year, and 25% of these approvals meet complex product criteria. And 20% of the total generic approvals represent complex products. The topic would benefit, generic drug industry, academic institutions, contract research organizations, consultants, and other stakeholders. Topic coverage includes small molecules, peptides and large molecules such as monocloncal antibodies.
11:40	**Advanced Characterization of Peptide Injectables: Recent Learnings from Regulatory Guidances, Publications & Funded Programs** **Sujoy Mukherjee** , Head-Complex Product Development , Baxter Pharmaceuticals India Pvt. Ltd. , India Characterization of peptide injectables is an essential step to proving sameness of generic drugs with their branded counterparts. Typically, this includes assessing primary, secondary, tertiary and higher order structures of the peptide API using orthogonal methods. Depending on the nature of complexity of the peptide, additional studies on oligomerization and aggregation are also usually requirements to demonstrate the sameness of the generic product. In addition to these "one-time" studies, proving functional efficacy of the peptide molecule in a given formulation to elicit appropriate biological response by suitable in-vitro biological assays is another fundamental requirement for approvability of peptide products. Finally, this talk will also dwell on FDA guidelines on immunological risk assessment for peptide formulations of synthetic origins as well as using requirements to qualify impurities that are above acceptable threshold.
12:10	**Exploring Structural Complexity in Glycopeptide Therapeutics: A Case Study** **Nitish Sharma** , Assistant Professor , National Institute of Pharmaceutical Education and Research, Ahmedabad , India In this study, the second-generation lipoglycopeptide Dalbavancin (DAL) was comprehensively evaluated under heat, light, freezethaw and mechanical agitation to assess stress-induced structural alterations. DAL exhibited sensitivity under all tested conditions, leading to the formation of diverse structural alterations and degradation products identified by high-performance liquid chromatography indicating modifications in its primary structure.
12:40	**Interactive Session**
13:20	**Group Photograph**
13:30	***Lunch***
14:30	**ANALYTICAL CONTROL: ENSURING SAMENESS IN COMPLEX INJECTABLES**

14:30	**Analytics of Complex Injectables: Characterization to control** **Satish Naik** , Principal Scientist , Delpharm Development Leiden , Netherlands This presentation will be delivered as a science-focused, case-driven discussion linking analytical method design to formulation behavior, process understanding, and regulatory expectations. Key topics include multi-technique particle size and morphology characterization, rheological assessment of injectability and syringeability, solid-state and molecular-weight analytics for polymer-based depots, and evolving in vitro release testing methodologies for long-acting injectables. Analytical artifacts associated with sample preparation and scale will be critically discussed. The talk will emphasize CQA-driven, phase-appropriate analytics within a QbD and risk-based framework, and conclude with emerging trends in digital and platform-based analytical strategies for **complex injectables.**
15:15	***Tea/Coffee Break***
15:45	**BRIDGING THE IN VITRO/IN VIVO INTERFACE: FROM REGULATORY IVRT TO ADVANCED SIMULATIONS**
15:50	**IVRT for Complex Parenterals: Regulatory Expectations and Practical Challenges** **Mukesh Kumar** , Founder Director , Ortiv-Q3 , India This presentation outlines key scientific and regulatory considerations in designing IVRT methods for complex injectables. It will cover the strengths and limitations of compendial and non-compendial systems, delivery-system-specific challenges, and practical pathways for establishing fit-for-purpose release methods.A special focus will be on Ortiv-Q3 Research's Microdialysis-based IVRT platform (Indian Patent Granted, US patent pending), developed to address current gaps in release testing of complex parenterals. The technology, recognized as a finalist in "Innovation of the year" category at the CPHI India Pharma Awards 2023, offers a novel, faster, more discriminatory and biorelevant approach to measuring drug release from advanced injectable systems.
16:20	**IVIVC development for complex injectables** **Matthias G. Wacker** , Professor of Biopharmaceutics , KU Leuven , Belgium This workshop will provide a practical, principle-based overview of IVIVC development for complex injectables, focusing on bioprediction fundamentals and fit-for-purpose model development strategies. Key topics will include selection of predictive in vitro tests, approaches for IVIVC model development and verification, and common validation expectations. The session will also highlight how IVIVC models can serve as a starting point for design space development, supporting formulation optimization and informed decision-making across development and lifecycle management.
16:50	**Technology Spotlight Presentation**
16:50	**Advanced Dissolution Testing of Complex Injectables Using USP Apparatus 4** **Satyawan Doke** , Application and Product Specialist (USP 4) , Labindia Analytical Instruments Pvt. Ltd , India This presentation discusses the limitations of USP Apparatus 1 and 2 for injectable products and highlights the technical and regulatory advantages of USP Apparatus 4 (Flow-Through Cell) in dissolution testing of complex injectables. Practical aspects of flow-through cell technology, open and closed loop configurations, and real case studies are presented to demonstrate how USP Apparatus 4 enables physiologically relevant dissolution testing and supports in-vitro–in-vivo correlation.

17:10	**Exhibition and Networking**
17:10	**Live Demonstration of Advance Dissolution Testing Apparatus**
17:30	**Explore & Network**
19:00	**The Gala Dinner**
21:00	**End of Day 1**

Friday, 30th January 2026

09:30	**INNOVATIONS IN COMPLEX INJECTABLE FORMULATIONS: FROM SELF-ASSEMBLING SYSTEMS TO LONG-ACTING CHALLENGES**
09:35	**Parenteral Drug Products Containing Nanomaterials: Nano-Suspensions, Nano-Emulsions, Liposome Formulations, Self-Assembling Nanotubes, Iron Complex Formulations** **Mayur Sankalia** , Senior Vice President - Formulation and Analytical R & D , Invengene Pvt Ltd , India This presentation provides an integrated, end-to-end perspective on nanomaterial-based parenteral drug products, covering nano-suspensions, nano-emulsions, liposomal formulations, self-assembling nanostructures, and iron complex formulations. A central theme of the talk is the evolution of the traditional Q1/Q2 paradigm. While qualitative and quantitative sameness (Q1/Q2) may be sufficient for conventional injectables, they are often inadequate for nanomaterial-based products. The session will touch upon advanced analytical characterization techniques as regulatory enablers rather than academic tools. Platform-specific techniques—including Cryo-TEM, SAXS/SANS, solid-state NMR, DSC, Mössbauer spectroscopy, XANES/EXAFS, circular dichroism, and advanced interfacial studies—are discussed in the context of how they elucidate structure, form, and assembly mechanisms. The presentation also discusses about realistic view of manufacturing, scale-up, and sterilization challenges, which are often the most critical failure points for nanomaterial parenterals.
10:05	**Complex Injectables: Tackling a Long-Acting Challenge** **Matthias G. Wacker** , Professor of Biopharmaceutics , KU Leuven , Belgium In this talk, I will share how our work on LAIs evolved from early exploratory studies that exposed fundamental blind spots in conventional in vitro testing, to the intentional construction of more physiologically and mechanically relevant test environments. I will show how systematic, data-driven interrogation of the literature using machine-learning tools helps to clarify which formulation strategies matter, which experimental variables dominate performance, and where common assumptions fail.A central part of the presentation focuses on the development and validation of BioJect, a new device platform designed specifically to interrogate long-acting injectable behavior under controlled yet dynamic conditions.This talk will offer a clear, experience-driven perspective on how to think about complex injectables: what to test, how to test it, and how emerging computational tools can be meaningfully integrated into LAI development workflows to move beyond trial-and-error toward truly informed design.

10:35	**A Lyophilization-Enabled Approach to Parenteral Nanocrystal Systems** **Arvind Bansal** , Professor , Department of Pharmaceutics, NIPER-Mohali , India I will present a case study using aspirin, highlighting how process variables—particularly freezing rate and the choice and concentration of bulking agents—critically define particle size and phase behavior. These insights offer a foundation for the systematic development of next-generation lyophilized parenterals featuring in-situ nanocrystallization, enabling broader access to challenging molecules and improving therapeutic outcomes.
11:05	***Tea/Coffee Break***
11:35	**SYNERGY IN FORMULATION AND HARDWARE: NAVIGATING COMPLEX DRUG-DEVICE COMBINATIONS**
11:40	**Innovations in Formulation and Drug–Device Integration for Biosimilar Therapeutics** **Vaibhav Dubey** , Senior General Manager , Kashiv Biosciences, LLC , India This presentation highlights advanced formulation and drug–device combination strategies that reconcile regulatory compliance with innovation, ultimately enhancing therapeutic performance, patient experience, and the commercial sustainability of biosimilar products.
12:10	**Complex Drug-Device Combination Products – Prefilled Syringe.** **Sanju Dhawan** , Senior Director GPRD and Site Leader , Baxter Pharmaceuticals Inc. , India Global prefilled syringe market comprises delivery for small drug molecule, peptides, biologics, oligonucleotide, gene therapy market; it is projected to expand from USD 74.38 billion in 2025 to approximately USD 133.24 billion by 2035, reflecting a CAGR of 6.% over the forecast period. The session would provide insights into various aspects of business, development, scale up and regulatory of new products .
12:40	**BIOEQUIVALENCE CONTROL: ENSURING SAMENESS IN COMPLEX INJECTABLES**
12:40	**Bioequivalence Approaches for Complex Injectable API and Formulations** **Arani Chatterjee** , President, CRO , Cadila Pharmaceuticals Ltd. , India The diverse nature of complex injectables poses challenges for the development of regulatory guidelines for generic versions. While complexity is not new in medicines, the technical capacity to measure and analyze data has increased. This requires a determination of which measurements and studies are relevant to demonstrate bioequivalence. This presentation provides pragmatic solutions for approving complex injectables by making best use of existing U.S. Food and Drug Administration’s abbreviated approval pathways. Decisions on submitting an application can build on the FDA’s complex drug product classification as well as the FDA’s much applauded product specific guidance documents.
13:20	**Lunch**
14:15	**THE FUTURE LANDSCAPE OF INJECTABLES: STERILITY, QUALITY, AND OPERATIONAL CHALLENGES**

14:20	**Complex Injectables: Opportunities, Challenges, and the Road Ahead** **Govind S. Pandey** , Director , Gamp Technologies Private Limited , India This presentation will analyze the critical scientific and technical hurdles faced by industry scientists across the product lifecycle. We will address the ambiguity of the Regulatory Landscape, including the lack of clear Bioequivalence criteria and the complexity of CMC data packages for generics in USFDA and EMA markets.Finally, the talk will map the road ahead, highlighting opportunities driven by technological advances (AI in formulation modeling, microfluidics) and favorable regulatory support (FDA's Complex Generics Guidance) to ensure commercial success and patient access.
14:50	**Sterility Assurance: Current Challenges and Future Changes** **Vikram Shukla** , President, Parenteral BU , Zydus Lifesciences , India In this presentation, key challenges in sterility assurance for injectable manufacturing will be discussed in light of evolving global regulatory expectations such as US FDA and EU GMP Annex 1. The session will highlight how advanced technologies—including isolators, automation, Rapid Microbiological Methods, and real-time monitoring—are enabling proactive, design-based contamination control through robust Contamination Control Strategies, ensuring stronger compliance and patient safety.
15:20	***Tea/Coffee Break***
15:50	**REGULATORY RIGOR AND INSPECTION READINESS: A FRAMEWORK FOR COMPLEX INJECTABLES**
15:55	**Regulatory and Compliance Challenges in Design, Development and Manufacturing of Complex Injectables** **Jayant Karajgi** , Chief Operating Officer , Shilpa Medicare , India This Talk will cover the practical aspects, based on actual case studies, for complex injectables. The specific focus shall be on lipid and nano particle based novel injectables, suspension injectables and drug-device combinations.The listeners shall get an overview of regulatory and quality challenges and problems encountered commonly during the scaleup and manufacture of some of complex injectables; including their risk mitigation and trouble shooting
16:25	**Regulatory Inspections - From Fear to Framework** **Deepak Murpani** , Chief Scientific Officer (CSO) & Chief Operational Officer (COO) , Andersen Pharma Global , Poland This talk will include the latest trends in regulatory inspections and the most frequent observations currently facing the industry, ranging from gaps in contamination control strategies to the heightened scrutiny of process variability in advanced formulations. The presentation highlights the critical pivot "From Fear to Framework," advocating for a move away from reactive audit preparation.

16:55	**PANEL DISCUSSION: High-Risk, High-Reward: Strategic Portfolio Selection for Highly Regulated Markets** MODERATOR **R J Shah,** R S Associates, India PANELISTS **Basavaraj Siddalingappa,** President and Head of R&D, Good Health Pharmaceuticals, Gujarat, India **Ajinath Shirsat,** Technical Lead, Formulation R&D - Injectable, Baxter International Inc., India **Ashish Gupta,** Founder & Chief Executive Officer, Ortiv-Q3 Research, India
17:30	**VALEDICTORY SESSION**