

Complex Generics 2026

19 Nov 2026 - 20 Nov 2026

CONFERENCE PROGRAMME

Thursday, 19th November 2026

08:00	**REGISTRATION**
09:00	**INAUGURAL SESSION**
09:00	**Introduction to Glostem**
09:05	**Welcome Address** **Sanjay Bajaj** , CEO & MD , Glostem Private Limited , India
09:15	**Navigating Generic Evolution: 505(b)(2) Strategies, Value-Added Medicines & Market Execution**
09:20	**From Complex Generics to 505(b)(2) and Value-Added Medicines: Formulation and Regulatory Strategies for Differentiated Drug Products** **Devendra N. Ridhurkar** , CEO & Founder , RidNova Pharmaceuticals , Spain Drawing on industry experience, the presentation will demonstrate how integrating formulation innovation, regulatory planning, and collaborative development models can reduce development risks, accelerate timelines, and create commercially viable, differentiated medicines for European and global markets.
10:00	**Navigating the Future of Generics: From Innovation to Implementation** **Saurabh Srivastava** , Professor & Head , National Institute of Pharmaceutical Education and Research , India Super generics thus represent a strategic growth avenue for companies with strong R&D, manufacturing, and regulatory expertise, ensuring continued advancement of patient-centric therapies in an increasingly competitive healthcare landscape. The presentation will be navigating the pedagogy of striving for excellence from Generics to Super-Nanogenerics.
10:40	**Tea/Coffee Break**
11:10	**Next-Generation Bioequivalence: Harmonizing In Vitro Methodologies for Complex Generic Approvals**

11:15	**In Vitro BE Methodologies for Complex Generics** **Mukesh Kumar** , Founder Director , Ortiv-Q3 , India The presentation will highlight how scientifically justified in vitro BE approaches can reduce reliance on conventional in vivo studies while providing a robust and clinically relevant assessment of product equivalence. Practical development considerations and emerging regulatory trends will also be discussed.
11:55	**Integrating In Vitro, In Vivo and Model-Informed Approaches to Demonstrate Bioequivalence of Complex Generics** **Carlos Bertoncini** , Clinical Development & Biopharmaceutics Manager , Chemo , Spain The talk will discuss how biorelevant and discriminatory dissolution methods, preclinical pharmacokinetic screening and pilot clinical data can be combined with in vitro–in vivo correlations (IVIVC), physiologically based pharmacokinetic (PBPK) modelling, population PK and PK/PD analyses. Particular attention will be given to defining clinically relevant dissolution specifications, using virtual BE simulations to select prototypes and optimise study design. A practical framework for de-risking pivotal BE studies will be discussed, reducing development iterations and shortening timelines to registration, together with insights into current FDA and EMA expectations for model-informed BE approaches in the US, EU and other regulated markets.
12:35	**TECHNOLOGY SPOTLIGHT PRESENTATION**
12:35	**TBD** **Anant Ketkar** , Principal Scientist and Scientific Lead , Electrolab , India
13:00	**Group Photo**
13:15	**Lunch**
14:15	**Enabling Complex Generics: Manufacturing Innovation, Quality Standards, and Global Compliance**
14:20	**Continuous Manufacturing: Enabling Science-Driven Development, Scale-Up, and Commercialization of Complex Generic** **Prabhat Shrivastava** , Associate Director & Vertical Head - Formulation Development , Piramal Pharma Solutions , India The discussion will highlight the application of CM, PAT, and RTRT in complex generic product development and manufacturing, demonstrating how these technologies enable science-based process control, accelerated product realization, and next-generation pharmaceutical manufacturing.
15:00	**Complex Products: Scientific Challenges and USP Standards-Based Solutions** **Prabhakar Reddy** , Senior Director of Pharmaceutical Sciences , US Pharmacopeia , US This presentation will include the scientific and regulatory challenges associated with complex products that facilitate product development, regulatory confidence, and global harmonization through documentary and physical standards from USP.

15:40	**Regulatory Excellence in Complex Generics: From Scientific Justification to First-Cycle Approval Success** **Santosh Kumar Narla** , Head RA, GM , Shilpa Medicare Ltd , India Focusing on Regulatory Excellence in Complex Generics, this presentation will demonstrate how early planning, science-based decision making, and high-quality submissions can streamline regulatory review, reduce deficiencies, and improve the likelihood of achieving first-cycle approval success in global markets.
16:20	**Tea/Coffee Break**
16:50	**Interactive Session**
17:30	**End of Day 1**

Friday, 20th November 2026

09:00	**Life-Cycle Management of Complex Generics**
09:00	**Challenges and Opportunities in Development and Life-Cycle Management of Complex Generics** **Raghupathi Kandarapu** , Vice-President, Technology Transfer , Medreich Limited , India Typically, a successful complex generic development of oral solid dosage forms encounter the hurdles of achieving desired *in-vitro* dissolution profile to warrantee the bioequivalence, stability profile, scalability, and manufacture consistence. Often, such additional hurdles are IP-fencing such as composition (excipients and levels), pill size (tablets and capsules), manufacturing process, and dissolution and plasma kinetics, including overall geometry of formulation. In this presentation, opportunities available for the life-cycle management and some of the scientific concepts of developing complex generics will be emphasized.
09:40	**Innovations in Complex Oral Delivery**
09:45	**Decoding the Complexity of Generic Oral Peptides Development - An Integrated Pathway from Development to Commercialization** **Anup Avijit Choudhury** , Vice President & Delivery Manager- Differentiated Formulations , Dr. Reddy's Laboratories , India Particular emphasis is placed on translating laboratory and clinical understanding into a commercially robust control strategy that preserves exposure-critical attributes during scale-up, technology transfer, packaging, distribution, and routine manufacture. By connecting scientific development with manufacturability, supply resilience, cost, and patient-use considerations, the framework provides a structured route from complexity to equivalence and commercialization. Ultimately, generic oral peptide development requires reproduction of a precisely engineered biological event, reliably, at scale, and with consistent patient performance.

10:25	**Strategic R&D Leadership in Complex Solid Oral Generics Development:** **Ravikumar Nithiyanandam** , President – Formulations R&D , Granules India Limited , India Demonstrating bioequivalence (BE) remains the core regulatory requirement. Developers must manage narrow therapeutic indexes, high intra-subject variability, and potential food-effect dynamics to establish therapeutic equivalence without full clinical trials. Strategic alignment among formulation science, robust scale-up engineering, and comprehensive regulatory submissions accelerates market entry. Ultimately, mastering complex solid oral generic development expands patient access to vital, cost-effective therapies while offering generic manufacturers high-value market differentiation.
11:05	**Tea/Coffee Break**
11:35	**Drug Device Combinations and Transdermal Delivery Systems**
11:40	**Development Strategies for Drug–Device Combination Generics in Highly Regulated Markets** **Carlos Bertoncini** , Clinical Development & Biopharmaceutics Manager , Chemo , Spain It will be discussed how the device and user interface are integral to equivalence and must be addressed from early development; how a tailored mix of in vitro, PK, PD and modelling evidence can address product-specific challenges where conventional BE is insufficient; and how early alignment with FDA and EMA expectations is critical to avoid late-stage redesign.
12:20	**Residual Drug in Transdermal Patches: From System Architecture to Abuse-Deterrence Considerations** **Pradeep Dabhi** , Co-Founder and Chief Scientific Officer , Cutyx Research , India How much drug remains is not an accident of testing. It follows from the choice of system architecture (reservoir, matrix or drug-in-adhesive), the adhesive and excipients, the drug load and the patch construction. Regulators now expect residual drug to be minimised, justified and compared with the reference product. They also expect the abuse-deterrence evidence for controlled substances to be built on reliable measurement of used patches. Lets discuss a design-to-evidence framework for developing and defending transdermal systems.
13:00	**Lunch**
14:00	**Complex Ophthalmic/Otic Suspension & Emulsions: Design and Development**
14:05	**Formulation Design & Development for Complex Ophthalmic/Otic/Injectable Suspension & Emulsions** **Simta Jadhav** , Vice President - Research & Development , Raay Neo Pharma , India Talk will highlight the critical selection of primary packaging materials, engineering precise tip geometries and dropper architectures to maintain drop-volume uniformity in ophthalmics. Furthermore, the talk will address the market’s shift toward innovation by examining the microbial and mechanical barriers involved in designing next-generation, **preservative-free multidose delivery systems**. Finally, the presentation will provide actionable mitigation strategies and Quality by Design (QbD) principles to de-risk the technology transfer process, ensuring a seamless, compliant transition from R&D scale to commercial manufacturing.
14:35	**Design and Formulation of Nasal and Inhalation Products**

14:40	**Advancing Nasal Drug Delivery: Key Device Considerations for Successful Product Development** **Deval Gupta** , Associate Vice President - Innovation & R&D (Pharma) , Pravesha Industries , India This presentation will examine key device considerations in the development of nasal drug-device combination products, with a comparative review of liquid-based nasal sprays and dry powder delivery systems. The discussion will highlight the advantages, limitations, and application-specific suitability of different nasal delivery technologies. Critical design factors, including dose delivery mechanisms, user interface considerations, device robustness, manufacturability, and human factors engineering, will be explored. Performance attributes such as delivered dose uniformity, spray pattern, plume geometry, droplet or particle size distribution, and device functionality will also be reviewed. Practical insights from product development programs will be shared to illustrate strategies for balancing performance, usability, and regulatory expectations throughout the product lifecycle.
15:20	**Tea/Coffee Break**
15:50	**Straight to the Lungs - Inhalation: Recent Innovations and What Sets Its Evaluation Apart** **Prem Singh** , Senior Director , Rising Pharmaceuticals , India Quality is proven with cascade-impactor distribution (MMAD), delivered dose and realistic mouth-throat models. Bioequivalence follows FDA’s weight-of-evidence route (in vitro, charcoal-block pharmacokinetics, pharmacodynamics or clinical) or the EMA’s stepwise route. Device and formulation are one product. Right size, right place, right dose.
16:30	**Nasal Formulation Development for Systemic Drug Delivery and Device Design** **Babasaheb Aware** , Sr. General Manager , Indoco Remedies Ltd. , India This presentation will discuss formulation strategies, critical quality attributes, and the integration of drug product and device design, including single-dose and bi-dose nasal delivery systems. It will also highlight development challenges, regulatory considerations, and emerging opportunities for creating differentiated nasal products that offer rapid onset of action, improved patient compliance, and an effective alternative to oral and injectable therapies.
17:10	**Closing Remarks & Vote of Thanks**
17:10	**Closing Remarks & Vote of Thanks** **Sanjay Bajaj** , CEO & MD , Glostem Private Limited , India