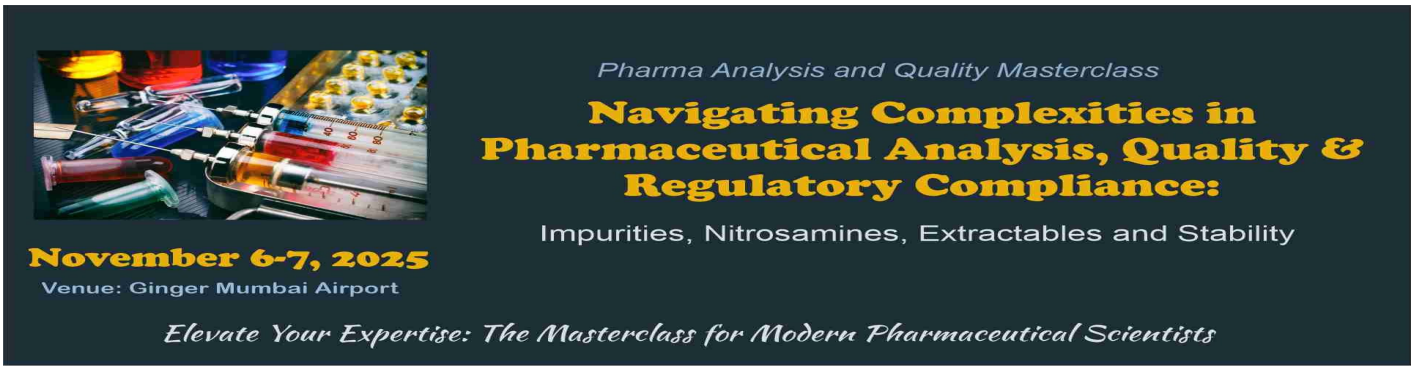

Pharmaceutical Analysis Masterclass (NCP25)

06 Nov 2025 - 07 Nov 2025

CONFERENCE PROGRAMME

Thursday, 6th November 2025

08:00	**REGISTRATION**
09:00	**Technical Session 1**
09:00	**Welcome Address** **Sanjay Bajaj** , CEO & MD , Glostem Private Limited , India
09:15	**Impurity Profiling and Regulatory Considerations for Impurities** **Saranjit Singh** , Professor & Head , NIPER Mohali Impurities in Drug substance and Drug Products (ICHQ3 A and B), Residual solvents (ICH Q3C), Elemental Impurities (ICH Q3D), Nitrosamine and Mutagenic Impurities (ICH M7), Extractibles and Leachable.
10:45	**Q/A - Impurity Profiling** **Saranjit Singh** , Professor & Head , NIPER Mohali
10:55	***Tea/Coffee Break***
11:10	**Technical Session 2**
11:10	**Challenges in Pharmaceutical Analysis** **P. Rita Santhakumar** , Consultant and Retired -Head– Analytical Development , SUN Pharmaceuticals , India Tools and Techniques (HPLC, GC, LC-MS, GC-MS. ICP MS), Method development and Analytical QbD and Validation (ICH Q2 and Q14), Sample preparation and Matrix effect, Trace level analysis
12:10	**Q/A - Analytical Challenges** **P. Rita Santhakumar** , Consultant and Retired -Head– Analytical Development , SUN Pharmaceuticals , India
12:20	**Analytical Method Development through Quality by Design (QbD)** **P Siva Sankara Reddy** , Director – Analytical Research & Development (Global) , Simson Pharma Limited , India
12:50	**Group Photograph**

13:00	**Lunch**
14:00	**Technical Session 3**
14:00	**Nitrosamine in Pharmaceuticals : Risk assessment and Safety Evaluation** **Pravin Karmuse** , Global Scientific Advisor , Veeprho Group , India In-depth understanding of nitrosamine & NDSRI formation pathways, Regulatory updates and current guidelines on nitrosamine & NDSRI control (EMA, FDA, etc.), Developing and implementing effective risk assessment strategies for nitrosamines & NDSRIs.
15:00	**Q/A - Nitrosamine Control** **Pravin Karmuse** , Global Scientific Advisor , Veeprho Group , India
15:10	**Tea/Coffee Break**
15:25	**Technical Session 4**
15:25	**Quality Control Systems for Nitrosamine and NDSRI Impurities** **Jörg Schlingemann** , Director, Global Quality Control Principal Expert , Merck , Germany Development and implementation of Quality Control System for Nitrosamines and NDSRI impurities in Pharmaceutical industry.
16:25	**Q/A - Quality Systems** **Jörg Schlingemann** , Director, Global Quality Control Principal Expert , Merck , Germany
16:35	**Nitrosamine and NDSRI Analysis: Challenges & Solutions** **Shailesh Damale** , Product Specialist, LC/MS and Automation Solutions , Agilent Technologies , India The session aims to provide a comprehensive understanding of nitrosamine analysis workflows, low level detection and quantitation to ensure reliable and reproducible results.
17:05	**Extractables & Leachables (E&L) Testing in Pharmaceuticals and Medical Devices** **Pramod Kumar Ragham** , Senior Director,Analytical Services Department , Daicel Chiral Technologies India Pvt. Ltd. , India Importance of Extractables and Leachables (E&L) studies in ensuring the safety and quality of drug products and medical devices, defining key concepts, outlining strategic study designs and critical considerations, and detailing the current regulatory and guideline landscape along with practical implementation approaches.
17:35	***End of Day 1***

Friday, 7th November 2025

09:00	**Technical Session 5**
09:00	**Deriving Safe Limits for Nitrosamines** **Jörg Schlingemann** , Director, Global Quality Control Principal Expert , Merck , Germany
09:45	**Q/A - Nitrosamine Limits** **Jörg Schlingemann** , Director, Global Quality Control Principal Expert , Merck , Germany
09:55	***Tea/Coffee Break***

10:10	**TECHNICAL SESSION 6**
10:10	**Analytical Considerations for Extractables & Leachable** **Thippani Ramesh** , Managing Director & CEO , DRHP Testing Solutions , India Analytical strategies for identifying and quantifying extractables from packaging and manufacturing components,Techniques for analysing leachable in drug products (GC-MS, LC-MS, ICP-MS), Method development and validation specificto E&L studies, Correlation of E&L data with toxicological risk assessment & Case studies.
11:10	**Q/A for Extractable and Leachable** **Thippani Ramesh** , Managing Director & CEO , DRHP Testing Solutions , India
11:20	**Cutting-Edge UFMS Approaches for NSA, NDSRIs, and E&L in Pharmaceuticals using GCMSMS & LCMSMS** **Dheeraj Handique** , Manager – GC/GCMS Product Marketing , Shimadzu India Pvt. Ltd., Mumbai , India
11:50	**Stability Studies and Shelf-Life Determination** **Saranjit Singh** , Professor & Head , NIPER Mohali Stress studies, Degradation Pathways and stability indicating methods, designing stability studies for drug substances anddrug products (ICH Q1 A and B), Accelerated Stability Assessment Program, Forced Degradation studies.
12:50	**Q/A for Stability** **Saranjit Singh** , Professor & Head , NIPER Mohali
13:00	***Lunch Break***
14:00	**Technical Session 7**
14:00	**Handling OOS/OOT Results** **Shital Pathak** , Senior Vice President-Head Analytical R&D , Glenmark Pharmaceuticals , India Handling out-of-specification (OOS) and out-of-trend (OOT) results, Case Studies, Handling of regulatory queries.
15:00	**Q/A - OOS/OOT Results** **Shital Pathak** , Senior Vice President-Head Analytical R&D , Glenmark Pharmaceuticals , India
15:10	***Tea/Coffee Break***
15:25	**Technical Session 8**
15:25	**Regulatory Expectations for Impurities and Stability Data in Pharmaceutical Submissions** **Nirav Chokshi** , Executive Director , ISAZI Group of Companies , India Regulatory requirements for impurity characterization, qualification, and control in drug applications (ANDA, NDA), Expectations for stability data and shelf-life justification in regulatory dossiers, Strategies for presenting analytical and stability data effectively to regulatory authorities, Addressing common regulatory queries related to impurities and stability, Best practices for ensuring data integrity and compliance with global regulatory standards, Preparing for and managing regulatory inspections related to analytical and quality functions.

16:25	**Q/A - Regulatory Submission** **Nirav Chokshi** , Executive Director , ISAZI Group of Companies , India
16:35	**Panel Discussion: Navigating Complexities in Pharmaceutical Analysis and Quality** **Saranjit Singh** , Professor & Head , NIPER Mohali Moderator- Saranjit Singh Panelists- 1. Priya Singh - FDC Limited 2. Rahul Singh - Macleods Pharma 3. Amit Gosarkar - Indoco Remedies
17:10	**End of Masterclass**