

# BIOPHARMACEUTICAL PRODUCT DEVELOPMENT

**INDULGE, INNOVATE & INSPIRE**

02-03 FEBRUARY 2023 | GOA, INDIA

## AGENDA

**DAY 1: 02 FEBRUARY 2023**

07:00 – 08:30	Registration and Networking Breakfast   Biopharma Exhibition and Poster set up		
08:30 – 09:30	Welcome Note and Inauguration		
09:30 – 11:00	<b>Leadership Conclave   mRNA Vaccine Development: Challenges and Opportunities   Venue: Grandball Room</b>		
	<b>Moderator</b>	Dr. Narendra Chirmule, SymphonyTech	
	<b>Speaker</b>	mRNA: Future of Vaccinology   Dr. Sanjay Singh, Genova Biopharmaceuticals	
		mRNA Vaccine Technology: Genital herpes and beyond   Dr. Sita Awasthi, University of Pennsylvania	
	<b>Panel Discussion</b>	Dr. Fouad Atouf, United States of Pharmacopeia Dr. Vikram Paradkar, Biological-E Ltd Dr. Subhasis Banerjee, Merck KGaA Mr. Darshan Parekh, Independent consultant	
11:00 – 11:30	<b>Biopharma Exhibition and Research Poster Presentation Inauguration   Coffee Break</b>		
11:30 – 13:00	<b>Session   PAT, Data Analytics and Industry 4.0: Next Generation   Venue: Grandball Room</b>	<b>Session   Protein Aggregation and Biophysical Characterization   Venue: Betul Hall</b>	<b>Session   Cell Line and Upstream Process Development   Venue: Mobor Hall</b>
	<b>Moderator</b>	<b>Moderator</b>	<b>Moderator</b>
	Dr. Parthasarathy Sampathkumar, Biocon Biologics Ltd	Dr. Navaratna Vajpai, Biocon Biologics Ltd	Dr. Sanjeev Gupta, Ipca Laboratories Ltd
	<b>Speaker</b>	<b>Speaker</b>	<b>Speaker</b>
	Model based Control of Continuous Bioprocesses   Dr. Anurag Rathore, IIT-Delhi	HOS of Biopharmaceuticals in-formulation state by NMR spectroscopy   Dr. Ashutosh Kumar, IIT-Bombay	Cell-line engineering using genome-engineering technologies   Dr. Sivaprakash Ramalingam, CSIR-IGIB
	Edge native cloud computing for data driven biomanufacturing in the Industry 4.0 paradigm   Mr. Anshuman Bansal, Factorian	Circular dichroism (CD) and Size exclusion chromatography (SEC) – Role in product understanding; An industry perspective   Mr. Pradeep Iyer, Hetero Biopharma	Emerging Cell Line Engineering technologies and their potential for High Yield Biopharmaceutical Production   Dr. Ravi Mishra, CSIR-IMTECH
	Raman PAT for Upstream Monitoring   Dr. Janice Tan, Merck KGaA	Dr. Dama Venugopal Rao, Dr. Reddy's Ltd	Perfusion Medium Flexibility and Scale-Down Considerations   Mr. Christopher Brau, Thermo Fisher Scientific
	Accelerating Biosimilar Development through Digital Transformation   Dr. Manish Khandagale, PerkinElmer, Inc.		Advanced technologies for media and process optimization for biologics manufacturing   Dr. Yaron Silberberg, Ajinomoto Genexine Co. Ltd
	<b>Panel Discussion</b>	<b>Panel Discussion</b>	<b>Panel Discussion</b>
	Dr. Anurag Rathore, IIT-Delhi Mr. Anshuman Bansal, Factorian Dr. Janice Tan, Merck KGaA Dr. Manish Khandagale, PerkinElmer, Inc.	Dr. Ravishankara N, Sunpharma Dr. Vadiraja B. Bhat, Agilent Technologies, India Dr. Ashutosh Kumar, IIT-Bombay Mr. Pradeep Iyer, Hetero Biopharma Dr. Dama Venugopal Rao, Dr. Reddy's Ltd	Dr. Venkata Ramana, Reliance Lifescience Dr. Sunit Maity, Syngene International Limited Dr. Yaron Silberberg, Ajinomoto Genexine Co. Ltd Mr. Christopher Brau, Thermo Fisher Scientific
13:00 – 14:30	<b>Lunch Break   Networking   Biopharma Exhibition</b>		
14:30 – 16:00	<b>Session   Single use technology in biomanufacturing   Venue: Grandball Room</b>	<b>Session   Mass Spectroscopy for Protein and Peptide Characterization   Venue: Betul Hall</b>	<b>Session   Advances in Purification Technologies   Venue: Mobor Hall</b>
	<b>Moderator</b>	<b>Moderator</b>	<b>Moderator</b>
	Mr. Om Narayan, Kashiv Biosciences	Dr. Annu Uppal, USP	Mr. Gaurav Nagar, Serum Institute of India
	<b>Speaker</b>	<b>Speaker</b>	<b>Speaker</b>
	Single use disposable BioSettlers for selective cell retention or primary clarification of CHO cells   Dr. Dhinakar Kompala, Sudhin Biopharma Co.	USP Standards and Tools to support Mass Spectrometry-based Characterization of Therapeutic Proteins   Dr. Diane McCarthy, USP	Process intensification for mAb downstream processing: productivity differences for Axial and Radial flow Protein A chromatography   Dr. Rahul Bhambure, CSIR-NCL
	Approaches to intensification of next generation processes utilising single use technologies   Dr. Andreas Castan, Cytiva	Spent media analysis: A metabolomics approach to bioprocess development   Dr. Pramod Wangikar, IIT-Bombay	Mechanistic modelling for twin column continuous process   Mr. Vinay Pandey, Biocon Biologics Ltd
	Advances in Single Use Technology applied in Biopharmaceuticals   Mr. Sudeep Sen, Thermo Fisher Scientific	Phase- appropriate mass spectrometry in early-stage biopharmaceutical development   Dr. Vaishali Sinha, Syngene International Ltd	Scalable, Flexible and Reliable Solutions to Simplify Your m-RNA Production   Mr. Niddivinayak Mishra, Sartorius
	Mr. Ravindra Patel, OmniBRx Biotechnologies Pvt Ltd		In-line concentration measurement using variable pathlength spectroscopy to accelerate process development and increase downstream process efficiencies   Mr. Larry Russo, Repligen Company
	<b>Panel Discussion</b>	<b>Panel Discussion</b>	<b>Panel Discussion</b>
	Dr. Huzaifa Choonia, Stelis Biopharma Mr. Prashant Godse, Lupin Mr. Sethu Madhavan, Biocon Biologics Dr. Dhinakar Kompala, Sudhin Biopharma Co Dr. Andreas Castan, Cytiva	Dr. Bhavesh Vats, Lupin Dr. Pramod Wangikar, IIT-Bombay Dr. Vaishali Sinha, Syngene International Ltd Dr. Diane McCarthy, USP	Dr. Rahul Bhambure, CSIR-NCL Mr. Vinay Pandey, Biocon Biologics Ltd Mr. Niddivinayak Mishra, Sartorius Mr. Larry Russo, Repligen Company Ms. Sirat Sikka, Thermo Fisher Scientific

16:00 – 16:30	<b>High Tea   Networking   Poster Presentation   Biopharma Exhibition</b>	
16:30 – 18:00	<b>Leadership Conclave   Novels: The future of biologics   Venue: Grandball Room</b>	
	<b>Moderator</b>	<b>Mrs. Kavitha Iyer Rodrigues</b> , Zumutor Biologics
	<b>Speaker</b>	<b>Dr. Nitin Damle</b> , SPARC
		Protein hermostabilizaton: application to viral vaccine design   <b>Dr. Raghavan Varadarajan</b> , IISc Bangalore
	<b>Panel Discussion</b>	<b>Dr. Prabuddha Kundu</b> , Premas Biotech <b>Dr. Pradip Nair</b> , Biocon Biologics <b>Dr. Manjula Das</b> , Mazumdar Shaw Medical Foundation <b>Dr. UmaSinha Datta</b> , Cytiva
18:00 – 18:30	<b>Product Launch no.1 – NanoMake: India's first mRNA LNP production platform   Product Launch no.2 – DynaSpin Single Use Centrifuge: Maximize your simplicity Product Launch no. 3 – Ramina Process Analyzer: Enabling accurate real-time results for process monitoring   Venue: Grandball Room</b>	
18:00 – 19:30	<b>Poster Presentation Evaluation- Round 1</b>	
18:00 – 19:00	Round Table Discussion   Policy towards startup and academic innovation to develop biotherapeutics and vaccine   Venue: <b>Betul Hall</b>	Round Table Discussion   How to make India as biomanufacturing hub for next generation therapies (Invite only)   Venue: <b>Mobor Hall</b>
	<b>Moderator</b>	<b>Dr. Jagadeesh Gandla</b> , Chief Operating Officer, FABA
	<b>Guest Members</b>	<b>Dr. Viswanadham Duppatla</b> , Chief Manager, IKP Knowledge Park <b>Dr. Mahesh Balghat</b> , Chief Operating Officer, Syngene International Ltd <b>Dr. Ramesh Matur</b> , Sr.Vice-President, Biological E <b>Dr. Alok Srivastava</b> , Christian Medical College <b>Dr. Taslimarif Saiyed</b> , CEO, C-CAMP <b>Dr. Sanjeev Khoshla</b> , Director, CSIR-IMTECH <b>Dr. Jaby Jacob</b> , Sr.President, BSV <b>Dr. Samir Vyas</b> , Country GM, Agilent Technologies <b>Dr. Vandana Patravale</b> , Professor, Institute of Chemical Technology
	<b>Moderator</b>	<b>Dr. Sridevi K</b> , Vice-President, Syngene International Ltd and <b>Dr. Rajiv Desai</b> , Vice-President, IPA
	<b>Guest Members</b>	<b>Dr. Gautham Nadig</b> , Executive Director Mynvax Private Limited <b>Dr. Anurag Rathore</b> , Professor, IIT-Delhi <b>Mr. Vijay Sudalaimuthu</b> , Senior Manager, Operations – Biologics at Biocon <b>Dr. Sanjay Singh</b> , Director, Gennova Biopharmaceuticals <b>Dr. Arun Anand</b> , Chief Operating Officer and Board Director, Immuneel Therapeutics <b>Mr. Sanjiv Navangul</b> , MD, CEO- Bharat Serums and Vaccines <b>Dr. Rahul Purwar</b> , Associate Professor, IIT-Bombay <b>Mr. Aditya Sharma</b> , Head - BioProcessing, Merck Lifescience <b>Dr. Jayapala Reddy</b> , Vice-President and Head, Anthem Bio
19:00 – 19:30	<b>Seating for Dr. K. Anji Reddy Memorial Fellowship Award Ceremony</b>	
19:30 – 21:00	<b>Dr. K. Anji Reddy Memorial Fellowship Award Ceremony   Venue: Grandball Room</b>	
	<b>Moderator</b>	<b>Dr. Ratnesh Jain</b> , Convener, BSW-ICT
	<b>Guest</b>	<b>Mr. Satish Reddy</b> , MD, Dr. Reddy's Lab
21:00 onwards	<b>Cocktail Dinner (Invite only event)   Venue: Mobor Hall Lawn</b>	

*Note: Biopharma Exhibition hall will close at 20:30 on day 1*

**DAY 2: 03 FEBRUARY 2023**

07:30 – 08:45	<b>Registration and Breakfast Networking   Biopharma Exhibition open   Poster Presentation-Evaluation Round 2</b>		
08:45 – 10:45	<b>Session</b>   FDA Compliance: Meeting regulatory expectations in product development and manufacturing   Venue: <b>Grandball Room</b>	<b>Session</b>   Cell-based potency assay -designs and considerations   Venue: <b>Betul Hall</b>	<b>Session</b>   Formulation Technologies and Excipient-Protein Interaction   Venue: <b>Mobor Hall</b>
	<b>Moderator</b>   <b>Dr. Dhananjay Patankar</b> , Independent Consultant	<b>Moderator</b>   <b>Dr. Shubrata Khedkar</b> , USP	<b>Moderator</b>   <b>Dr. Sachin Dubey</b> , KBI Biopharma
	<b>Speaker</b>   Regulatory Expectations for Biosimilar Manufacturing   <b>Dr. Sarah McMullen</b> , US-FDA	<b>Speaker</b>   Fc Functionality assays for IgG-based Therapeutics and Key Considerations   <b>Dr. Abhishek Mathur</b> , Biolexis Pvt Ltd	<b>Speaker</b>   Vaccine development: improving stability to enable global access   <b>Dr. Martinus Capelle</b> , Johnson & Johnson
	Pre-Approval Inspections for Biosimilars   <b>Dr. Sriram Akundi</b> , Biocon Biologics Ltd	Ligand binding assays for characterization of biologics   <b>Dr. Pallavi Karnik</b> , Intas Pharmaceutical	<b>Dr. Nupur Mehrotra</b> , Premas Biotech
		Development of T-cell based bioassays   <b>Dr. Nimesh Gupta</b> , National Institute of Immunology	The Viscosity reduction Platform: Enabling subcutaneous (subQ) delivery   <b>Dr. Smita Rajput</b> , Merck KGaA
		Surrogate potency assays using Biacore systems   <b>Dr. Shubhendu Seal</b> , Cytiva	
	<b>Panel Discussion</b>   <b>Dr. Swapnil Ballal</b> , Q-Exl Partners <b>Dr. Shaligram Rane</b> , Lupin <b>Dr. Sarah McMullen</b> , US-FDA <b>Dr. Sriram Akundi</b> , Biocon Biologics Ltd	<b>Panel Discussion</b>   <b>Dr. Shashwati Basak</b> , Intas Pharmaceutical <b>Dr. Diane McCarthy</b> , USP <b>Dr. Abhishek Mathur</b> , Biolexis Pvt Ltd <b>Dr. Pallavi Karnik</b> , Intas Pharmaceutical	<b>Panel Discussion</b>   <b>Dr. Ajay Singh</b> , Genova Biopharmaceuticals <b>Dr. Rajendar Burki</b> , Biological-E Ltd <b>Dr. Martinus Capelle</b> , Johnson & Johnson <b>Dr. Nupur Mehrotra</b> , Premas Biotech
10:45 – 11:15	<b>Coffee Break   Biopharma Exhibition   Networking</b>		
11:15 – 12:00	Biopharma Startup and Innovation: A stepping stone   Venue: <b>Betul Hall</b>		Biopharmaceutical Product Journey: Indulge, Innovate and Inspire   Venue: <b>Mobor Hall</b>
	<b>Moderator</b>   <b>Dr. Chaitra Harsha</b> , Vipragen	<b>Moderator</b>   <b>Dr. Narendra Chirmule</b> , Co-founder, SymphonyTech	<b>Speaker</b>   <b>Dr. Laxmi Adhikary</b> , Head R&D, Intas Pharmaceuticals <b>Dr. Dhananjay Patankar</b> , Independent Consultant <b>Dr. Bala Reddy</b> , Whole-Time Director, Hetero Biopharma Ltd <b>Dr. Karthik Ramani</b> , Associate Vice President, Biocon Biologics Ltd
12:00 – 13:00	<b>Leadership Conclave   Cell and Gene Therapy Product Development: Challenges and Opportunities   Venue: Grandball Room</b>		
	<b>Moderator</b>   <b>Dr. Shashwati Basak</b> , Intas Pharmaceuticals		
	<b>Speaker</b>   The Promise and Excitement of CAR T-cell therapy   <b>Dr. Sattva Neelapu</b> , University of Texas, MD Anderson Cancer Centre		
	<b>Dr. Rahul Purwar</b> , IIT-Bombay		
	<b>Panel Discussion</b>   <b>Dr. Mohua Chakraborty Choudhury</b> , IISc-B <b>Mr. Syd Daftary</b> , Advy Chemicals <b>Dr. Stephan Grupp</b> , Children’s Hospital of Philadelphia <b>Dr. Sattva Neelapu</b> , University of Texas, MD Anderson Cancer Centre <b>Dr. Rahul Purwar</b> , IIT-Bombay		

13:00 – 14:15	<b>Lunch break   Networking   Biopharma Exhibition   Poster Presentation</b>		
14:15 – 15:00	Valedictory and Award Ceremony   Venue: <b>Grandball Room</b>		
15:00 – 17:00	<b>Session</b>   Challenges in Clinical Trials for Cell and Gene Therapies   Venue: <b>Grandball Room</b>	<b>Session</b>   Challenges and Opportunities in MSAT   Venue: <b>Betul Hall</b>	<b>Session</b>   Special Guidance session by DCGL and RCGM on Biosimilars/Vaccine product approval   Venue: <b>Mobor Hall</b>
	<b>Moderator</b>   <b>Dr. Gaurav Narula</b> , Tata Memorial Hospital	<b>Moderator</b>   <b>Mr. Vivek Farkade</b> , BSV	<b>Moderator</b>   <b>Dr. Swapnil Ballal</b> , Q-exl Partners
	<b>Speaker</b>   Challenges in Clinical Trial Development and Implementation for CAR T- Cell Therapies for Leukemias   <b>Dr. Stephan Grupp</b> , Children’s Hospital of Philadelphia	<b>Speaker</b>   CPV challenges and approach: MSAT perspective   <b>Mr. Mayank Garg</b> , Biocon Biologics Ltd	<b>Guest</b>   <b>Dr. Y. K Gupta</b> , Director AIIMS-Bhopal
	Challenges in Clinical Trial Development and Implementation for Gene Therapies with focus on Sickle Cell Disease   <b>Dr. Akshay Sharma</b> , St. Jude Children’s Hospital	Criticality of MSAT in Evolving CDMO space   <b>Dr. Mohan Kumar</b> , Syngene International Ltd	
	Challenges in Clinical Trial Development and Implementation for Cell & Gene Therapies in India   <b>Dr. Alok Srivastava</b> , Christian Medical College		
<b>Panel Discussion</b>   <b>Dr. Nikita Mehra</b> , Cancer Institute (WIA) <b>Dr. Hasmukh Jain</b> , Tata Memorial Hospital <b>Dr. Sattva Neelapu</b> , University of Texas, MD Anderson Cancer Centre <b>Dr. Stephan Grupp</b> , Children’s Hospital of Philadelphia <b>Dr. Akshay Sharma</b> , St. Jude Children’s Hospital <b>Dr. Alok Srivastava</b> , Christian Medical College	<b>Panel Discussion</b>   <b>Dr. Prateek Gupta</b> , Stelis Biopharma <b>Dr. Narahari Rao</b> , Independent consultant <b>Mr. Mayank Garg</b> , Biocon Biologics Ltd <b>Dr. Mohan Kumar</b> , Syngene International Ltd		
17:00 – 17:15	<b>Vote of Thanks   Dr. Ratnesh Jain, Convener, BSW-ICT</b>		

*Note: Biopharma Exhibition will close at 16:00 on day 2*