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presents



2nd Global Biologics India

16-17 April 2025, **Le Meridien, Hyderabad, India**

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WHEN YOU NEED TO BE SURE

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Welcome to

2nd Global Biologics India

16-17 April 2025

Welcome to the 2nd Global Biologics India conference at Hyderabad

Biotech Stage was created to link various biotech professionals at one place to promote an easy and constructive flow of scientific discussions, trouble shooting, and shared individual learnings. We aim to provide biotech professionals with the means of building confidence in their capabilities by providing them with a platform to express their scientific ideas as well as an opportunity to present in front of a wider audience at conferences/trade shows. We believe this will not only help biotech professionals but also the whole biotech industry.

During the current conference, we have two full days of scientific discussions covering various aspects of biotechnology ranging from upstream work, process development, and scale up leading to manufacturing (including facility design), current GMP regulations along with the issues on patents and regulatory challenges. While day one in a combined session will cover issues that are common for both Cell/Gene Therapy and for mAbs/Proteins, day two will have two tracks- one of Cell/Gene Therapy and another one on mAbs/Proteins.

We have different companies exhibiting their capabilities and products. Please take a moment to visit these exhibits to explore their innovative products and how these can be helpful in your applications.

We thank you again for joining us at the conference. If there is anything that we can do to meet your objectives, please let us know. We will do our best to make sure that you have a fruitful experience.

Arun Singhal, Ph.D., MBA
Founder and CEO

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New opportunities at every step

email: arun@biotechstage.com phone +1- 832-455-3700

<https://biotechstage.com>

About us:



BiotechStage was started and founded by Arun Singhal. He has vast experience in the biotech industry in Sales/Marketing and has deep technical knowledge of the science behind the biotech applications.

Arun Singhal has a Ph.D. in Biochemistry and MBA from University of Houston (USA). He has worked in US with different cell culture companies in leading sales and marketing roles, including Hyclone (now Cytiva), Gibco (now Thermo Fisher) and Irvine Scientific (FujiFilm) to develop markets in different regions of the world, including South East Asia, Australia and South America. On the technical side, he has done postdoctoral work on gene expression and liposomes at Medical College of Virginia and University of Pittsburgh. He also worked as senior scientist at a gene therapy company in Texas, USA for few years. He has published research articles in leading scientific journals and wrote book chapters in the area of gene therapy.



Shawn Smith is an advisor/consultant for BiotechStage. After receiving a degree in Biochemical Pharmacology, Shawn spent his entire career in Life Sciences, gaining diversified experience from roles in R&D, Manufacturing, Commercial Operations, and culminating as President & CEO of ZeptoMetrix, a molecular diagnostics company that doubled in size and was sold to private equity under

his leadership.

In supporting the efforts of the global cell culture bioprocessing community since the mid-1990s, Shawn led key functions at such companies as Invitrogen (GIBCO), Kerry, HyClone, Irvine Scientific, Pall, and Millipore-Sigma. While predominantly focused on upstream processing, from media to single-use bioreactors, he has also gained holistic expertise spanning the various business and regulatory aspects of the market.

Conference Agenda

Day 1- Wednesday, 16 April 2025

A combined session of Cell/Gene Therapy and mAbs/Proteins

Timings	Event/Topics and Speakers (and Panelists)
8:15 AM	Registration – Speakers and Attendees
9:00 AM	Welcome address/Opening Remarks Arun Singhal , Ph.D., MBA BiotechStage
Module 1-1: Opening Talks- New Trends in Successful Biologics Development	
9:15 AM	Introduction and Creative Activities to get started Arun Singhal and others
9:30 AM	Navigating Global Waves: Trends in Medicine Regulations and GMP/GDP Inspections Dinesh Khokal , Ph.D., Global Director, GxP Surveillance & Quality External Affairs BeiGene, Singapore
10:00 AM	Early-Stage Biologics into IND-ready Drugs: A Strategic Development Path Amit Jogi , Ph.D., Head, CDMO Biologics Aurigene Pharmaceutical Services, India
10:30 AM	Charge Variant Characterization of a biomolecule by cIEF Fractionation using MauriceFlex and Mass Spectrometry Fatima D'Souza , COO, Zelle Biotechnology
10:50 AM	 Tea Break
Module 1-2: Panel Discussion: mABs and Biosimilars Convenor: S. Dravida	
11:25 AM	Panel Discussion: mAbs/Biosimilars: Functional Assessment/Analytics/Reg Inspection Moderator: Dinesh Khokal , Ph.D. (BeiGene) Panel: Siva Sankar (Aragen), Satish Makkina (Procell), Dhananjay Patankar (Consultant), Nageswara Rao (Hetero), Anurag Tulsyan (Zelle Biotechnology), Sanjay Shah (XenPharm)
11:55 AM	Panel Discussion contd...
12:25 PM	 Lunch

Module 1-3: Panel discussion: Cell and Gene Therapy Convenor: S. Dravida	
1:25 PM	Panel Discussion: Cell and Gene Therapy- Progress, Challenges, and Future Outlook Moderator: Renu Kundu , Ph.D. (East Ocyon) Panel: BN Manohar (Stempeutics), Vishwas Kaveeshwar , Ph.D. (SDM Uni), Sattva Neelapu , MD (MD Anderson, USA), Yogananth Rajendran (Immuneel), Rod Stuart (Cellagility)
1:55 PM	Panel Discussion contd...
2:25 PM	Successful Commercialization of Cell Therapy products in India BN Manohar , MD and CEO Stempeutics, India
2:55 PM	Allogeneic CAR-T: Insights from the clinic and the path forward Sattva S Neelapu , MD, Professor and Deputy Chair Uni of Texas MD Anderson Cancer Center, USA
3:25PM	Global Regulatory Landscape of Biological molecules Sweety Mathew , Global RA CMC Lead Novo Nordisk, India
3:50 PM	 Tea Break
Module 1-4: Manufacturing Facilities and AI- Important Players in Biopharma Convenor: Rod Stuart	
4:20 PM	AI-enabled New Approach Methodologies to support Biopharma Workflows- Decentralized Assessments- A Proven Strategy Subhadra Dravida , Founder and CEO Transcell Biologics, India
4:45 PM	Biopharma manufacturing in India, current gaps and opportunities Sanjay Shah Founder and Consultant Xenpharm India
5:15PM	Draw for Gifts All
5:30PM	End of Day 1

Day 2- Thursday, 17 April 2025

Two Parallel Tracks

Track 1: Cell and Gene Therapy

Track 2: mAbs and Proteins

Timings	Event/ Topics Speakers	Timings	Event/ Topics Speakers
	Module 2-1: Cell Therapy- New Approaches: Challenges and Solutions Convenor: Ruchi Singhal, M.D.		Module 2-5: Upstream and Clone Development Convenor: Sanjay Shah

9:00 AM	Harnessing Optical Genome Mapping for Innovation in Gene and Cell Therapy Rashmi Kanagal-Shamanna, MD, Professor MD Anderson Cancer Center, USA	9:00 AM	Clone Development: Unlocking potential, Lessons learnt and future directions Saranaya Ganapathy, Ph.D., Sr Manager IPCA, India
9:30 AM	Q/A	9:30AM	Overview of Upstream and Downstream Process Development for Biosimilars with Perfusion/ Conc. Fed batch and scale up challenges Harshit Shah, Ph.D., Group Lead MSAT Dr Reddys Lab, India
10:00 AM	Role of critical raw materials in Cell and Gene therapy Rohan Kamat, Ph.D., COO Kodo Life Sciences, India	10:00 AM	Emerging modalities and Controlling complexities in Upstream: Vial to Vial story Chandrashekhar KN, Sr Sci Manager Biocon, India
10:30 AM	Translating Cell and Gene Therapies: From Concept to Commercialization Renu Kundu, Ph.D., Director and Co-Founder East Ocyon, India	Module 2-6: New Tools and Products Convenor: Sanjay Shah	
11:00 AM	 Tea Break	10:30 AM	Next-Gen Protein Characterization: Precision Tools for Structural and Physicochemical Excellence Manish Singh, Director Agile Biosciences, India
Module 2-2: Challenges in CAR T Therapy Convenor: Ruchi Singhal, M.D.		10:55 AM	 Tea Break
11:25AM	New Horizons in CAR T Therapies Murali Addepalli, Ph.D., Co-Founder/CSO Lextro Bio Solutions, India	Module 2-6: New Tools and Products contd... Convenor: Sanjay Shah	
11:55 AM	CARs, BiTEs, TriTEs, QuTEs.....The Power of the T Cell Kishore Kunapuli, Ph.D., CSO Pulse Pharma, India	11:20AM	Multiparameter Stability Characterization of Biologics with Prometheus Panta Saji Menon, Ph.D. Sr. Field Application Scientist NanoTemper Technologies, India
12:25 PM	 Lunch	11:40AM	Multimics and ML for Development of Advanced Bioprocess Products and Solutions Yaron Silberberg, Ph.D., Director Ajinomoto, Korea
Module 2-2: CAR T contd... Convenor: Rod Stuart		Module 2-7: Accelerated QC Convenor: Sanjay Shah	
1:30 PM	CAR-T Characterization: Leveraging Live-Cell Analysis and HTS Cytometry Derya Deveci Field Application Scientist Sartorius, Netherlands	12:05 PM	Accelerated Quality Control: Regulatory & Technical review Impact on TAT Prerna Sood Business Development Manager SGS, India
Module 2-3: Raw Materials and Product Development Convenor: Rod Stuart			

		12:30PM		Lunch
		Module 2-8: Clinical Development and CMC		
		Convenor: Dinesh Khokal, Ph.D.		
1:50 PM	Q/A CAR T Cell Therapy	1:25 PM	Global Clinical Development strategies for Biosimilars Chirag Shah , Ph.D., Head Clinical Opr Raptim Research, India	
2:10 PM	Navigating CMC challenges for Cell and Gene therapy Yogananth Rajendran , M Pharm Head Regulatory Affairs Immuneel, India	1:55PM	Analytical Perspective of Chemistry, Manufacturing and Control (CMC) for Biologics development Sabyasachi Halder , Ph.D. Group Lead Analytical R&D Aurigene Pharma Services, India	
		Module 2-9: Bio Analytics- New Waves		
		Convenor: Dinesh Khokal, Ph.D.		
2:40PM	USP approach to Standards for Cell and Gene Therapy Product Development Dipankar Das , Ph.D. Director and Head, Global Biologics USP, India	2:25 PM	Functional Assessment of mAbs: Regulatory Expectations Sanjeeva Metikala , Ph.D. Prin Scientist CuraTeQ, India	
3:10PM	Insights into Next Generation Stem Cell Therapies Vishwas Kaveeshwar , Ph.D. Head, CRL SDM University, India	2:55 PM	Critical Quality Attributes of the Comparability and Similarity testing panel of Biosimilar mAbs against the Reference Product Jakub Knurek , Marketing Specialist Mabion, Poland	
3:35 PM	 Tea Break	3:25PM	 Tea Break	
Module2-4: Open Discussion		3:50PM	Challenges in Immunogenicity testing of Biosimilars Kamala Bhavaraju , Ph.D., Head Clinical BioAnalytics Dr Reddys Lab, India	
Convenor: Rod Stuart		4:20PM	Performance Assessment of the Multi-Attribute Method vs. Conv QC methods GS Sameer Kumar , Ph.D. Sr Manager and Team Lead USP, India	
4:00 PM	Cell and Gene Therapy Feedback, concerns, obstacles, and challenges Probable Solutions and Networking All	Module 2-10: Bio Analytics- New Waves		
4:30 PM	Draw for Gifts All	Convenor: Dinesh Khokal, Ph.D.		
5:00PM	End of Day 2	4:50PM	Escherichia coli Secretion Systems for Recombinant Protein Production Sudarshan Reddy , Ph.D., Founder/CEO Oncosimis, India	
		5:10 PM	Draw for Gifts All	
		5:20PM	End of Day 2	

Notes / Plan your over of Yorkers:

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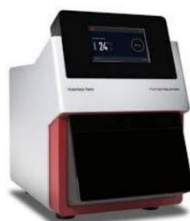
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Biotech Fun Facts

1. **How many biotech professionals with science background are in India including all research institutes, universities, and companies?**
A. About 15,000 B. About 25,000 C. About 50,000 D. Over 75,000
2. **How many Kgs of MABs (mammalian culture-whole world) is being made on an annual basis?**
A. 1000 kg B. 10,000 kg C. 25,000 kg D. 50,000 kg
3. **Which of the following seems right for international price for therapeutic MAB:**
A. \$100-\$1000/g B. \$5000-\$10,000/g C. 10,000-\$50,000/g D. >\$50,000/g
4. **What percentage does the cost of all media, reagents, buffer, purification resins and columns make for the total cost of MABs?**
A. up to 10% B. 10 to 25% C. 25% to 50% D. 50% and higher

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Ans. 1. D, 2. D, 3. B, 4. B (Let's discuss if you do not agree here)



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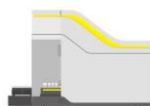
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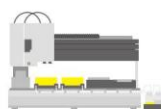
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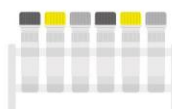
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