Centre of Excellence
Biopharmaceutical Technology

Department of BioTechnology, Government of India

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Dec 2024

CBT COURSE SERIES BROCHURE

Commercial Manufacturing
Mechanistic Modelling
Biologics Development
Good Manufacturing Practices (GMP)
Cell line Development
Capillary Electrophoresis (CE)
Glycan Analysis of Biotherapeutics

Bioprocessing

Good Clinical Practices(GCP)
Validation & Monitoring of Large Scale Biotherapeutics
Data Analytics & Statistics
Characterization of mAbs

Industry 4.0
viral Safety
DOE

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Welcome to the Centre of Excellence for Biopharmaceutical Technology

The Centre of Excellence for Biopharmaceutical Technology (CBT) was established at IIT Delhi in 2015 by the Department of Biotechnology, Government of India, in recognition of the importance of Biotechnology for India, particularly that of producing affordable biotech therapeutics.

The vision of CBT is to deliver innovation in biopharmaceutical technology to effectively address the challenges faced by the Indian biotech industry and thereby assist in the "Make in India" initiative by making India the global hub of manufacturing economical, safe and efficacious therapeutics.

CBT aspires to achieve this tall objective by providing a foundation for scientific and technological development to create novel technologies, engage with the biotech industry to translate these into applications, and finally to offer short term training courses to industry, academia, and regulatory agencies to facilitate creation of an ecosystem that delivers affordable biotech therapeutics to India and to the world.

CBT is bringing forth a world class training program that brings together leaders from across the world to come together and share the best practices and cutting-edge technologies on a diverse set of topics:

Scale Up and Scale Down Approaches for Upstream Process Development	**Process Development and Optimization for Microbial and Mammalian Cell Culture**	**Cell Engineering for Expression of Recombinant Proteins for the Biopharmaceutical Industry**
Continuous Processing for Downstream Processing of Biotherapeutics	**Single Use Technologies for Downstream Processing**	**Downstream Process Development and Optimization for Novel Biotherapeutics**
Mass spectrometry-Based Multi-attribute Monitoring of Post-Translational Modifications in Biopharmaceuticals	**Impact of Formulation on Stability of Biopharmaceuticals**	**Recent Advances in Higher-Order Structure Characterization of Biopharmaceuticals**
Biosimilar Regulatory Framework, Approval Pathway and Role of Key Stakeholders in India	**Regulatory Operations: Preparing Regulatory Filing for FDA, EMA and India**	**----**
Transforming Bioprocessing: Unlocking the Power of AI and Machine Learning	**Unleashing the Power of Industry 4.0: Navigating Through Bioprocessing in the Age of I4.0**	**Application of CFD in Biopharma Manufacturing**
		Mastering Design of Experiments (DOE)

Prof. Anurag S Rathore
Coordinator, CBT, IIT Delhi

Prof. James Gomes
Co-Coordinator, CBT, IIT Delhi

Registration Link: https://forms.gle/VLtFkSBxYGLzGnHPA

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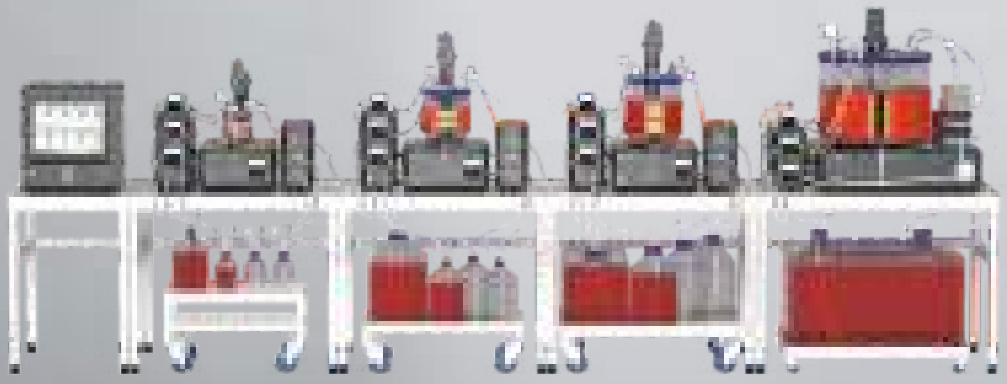

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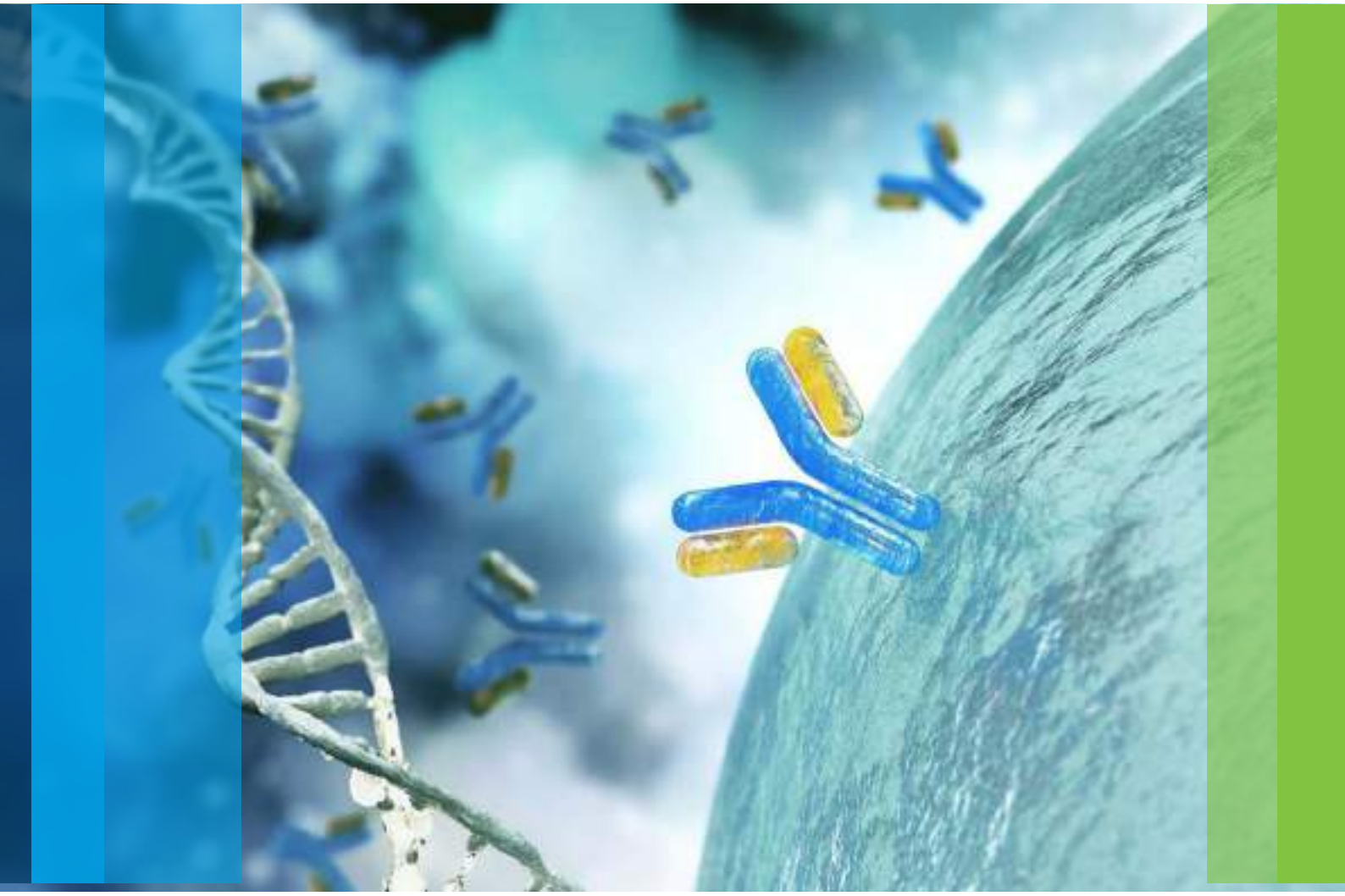

End to End Workflows for Biopharmaceutical Applications

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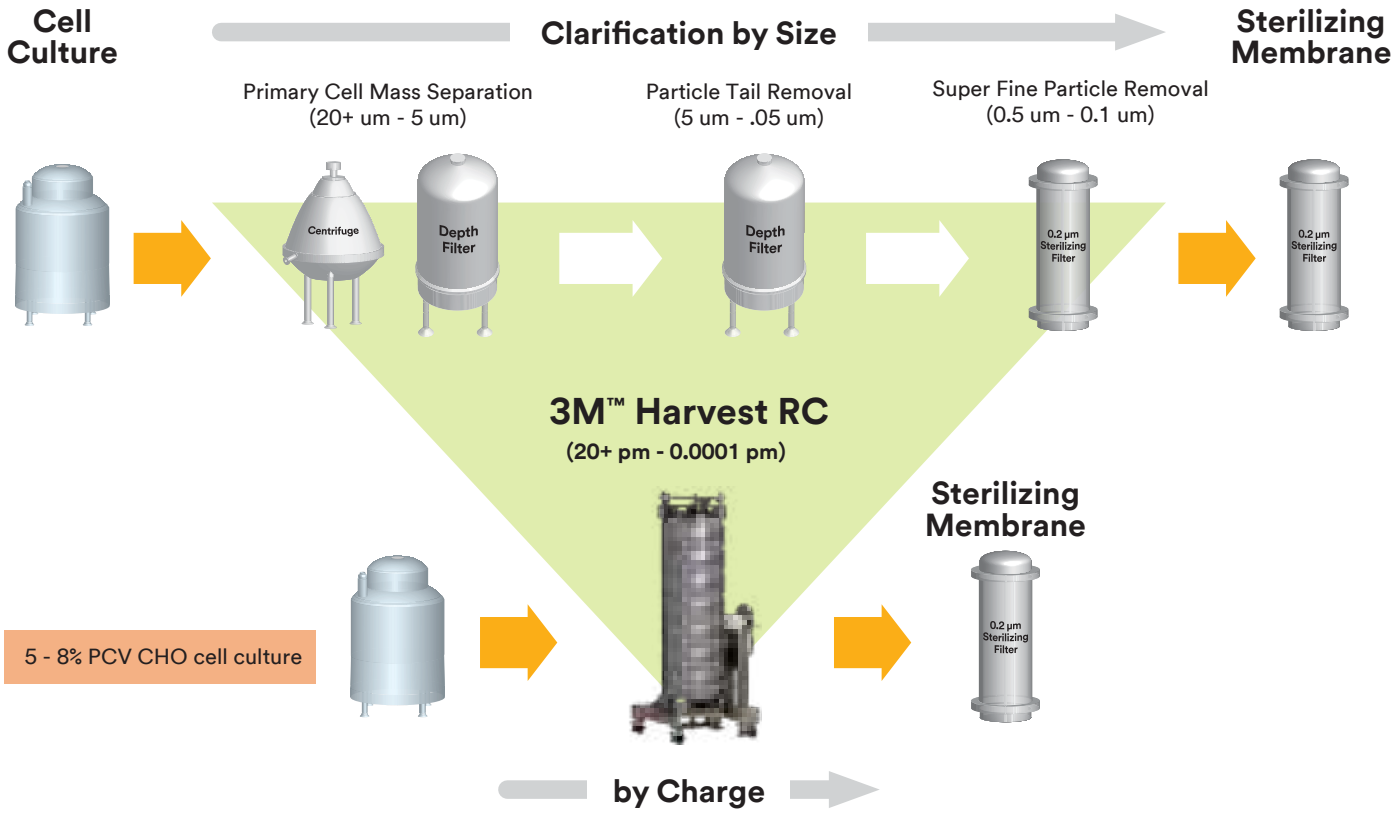

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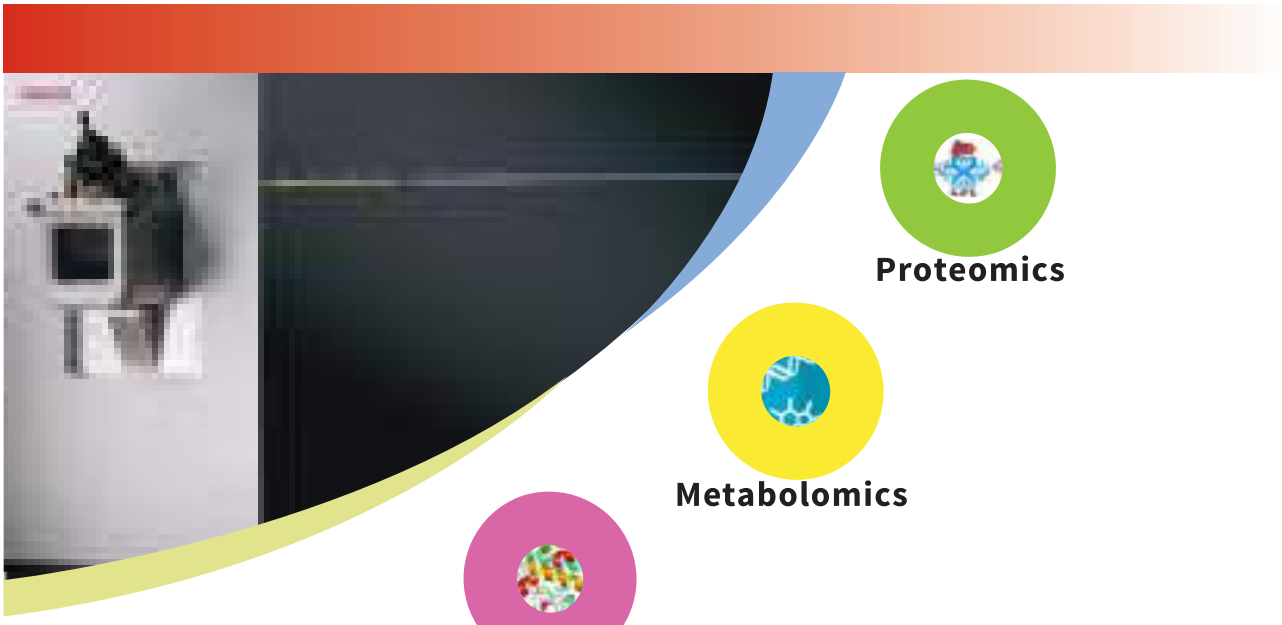

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BPI

BIOPROCESSING SOCIETY-INDIA

ABOUT US

The Bioprocessing Society India (BPI) is a premier platform dedicated to advancing education, collaboration, and research in bioprocessing. Since its inception at IIT Delhi in 2013, the BPI Conference Series has fostered nationwide engagement, traveling through prominent institutes like ICT Mumbai, IIT Madras, and IISER Mohali, among others. Focused on bioprocessing advancements in healthcare, bioenergy, and the environment, BPI uniquely combines academic and industrial perspectives, drawing global participation. Members enjoy benefits like discounted registrations, travel awards, volunteering opportunities, and recognition through the Young Investigator Award, making BPI an ideal hub for professionals, students, and researchers.

MEMBERSHIP PLANS

General body membership is open to students, post docs, faculty, and professionals within the bioprocessing

	Student	Post-Doc/Faculty	Industry
Annual	INR 1,180	INR 5,900	INR 5,900
5 year	INR 3,540	INR 11,800	INR 17,700
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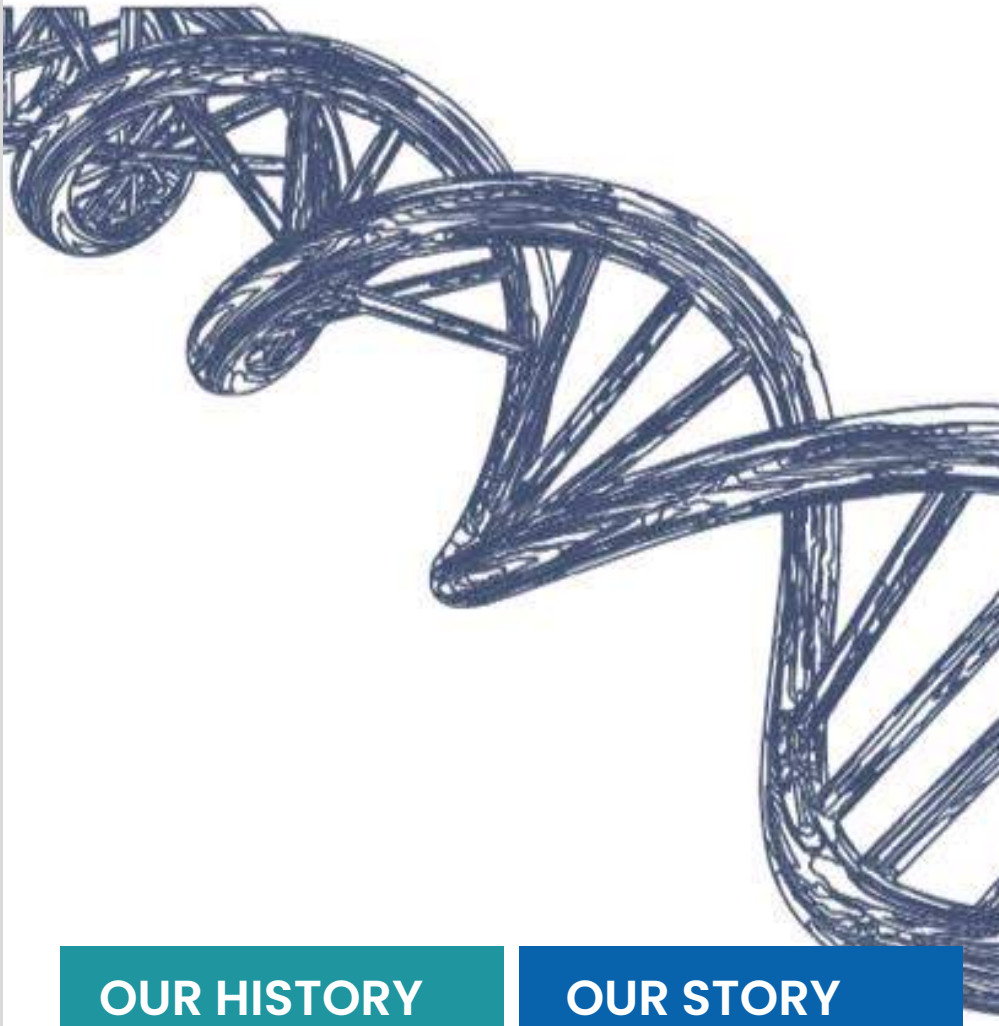

OUR HISTORY

Launched in IIT Delhi in 2020, Edna BioLabs produces speciality enzymes and Reagent for the Indian and global markets. Our founding team has leveraged years of experience in biomolecule production in top universities (IIT Delhi, ICT Mumbai) and leading companies (Biocon, Syngene, Intas) to launch Edna as a commercial venture.

OUR STORY

Having experienced the difficulties and expenses involved in procuring high-quality enzymes and reagents for our research, we are determined to make a difference in the Indian market by providing top-quality speciality enzymes at an affordable price to academic and industrial research labs.

OUR VISION

Speciality enzymes are critical reagents in many IVD testing and biomarker detection kits and are currently majorly imported from the USA, Europe, and China. Our goal is to emerge as a potential substitute for imported speciality enzymes and reagents.

OUR MISSION

Our Mission is to provide specialty enzymes and reagents of excellent quality at an affordable price. We believe that the availability of high-quality domestic enzymes will improve affordability and accessibility to diagnostics information for Indians across the country.

WHAT WE SERVE

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Centre of Excellence
Biopharmaceutical Technology

December 10, 2024
Venue: LHC 408

Track 1 Upstream Processing for Biopharmaceutical Production

Module 1 Scale Up and Scale Down Approaches for Upstream Process Development

Description This course is focused on clarifying the fundamentals of scale up and scale down processes of upstream unit operations. A scale down is an essential tool in biopharmaceutical process development, enabling process developers and manufacturing teams to define a range in which the process can be considered optimal and under control. Scale up is defined as taking a biopharmaceutical manufacturing process from the laboratory scale to the commercial scale. Recent developments, process flow and challenges related to scale down and scale up will be addressed.

OUTLINE

08:30-09:00	**Breakfast**
09:00-09:30	Welcome Address ***(Raj K. Shirumalla, BIRAC)***
09:30-10:00	Welcome Address ***(Anurag S. Rathore, IIT Delhi)*** — LHC410
10:00-10:45	Scale up Principles and Scale down Model Qualifications ***(Christoph Herwig, Korber Pharma, Austria)***
10:45-11:00	**Tea Break**
11:00-11:35	Scale up of Upstream Processes: A Gene-therapy Perspective ***(Yogender Kumar Gowtham, Asklepios BioPharmaceutical, Inc., USA)***
11:35-12:05	Scale down Model Development for a Perfusion Based Upstream Process ***(Yogender Kumar Gowtham, Asklepios BioPharmaceutical, Inc., USA)***
12:05-12:45	Scale down Approach to Troubleshoot Large Scale Manufacturing issues - Case Study ***(Rithvija Avvari, Biogen, Raleigh, North Carolina, USA)***
12:45-13:00	Discussion + Q&A
13.00-14:00	**Lunch**
14:00-14:45	Modelling And Control Strategies for Upstream Process Development ***(James Gomes, IIT Delhi)***
14:45-15:10	Role of Advance Simulation Tools in Scale up and Scale down Processes ***(Nirmal Mallick, IIT Delhi)***
15:10-15:30	**Tea Break**
15:30-16:15	Solaris Bioreactor Automation and Hydrodynamics Modelling ***(Mihir Shah &Vikram Bisht, Donaldson Life Sciences)***
16:15-16:30	Discussion + Q&A
16:30-18:00	Industry Demo: Solaris Bioreactor and Automation ***(Donaldson Life Sciences)***
18:30-20:00	**Dinner**

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Biopharmaceutical Technology

December 11, 2024
Venue: LHC 408

Track 1 **Upstream Processing for Biopharmaceutical Production**

Module 2 **Process Development and Optimization for Microbial and Mammalian Cell Culture**

Description This course is aimed at describing the role of fermentation, culture media development, and process optimization in biopharmaceutical industry. These processes play an important role in cultivating microorganisms into essential biopharmaceuticals products. The purpose of optimization is to achieve the "best" design relative to a set of prioritized criteria or constraints. These include maximizing factors such as productivity, strength, reliability, stability, efficiency, and cost-effectiveness. Basics of fermentation, role of optimization in media and process development, and recent advancement related to these areas will be addressed.

OUTLINE

08:30-09:00	**Breakfast**
09:00-10:45	Digital Twins in Bioprocess Development: Workflows and Benefits ***(Christoph Herwig, Korber Pharma, Austria)***
10:45-11:00	**Tea Break**
11:00-11:35	An Optimized Fermentation Process Development for Recombinant Protein Production ***(Richa Katiyar, IIT Delhi)***
11:35-12:10	Perfusion Process Intensification for High Cell Density Cultures ***(Abhishek Mule, Eppendorf Group)***
12:10-12:45	Microbial Upstream Process Development for Therapeutic Peptides: Pramlintide as a Case Study ***(Nida Khan, IIT Delhi)***
12:45-13:00	Discussion + Q&A
13.00-14:00	**Lunch**
14:00-14:35	Microbial Upstream Process Development for Monoclonal Antibody Fragments: Ranibizumab as a Case Study ***(Sami Ullah Bhat, IIT Delhi)***
14:35-15:10	Glycosylation and Charge Variants Control in Mammalian Cell Culture ***(Neha Dixit, IIT Delhi)***
15:10-15:30	**Tea Break**
15:30-16:15	CellBRx Single-use Bioreactor Systems ***(Jagadish Bennale, OmniBRx Biotechnologies)***
16:15-16:30	Discussion + Q&A
16:30-18:00	Industry Demo: CellBRx Single-use Bioreactor Systems ***(OmniBRx Biotechnologies)***
18:30-20:00	**Dinner**

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December 12, 2024

Venue: LHC 408

Track 1 **Upstream Processing for Biopharmaceutical Production**

Module 3 **Cell Engineering for Expression of Recombinant Proteins for the Biopharmaceutical Industry**

Description This course highlights the concepts of cell engineering and cloning in defining and implementing upstream process development for manufacturing biopharmaceutical products. Genetic engineering and cloning provide a way to create new biopharmaceutical products such as therapeutic antibodies, vaccines, and hormones used to treat various diseases. The course will focus on the basics of cloning, types of cloning strategies, recent advancements, and challenges in the production of biotherapeutics via microbial and mammalian cell culture. The participants will learn about cutting edge techniques in upstream bioprocessing.

OUTLINE

08:30-09:00	**Breakfast**
09:00-09:45	Points-to-Consider for Biopharmaceutical Protein Expression from Recombinant Microbial Cells ***(E. K. Lee, Hanyang University-ERICA, Ansan, Korea (South))***
09:45-10:45	Cloning and Expression of Recombinant Proteins in Microbial Cells ***(Preeti Srivastava, IIT Delhi)***
10:45-11:00	**Tea Break**
11:00-11:45	Cell Engineering for Mammalian and Microbial Cells – Case Study ***(Manidipa Banerjee, IIT Delhi)***
11:45-12:15	Introduction to Metabolic Modeling ***(Rajib Saha, University of Nebraska-Lincoln, USA)***
12:15-13:00	Omics Data-Integrated Metabolic Modeling ***(Rajib Saha, University of Nebraska-Lincoln, USA)***
13.00-14:00	**Lunch**
14:00-14:45	Neurodegeneration: Amyotrophic Lateral Sclerosis in Indian Patients ***(James Gomes, IIT Delhi)***
14:45-15:10	Enhancing the Production of HPV-VLPs in *Pichia pastoris* ***(Abhilasha Rani, IIT Delhi)***
15:10-15:30	**Tea Break**
15:30-16:15	BioLector XT | Microbioreactors: High Throughput Technology Platform in Upstream Processing ***(Maria Savino, Beckman Coulter Life Sciences)***
16:15-16:30	Discussion + Q&A
16:30-18:00	Industry Demo: BioLector XT Microbioreactor ***(Beckman Coulter Life Sciences)***
18:30-20:00	**Dinner**

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December 10, 2024
Venue: LHC 410

Track 2 **Downstream Processing for Biopharmaceutical Production**

Module 4 **Continuous Processing for Downstream Processing of Biotherapeutics**

Description This course series aims to highlight various aspects of the continuous processing of biotherapeutics molecules. The major focus will be on development and implementation of continuous processing. Role of modelling and process control strategies in the context of continuous processing will also be elucidated.

OUTLINE

08:30-09:00	**Breakfast**
09:00-09:30	Welcome Address ***(Raj K. Shirumalla, BIRAC)***
09:30-10:00	Welcome Address ***(Anurag S. Rathore, IIT Delhi)*** } LHC410
10.00-10:45	Introduction to Continuous Downstream Processing ***(Anurag S. Rathore, IIT Delhi)***
10:45-11:00	**Tea Break**
11.00-12:00	Introduction to Continuous Chromatography ***(Rahul Bhambure, NCL, Pune)***
12.00-13:00	Characteristics and Economics of Continuous Bioprocessing for Therapeutic mab Manufacturing ***(E. K. Lee, Hanyang University-ERICA, Ansan, Korea (South))***
13.00-14:00	**Lunch**
14.00-14:45	Continuous Refolding for Peptibody Therapeutics ***(Rahul Bhambure, NCL, Pune)***
14.45-15:30	Process Economics (Batch v/s Continuous) ***(Rahul Bhambure, NCL, Pune)***
15.30-15.45	**Tea Break**
15.45-16:30	Monitoring and Control of Continuous Process ***(Nikita Saxena, IIT Kharagpur)***
16.30-17:00	Mechanistic v/s Empirical v/s Hybrid Control Strategies ***(Rishika Trivedi, IIT Delhi)***
17.00-17:45	Case Study: Continuous Chromatography ***(Anupa, IIT Delhi)***
17.45-18:30	Case Study: Continuous TFF ***(Naveen G. Jesubalan, IIT Delhi)***
18:30-20:00	**Dinner**

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Track 2 **Downstream Processing for Biopharmaceutical Production**

Module 5 **Single Use Technologies for Downstream Processing**

Description This course series will discuss the recent developments in the field of single use technologies. It aims to highlight the need, use, and limitations of single use technologies. The focus will be the integration, cost effectiveness, and sustainability of single use devices.

OUTLINE

08:30-09:00	**Breakfast**
09:00-09:45	Single-Use TFF and Chromatography Systems for Redefining the Flexibility in mAb Downstream Processing ***(Rahul Bhambure, NCL, Pune)***
09:45-10:45	Single-use Technologies in Downstream Processing in ADC (Antibody-Drug Conjugate) Manufacturing ***(E. K. Lee, Hanyang University-ERICA, Ansan, Korea (South))***
10:45-11:00	**Tea Break**
11:00-11:45	Advantages and Challenges in the Integration of Single-use Technologies in DSP ***(Krunal Mehta, Merck, USA)***
11:45-12:30	Strategy Towards Restructuring of key BioPharma Supplies ***(E. K. Lee, Hanyang University-ERICA, Ansan, Korea (South))***
12.30-13.30	**Lunch**
13:30-15:30	Industry Demo ***(Aglient Technologies)***
15:30-16:00	**Tea Break**
16:00-17:00	Single-use Devices in Continuous Manufacturing ***(Jobin Maliyil, 3M)***
17:00-18:00	Case Studies in Integration of Single-use Technologies in DSP ***(Krunal Mehta, Merck, USA)***
18:00-20:00	**Dinner**

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Track 2 **Downstream Processing for Biopharmaceutical Production**

Module 6 **Downstream Process Development and Optimization for Novel Biotherapeutics**

Description This course focuses on clarifying the fundamentals of downstream process development for novel biotherapeutics. The course will highlight the unit operations and control strategies required for the optimization of process parameters for downstream purification of biopharmaceutical molecules.

OUTLINE

08:30-09:00	**Breakfast**
09:00-10:00	Multimodal Chromatographic Purification of Biosimilar Anakinra ***(Rahul Bhambure, NCL, Pune)***
10:00-10:45	Role of Models (Both Mechanistic and Data-based) in Process Development and Optimization ***(Nikita Saxena, IIT Kharagpur)***
10:45-11:00	**Tea Break**
11:00-12:00	Predictive Mechanistic Model for Separation of mAbs, fAbs and Aggregate Species on Multimodal Chromatography ***(Lalita Kanwar Shekhawat, IIT Patna)***
12:00-12:30	Case Study: Process Optimization for Continuous Mixing Reactions ***(Nitika, IIT Delhi)***
12:30-13:00	Case Study: Downstream Process Development and Optimization of mAb Fragments ***(Anupa, IIT Delhi)***
13:00-14:00	**Lunch**
14:00-14:30	Case Studies: Process Development for the Purification of Lethal Toxin Neutralizing Agent ***(Subhankar Metya, IIT Delhi)***
14:30-15:30	Purification Solutions for Standard and Next Generation Antibody Modalities ***(Sandip Kadam, Thermo Scientific)***
15:30-15:45	**Tea Break**
15:45-16:15	Case Study: Downstream Process Development for Virus Like Particles ***(Rashmi Sharma, IIT Delhi)***
16:15-17:00	Case Study: Preparation of Bio-composites for Applications in Biopharmaceutical Technology (***Pragya Prakash, IIT Delhi)***
17:00-17:45	Case Study: Process Development for the Preparation of Antibody Drug Conjugates ***(Subhankar Metya, IIT Delhi)***
17:45-18:30	Case Study: Refolding Optimization of fAbs ***(Rashmi Sharma, IIT Delhi)***
18:30-20:00	**Dinner**

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Venue: LHC 416

Track 3 **Analytical Characterization and Comparability**

Module 7 **Mass spectrometry-Based Multi-attribute Monitoring of Post-Translational Modifications in Biopharmaceuticals**

Description Post-Translational modifications (PTMs) are crucial for the structure, stability, and function of biopharmaceuticals, particularly protein-based therapeutics like monoclonal antibodies, enzymes, and hormones. Common PTMs include glycosylation, phosphorylation, oxidation, deamidation, and others, each of which can significantly impact a drug's efficacy, immunogenicity, and pharmacokinetics. The ability to accurately monitor and quantify these modifications is essential for quality control during the development and production of biopharmaceuticals. Mass spectrometry (MS)-based multi-attribute monitoring (MAM) has emerged as a powerful tool for comprehensive, high-resolution analysis of PTMs, offering significant advantages over traditional methods.

OUTLINE

08:30-09:00	**Breakfast**
09:00-09:30	Welcome Address ***(Raj K. Shirumalla, BIRAC)***
09:30-10:00	Welcome Address ***(Anurag S. Rathore, IIT Delhi)*** — LHC410
10:00-10:45	Introduction to Mass Spectrometry in Biopharmaceuticals ***(Alain Beck, Pierre Fabre Laboratories, France)***
10:45-11:00	**Tea Break**
11:00-11:30	Post-Translational Modifications (PTMs) and Multi-Attribute Monitoring (MAM) ***(Anu Uppal, US Pharmacopeia, India)***
11:30-12:00	Multi-Attribute Method: Concept, Current Status and Future Developments ***(Alain Beck, Pierre Fabre Laboratories, France)***
12:00-12:30	Peptide Mapping in MAM for PTM Identification ***(Anu Uppal, US Pharmacopeia, India)***
12:30-13:00	Quantitative PTM Monitoring via MAM ***(Sumit Kumar Singh, IIT BHU)***
13.00-14.00	**Lunch**
14:00-14:45	Case Study: LC-MS Characterization and Stability Assessment to Elucidate Correlation Between Charge Variant Composition and Degradation of Monoclonal Antibodies ***(Neh Nupur, NIPER Guwahati)***
14:45-15:15	Case Study: Titer and Charge Based Heterogeneity using MAM ***(Deepika Sarin, IIT Delhi)***
15:15-15:30	**Tea Break**
15:30-18:00	Industry Demo: Aglient Technologies
18:30-20:00	**Dinner**

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Track 3 Analytical Characterization and Comparability

Module 8 Impact of Formulation on Stability of Biopharmaceuticals

Description The stability of biopharmaceuticals, particularly protein-based therapeutics such as monoclonal antibodies, peptides, and fusion proteins, is critically influenced by their formulation. Stability is essential to ensuring the efficacy, safety, and shelf life of these drugs. Excipients play a crucial role in biopharmaceutical formulations, contributing to stability and efficacy. These inactive ingredients are carefully selected based on their functionality and compatibility to the drug product. Proper formulation is vital to mitigate these risks, optimizing drug stability from manufacturing to storage and administration.

OUTLINE

08:30-09:00	**Breakfast**
09:00-10:00	Antibody and Antibody-Based Product Developability ***(Alain Beck, Pierre Fabre Laboratories, France)***
10:00-10:45	Role of Excipients in Biopharmaceutical Formulation ***(Neh Nupur, NIPER Guwahati)***
10:45-11:00	**Tea Break**
11:00-12:00	Role of Analytical Methods in Formulation Development ***(Krishna M.G. Mallela, University of Colorado)***
12:00-13:00	Regulatory Considerations in Formulation Development of Biopharmaceuticals ***(Krishna M.G. Mallela, University of Colorado)***
13.00-14:00	**Lunch**
14:00-14:45	Unexplored Excipients in Biotherapeutic Formulations ***(Neh Nupur, NIPER Guwahati)***
14:45-15:15	Case Study: Impact of Buffer Exchange and Extraction on mAb Stability (***Kunal Krishna, IIT Delhi)***
15:15-15:30	**Tea Break**
15:30-18:00	Industry Demo: Aglient Technologies
18:30-20:00	**Dinner**

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Track 3 **Analytical Characterization and Comparability**

Module 9 **Recent advances in Higher-Order Structure Characterization of Biopharmaceuticals**

Description The characterization of Higher-Order Structures (HOS) is crucial for understanding the function, stability, and efficacy of biopharmaceuticals, particularly protein-based therapeutics like monoclonal antibodies and fusion proteins. HOS refers to the complex three-dimensional folding and structural arrangement of biomolecules beyond their primary amino acid sequence. Recent advances in analytical techniques have significantly improved the ability to Study and characterize these structures, contributing to enhanced drug development, quality control, and regulatory compliance.

OUTLINE

08:30-09:00	**Breakfast**
09:00-09:45	Fundamentals on Higher-Order Structure Characterization of Biopharmaceuticals ***(Krishna M.G. Mallela, University of Colorado)***
09:45-10:15	Emerging Analytical Techniques for HOS Characterization ***(Krishna M.G. Mallela, University of Colorado)***
10:15-10:45	Case Study: Size-Based Heterogeneity using DLS ***(Anuj Shrivastava, IIT Delhi)***
10:45-11:00	**Tea Break**
11:00-12:00	Raman and FTIR Spectroscopy as Characterization Tools ***(Sudip K Pattanayek, IIT Delhi)***
12:00-13:00	Regulatory Considerations for HOS in Biopharmaceuticals ***(Neh Nupur, NIPER Guwahati)***
13.00-14:00	**Lunch**
14:00-14:45	Case Study: HOS Characterization of Biopharmaceuticals (***Kunal Krishna, IIT Delhi)***
14:45-15:15	Case Study: HOS Characterization of Biopharmaceuticals ***(Vineela Peruri, IIT Delhi)***
15:15-15:30	**Tea Break**
15:30-18:00	Industry Demo: Aglient Technologies
18:30-20:00	**Dinner**

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Track 4 Key Concepts of Regulatory Approval for Biopharmaceuticals

Module 10 Biosimilar Regulatory Framework, Approval Pathway and Role of Key Stakeholders in India

Description This module comprehensively analyses the biosimilar regulatory framework, emphasizing the critical role of stakeholders such as CDSCO, RCGM, DBT, CCSEA, WHO, USFDA, industry leaders and healthcare professionals. It highlights the importance of a well-structured regulatory framework, including reference product selection, quality assessment and characterization to ensure safety, efficacy, and quality of biosimilars, which is essential for building trust among stakeholders and fostering innovation in the biopharmaceutical sector. Discussion will also include regulatory trends for animal experimentation in India and other parts of the globe.

OUTLINE

08:30-09:00	**Breakfast**
09:00-09:30	Welcome Address ***(Raj K. Shirumalla, BIRAC)*** } LHC410
09:30-10:00	Welcome Address ***(Anurag S. Rathore, IIT Delhi)***
10:00-10:30	FDA India Office Overview & Future Engagement: Exploring Collaborations, Innovations, and Regulatory Partnerships ***(Gregory (Greg) Smith, USFDA)***
10:30-11:15	Regulatory Landscape of India and Biosimilar Application Framework ***(Arvind Kukrety, CDSCO)***
11:15-11:30	**Tea Break**
11:30-12:00	Reference Product Selection, Quality Assessment and Characterization ***(Samir Sangitrao, Zydus Cadila)***
12:00-12:30	Manufacturing Considerations: Host Selection, Upstream, Downstream Process and Control ***(Samir Sangitrao, Zydus Cadila)***
12:30-13:00	Biosimilar Filing Process at CDSCO including Testing and Marketing Requirements ***(Arvind Kukrety, CDSCO)***
13.00-14:00	**Lunch**
14:00-15:00	Regulatory Framework for Animal Experimentation in India: The Role of CCSEA ***(Vivek Tyagi, CCSEA)***
15:00-15:15	**Tea Break**
15:15-16:00	Approval Process for Research Involving GMOs: RCGM Guidelines/ (BioRRAP Requirements) ***(Nitin Jain, DBT)***
16:00-17:00	Pre-Clinical Studies: Data Requirements, PK, PD and Toxicological Studies, Animal Model Selection ***(Narendra Chirmule, SymphonyTech)***
17:00-17:30	Clinical Studies: Data Requirement, PK, PD and Toxicological Studies, Study Waiver ***(Narendra Chirmule, SymphonyTech)***
17:30-18:30	Pharmacovigilance Strategies to Improve Patient and Healthcare Provider Awareness for Biosimilars ***(Y.K. Gupta, VaidyaRx)***
18:30-20:00	**Dinner**

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Track 4 **Key Concepts of Regulatory Approval for Biopharmaceuticals**

Module 11 **Regulatory Operations: Preparing Regulatory Filing for FDA, EMA and India**

Description

Bio-similarity approval by the U.S. Food and Drug Administration (USFDA) and EMA is a rigorous regulatory process designed to ensure that biosimilar products, which are highly similar but not identical to already-approved biologics, meet the same high standards for safety and efficacy. Participants will explore the regulatory approval process for biosimilars in India, UK and USA. The module will discuss the evolving USFDA and EMA requirements and the pathway for biosimilar approvals, comparing it with the Indian framework. Special focus will be placed on the role of international regulatory harmonization efforts to enhance global market access for Indian biosimilars.

OUTLINE

08:30-09:00	**Breakfast**
09:00-10:00	Manufacturing Considerations: Product and Process Characterization; GMP Manufacturing ***(Dhananjay Patankar, Industry Expert)***
10:00-10:45	Innovations in Regulatory Framework of Biosimilars: Advancing Science, Safety and Affordability ***(Sonia Gandhi, BIRAC)***
10:45-11:00	**Tea Break**
11:00-11:45	Biosimilar Product Development Strategy: India First and Global Next vs Global First and India Next ***(Dhananjay Patankar, Industry Expert)***
11:45-12:15	Various Aspects of Regulatory Affairs ***(Samir Sangitrao, Zydus Cadila)***
12:15-13:00	Regulatory and Analytical Considerations for Peptide Therapeutics ***(Annu Uppal, US Pharmacopeia)***
13.00-14:00	**Lunch**
14:00-15:15	Harmonising Regulatory Pathways for mAbs ***(Rajat Goyal, IAVI)***
15:15-15:30	**Tea Break**
15:30-16:30	WHO-PQ Requirements for Biosimilars ***(P S Chandranand, WHO)***
15:30-17:30	Failures in Regulatory Filings: Lessons Learned ***(Narendra Chirmule, Symphony Technology)***
17:30-18:30	Charting the Future for Biosimilars: Replicating the Success of Small Molecules ***Dhananjay Patankar & Samir Sangitrao, Zydus Cadila & Narendra Chirmule, Symphony Technology)***
18:30-20:00	**Dinner**

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Track 5 Data Analytics & Industry 4.0 in Biopharma Manufacturing

Module 12 Transforming Bioprocessing: Unlocking the Power of AI and Machine Learning

Description

Artificial Intelligence (AI) and Machine Learning (ML) are transforming biopharma by unlocking new possibilities in process optimization, drug discovery, and biological system analysis. This module focuses on leveraging AI/ML to analyze complex datasets, build predictive models, and drive data-driven decision-making in bioprocessing. Participants will gain insights into cutting-edge techniques, including deep learning and advanced algorithms, to address real-world challenges and revolutionize biomanufacturing with smarter, more efficient solutions.

OUTLINE

08:30-09:00	**Breakfast**	
09:00-09:30	Welcome Address ***(Raj K. Shirumalla, BIRAC)***	LHC410
09:30-10:00	Welcome Address ***(Anurag S. Rathore, IIT Delhi)***	
10:00-10:45	Introduction: Data Handling, Feature Selection and Optimization Techniques ***(ManojKumar Ramteke, IIT Delhi)***	
10:45-11:00	**Tea Break**	
11:00-11:45	Introduction to Neural Networks: DNN / CNN / RNN/ LSTM ***(ManojKumar Ramteke, IIT Delhi)***	
11:45-12:25	Explainable AI: LIME and SHAP ***(Naveen G. Jesubalan, IIT Delhi)***	
12:25-13:00	Introduction to LLMs ***(Sanjeet Patil, IIT Delhi)***	
13.00-14:00	**Lunch**	
14:00-14:30	AI in Drug Discovery ***(Avinash Mishra, GrowdeaTech)***	
14:30-15:05	Case Study: AI/ML in Biopharmaceutical Manufacturing (Reinforcement Learning) ***(Nikita Saxena, IIT Kharagpur)***	
15:05-15:40	Case Study: Revolutionizing Biomanufacturing with AI/ML ***(Rajib Saha, University of Nebraska-Lincoln, USA)***	
15:40-16:10	**Tea Break**	
16:10-16:55	Good Practices to Achieve Data Quality and Data Maturity for the Product Life Cycle ***(Christoph Herwig, Korber Pharma, Austria)***	
16:55-17:45	AI-enhanced PAT ***(Naveen G. Jesubalan, IIT Delhi)***	
17:45-18:30	End-to-End Process Modelling for Streamlining the Product life Cycle and Real Time Release ***(Christoph Herwig, Korber Pharma, Austria)***	
18:30-20:00	**Dinner**	

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Track 5 **Data Analytics & Industry 4.0 in Biopharma Manufacturing**

Module 13 **Unleashing the Power of Industry 4.0: Navigating Through Bioprocessing in the Age of I4.0**

Description Industry 4.0, or the Fourth Industrial Revolution, represents the digital transformation of the industrial sector through data, connectivity, analytics, human-machine collaboration, and robotics. In biopharmaceuticals, it emphasizes automation and data analysis tools to create smart factories capable of autonomous control. This approach optimizes processes, reduces physical testing, ensures operations stay within design limits, and improves real-time monitoring and diagnostics. Key topics include digital twins, cyber-physical systems, digitalization, and continuous manufacturing.

OUTLINE

08:30-09:00	**Breakfast**
09:00-09:30	Navigating the Fourth Industrial Revolution through Innovation and Integration ***(Raj Shirumalla, BIRAC)***
09:30-10:15	Introduction to Industry 4.0 ***(Vinesh Balakrishnan Yezhuvath, TCS)***
10:15-10:45	Cyber Security ***(Sai Prasad, TCS)***
10:45-11:00	**Tea Break**
11:00-12:30	Digital Twin of a Bioreactor ***(Venkata Sudheendra Buddhiraju, TCS)***
12:30-13:15	Digital Twins and their Applications ***(Venkataramana Runkana, TCS)***
13.15-14:00	**Lunch**
14:00-14:40	Case Study: Cyber Physical Systems (CPS) ***(Nikita Saxena, IIT Kharagpur)***
14:40-15:25	Digital Transformation or How to Survive ***(Christoph Herwig, Korber Pharma, Austria)***
15:25-15:40	**Tea Break**
15:40-16:25	Case Study: Continued Process Verification ***(Naveen G. Jesubalan, IIT Delhi)***
16:25-17:05	Case study: Bioprocessing in I4.0 ***(Rajib Saha, University of Nebraska-Lincoln, USA)***
17:05-17:45	Multi-Objective Optimization ***(Naveen G. Jesubalan, IIT Delhi)***
17:45-18:30	Case Study ***(Rajib Saha, University of Nebraska-Lincoln, USA)***
18:30-20:00	**Dinner**

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Track 5 **Data Analytics & Industry 4.0 in Biopharma Manufacturing**

Module 14 **Application of CFD in Biopharma Manufacturing**

Description The workshop will provide a comprehensive overview of CFD simulation in the biopharmaceutical industry, focusing on Ansys tools and their applications. A step-by-step demonstration of how to use Ansys Fluent for pharma/bio-pharma manufacturing, such as mixing tank simulation, will provide attendees with valuable practical experience. In this workshop, we will also cover case studies on digital twin solutions for optimizing bioreactor process efficiency

OUTLINE

08:30-09:00	**Breakfast**
09:00-09:40	CFD for Bioreactor Design to Understand Biomechanics ***(Jayati sarkar, IIT Delhi)***
09:40-10:15	Application of CFD in Determine Underlining Correlations in a Bioreactor ***(Nirmal Mallick, IIT Delhi)***
10:15-10:30	Session Q & A
10:30-10:45	**Tea Break**
10:45-12:30	Introduction to CFD Simulation ***(Vignesh S. M., CADFEM India Private Limited)***
12:30-13:00	Ansys Simulation Technologies for Biopharmaceutical Industry ***(Vignesh S. M., CADFEM India Private Limited)***
13:00-13:45	**Lunch**
13:45-15:00	Demonstration of Mixing Tank Analysis for Flow Blending Time Prediction ***(Vignesh S. M., CADFEM India Private Limited)***
15:00-15:15	Session Q & A
15:15-15:30	**Tea Break**
15:30-18:30	Application Brief of Maximizing Bioreactor Efficiency using Ansys Technologies ***(Vignesh S. M., CADFEM India Private Limited)***
18:30-20:00	**Dinner**

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Module 15 **Mastering Design of Experiments (DOE)**

Description Design of Experiments (DOE) and Quality by Design (QbD) are effective methods for improving processes, products, and outcomes across industries, including biopharmaceuticals. The training aims to improve understanding of the Quality by Design (QbD) approach, focusing on regulatory compliance and JMP software's integrated workflows. Attendees will receive expert guidance on risk assessment, experiment design, and process optimization, leading to increased production quality and efficiency.

OUTLINE **Module Instructor:** ***Muralidhara Anandamurthy, JMP***

08:30-09:00	**Breakfast**
09:00-09:45	Introduction to DOE: Strategy of Experimentation, Terminologies in DOE
09:45-10:45	Screening Designs: Factorial & Fractional Factorial Experiments: Cases with Hands-on Exercises
10:45-11:00	**Tea Break**
11:00-13:00	Optimization Designs: Response Surface Methodology (RSM), Sequential Experimentation, Central Composite and Box Behnken Designs, Prediction, Simulation, and Optimization: Cases with Hands-on Exercises
13.00-14:00	**Lunch**
14:00-15:15	Modern & Computer-Generated Designs: Custom Design and Definitive Screening Designs (DSD); Quality by Design (QbD): Design Space Profiler and Quality Risk Assessment; (QRM): Cases with Hands-on Exercises
15:15-15:30	**Tea Break**
15:30-18:00	Formulation/Mixture Designs, Mixture with Process factors, Mixture with Constraints: Cases with Hands-on Exercises
18:30-20:00	**Dinner**

OUR SPEAKERS

ANANDAMURTHY MURALIDHARA is part of the JMP Global Team and heads JMP Academic for India. He holds a B.Tech, MBA, and Ph.D. With over 22 years of experience in the Analytics and Data Science industry, he has held various leadership positions at Genpact, Target, and Danske. He is also a trainer in Statistical Data Analysis, Data Science & ML, and Design of Experiments (DOE), and has conducted workshops at numerous academic institutions. He has authored several case studies for teaching and is a co-author of the book Machine Learning for Business Analytics from Wiley International Publications. He remains committed to learning and sharing insights on Statistical Thinking for problem-solving.

AVVARI RITHVIJA is a Senior Manufacturing Sciences Engineer at Biogen in RTP, specializing in upstream bioprocessing. A passionate chemical engineer, Rithvija thrives on troubleshooting and problem-solving, driving efficiency and innovation in the biopharmaceutical industry with the goal of improving lives through advanced science. Since 2019, Rithvija has been an active member of the American Chemical Society (ACS) Biotechnology Division and has recently taken on the role of mentoring students as an industry expert. A strong supporter of STEM initiatives, Rithvija is dedicated to fostering interest in science and engineering among young learners.

BANERJEE MANIDIPA received her PhD from the University of California, San Diego, where she studied the molecular mechanism of bacterial pathogen entry into host cells using biochemical and biophysical methods. She carried out her postdoctoral research at the Scripps Research Institute, California where she studied non-enveloped virus entry mechanisms using X-ray crystallography and cryoelectronic microscopy. Banerjee is currently a Professor at the Kusuma School of Biological Sciences, Indian Institute of Technology, Delhi. The research interests of her laboratory are in the molecular mechanism of virus-host interaction, and in developing virus-based nanoparticles for biomedical applications.

BECK ALAIN is Senior Director, Biologics CMC and Developability (Institut de Recherche Pierre Fabre, France), co-founder and Associate Editor of mAbs journal and chairman of MabDesign SAB. He is or was involved in +12 clinical stage biologics R&D programs including dalotuzumab/IGF1R (Merck), telisotuzumab/ telisotuzumab vedotin/ cMet (AbbVie), h515H7/ CXCR4 mAb, lonigutamab ugodotin ADC/ IGF1R, W0180 Vista mAb (PF), VERT-002/ cMet (Vertical Bio), efsudenermin alpha (Fc: EDA1, ER004) fusion protein and lonigutamab. He is author/ co-author of +270 publications (h-index: 71; +18,300 citations). He has contributed to +300 scientific meetings (AIS, BAS, Bioproduction, CASSS, CTDP, EAC, FOB, GlycoBiotec, PEGS, SCT, WADC, WBC, WCBP) as chairman, invited speaker, panellist, moderator, advisor, and/ or organizer (IO mAbs, ADCs/ BsADCs, Biobetters, Biosimilars, pAbs, Bs/MsAbs, Fc-fusions, Immunocytokines, Protein Scaffolds, Mass Spec, Med Chem, PK/PD, separative sciences). He was ranked 6/50 global antibody industry influencers (2013), was 6th WADC (2019), 10th AIS Award (2022) and Medecine Maker Power List 2024 award winner. He is a member of the MAB Working Party (EDQM/ PhEur) and involved in workshops with ANSM, EU, EMA, FDA, NIST, USP and WHO.

BENNALE JAGADISH introduced The First - Microfluidics based Robotics enabled High Throughput Fermentation Technology Platform (Robolector by m2p- labs GmbH) in India. Now, he is working at Beckman Coulter Life Sciences (Operating Company of Danaher Corporation), a global science and technology innovator committed to helping our customers solve complex challenges and improving quality of life around the world. Danaher companies have a powerful Shared Purpose—Helping Realize Life's Potential—and Core Values have made us who we are today and will guide us into the future.

BHAMBURE RAHUL is currently leading the Bioprocess Technology group in Chemical Engineering and Process Development Division of CSIR - National Chemical Laboratory, Pune. My area of research covers both experimental and theoretical grounds applied mainly to the field of process and product development for biopharmaceuticals. F or the last ten years, I have been working in bioprocess development for recombinant protein and nucleic acid therapeutics. My future research interest will be more focused on applied protein biophysics and biochemical engineering for developing novel processes at various stages of biopharmaceutical manufacturing like upstream, downstream and formulation.

BISHT VIKRAM has a background in Mechanical Engineering along with specialization in Energy Engineering. He is currently working as a modelling scientist in Donaldson Company Inc. He has an engaging interest in the bioprocess industry and is keen about learning innovative digital technologies applied in Bioprocess. His enthusiasm and commitment to professional excellence make him a valuable contributor to any discussion on engineering and innovation.

BUDDHIRAJU VENKATA SUDHEENDRA is Senior Scientist at TCS Research. He has a Ph.D. from IIT Kanpur in chemical engineering. He has more than 15 years of experience in Process modeling and simulation, Nanoparticle synthesis and growth, Ultrafine grinding, Functional nanofibers, Energy storage materials, CFD and DEM approaches for process modeling and drug delivery systems**.**

CHIRMULE NARENDRA, Immunologist – 3-decade-Drug-Development Experience – play the Flute Narendra Chirmule is a co-founder of SymphonyTech Biologics, a data analytics company focused on engineering solutions for biology. He currently teaches drug development at UPenn, and Indian Institute of Technology, Mumbai and Delhi. As former Head of R&D at Biocon (Bangalore), and in leadership positions at Amgen (Thousand Oaks, CA) and Merck Vaccines (West Point, PA), he has contributed to the clinical development of vaccines, biologics, and cell-and-gene therapies. During his academic career, he has worked on the development of a leprosy vaccine, the pathogenesis of AIDS (Cornell, New York, NY), and gene therapy for several rare diseases (UPenn, Philadelphia, PA). Dr Chirmule is on the NIH advisory committee for HIV vaccines. He is a TEDx speaker and published a book "Good Genes Gone Bad" by Penguin Press, both of which describe lessons learned from colossal failures in drug development.

GANDHI SONIA is DGM & Head, Regulatory Affairs and Policy Advocacy at BIRAC. She has been instrumental in establishing a unique single window platform "FIRST Hub" of key government bodies including CDSCO, DBT, BIS, NIB, ICMR, GeM and FSSAI for regulatory facilitation of bio startups. This platform has successfully addressed 1000+ queries of innovators. Her latest initiative "REFINE" builds on the success of the FIRST Hub and further refine product or technology-specific queries and assist startups with regulatory documentation and licensing requirements. She has extensive experience in the techno-commercial evaluation and due diligence of innovative biotech projects and audited more than 100 Indian life sciences companies. She has conceptualized and implemented many national and international programs in collaboration with organizations like WHO, World bank, IKP, USAID, ICMR, MeitY, THSTI, etc. Prior to joining BIRAC, she was managing the quality assurance of Bio-pharmaceutical products at Reliance Life Sciences, Navi Mumbai, India. She has participated as a delegate and speaker in various national and international workshops. By qualification, she is a certified quality management professional and holds double master's degrees in biotechnology and quality by BITS Pilani and is a research scholar from IIT -Delhi. Her research interests include pricing mechanisms for biologics, health economics, price control, and the affordability of biosimilars in developing nations.

GOMES JAMES received his bachelor's degree in chemical engineering from Jadavpur University and M.S. and Ph.D. from Tulane University, New Orleans, USA. As a graduate student at Tulane, he received several awards including the prestigious Sigma Xi research award. He worked as Senior Process Engineer for Process Services Inc., Baton Rouge and as Executive Engineer for L&T, Powai, Mumbai, before joining IIT Delhi. His current research interest is in Systems and Network Biology. His group applied mathematical and computational methods to study disease networks, understand disease progression and determine new drug targets, followed by directed experiments. His group is interested in neurodegenerative diseases, virus-host interaction networks and malaria. The results of his work on Angiogenin give a cohesive and comprehensive picture of the molecular origins of functional loss of all ALS associated ANG mutants. His lab recently created NeuroDNet, a database with interactive tools that enables the creation of interaction networks for neurodegenerative diseases under one portal for interrogation and analyses. It enables the construction and analysis of neurodegenerative diseases through protein interaction networks, regulatory networks and Boolean networks.

GOWTHAM YOGENDER KUMAR is a bioprocess engineer with over a decade of experience in cell culture process development and technology transfer to GMP manufacturing facilities. With a robust background in mammalian cell culture operations, he has successfully managed projects across various scales, from micro-scale to pilot-scale bioreactors. His expertise spans multiple product modalities, including monoclonal antibodies and gene therapy viral vectors. Currently, as a Principal Scientist at Asklepios Biopharmaceuticals Inc. (a Bayer AG subsidiary), Yogender leads upstream process development for several clinical gene therapy programs and supports innovative new technology initiatives for productivity improvements and ensuring robust manufacturing processes. He has a proven track record of optimizing clinical manufacturing processes and mentoring teams to enhance professional growth. Yogender holds a Ph.D. in Bioengineering from Clemson University, where he researched the transcriptome of CHO cell lines. As an author of multiple patents and publications, he continues to contribute to advancements in bioprocessing and cell culture methodologies.

GOYAL RAJAT is Country Director at IAVI, where he oversees IAVI's strategic direction in India. He is a global expert in biopharmaceutical innovation who has catalyzed high-end R&D programs with the Government of India, international governments, global development agencies, and industry leaders to accelerate integrated discovery and enable equitable access for innovative biomedical products in LMICs. He has been working in the fields of cancer, HIV, vaccine R&D, and public health for more than 30 years.

GUPTA Y K, M.B.B.S (1974), M.D (Pharmacology, 1979) from King Georges Medical College, Lucknow, is currently the President at AIIMS Jammu and AIIMS Bhopal, along with being the Chief Medical Officer at VaidyaRx & SiCureMi Healthcare Technologies Pvt. Ltd., and the Principal Advisor (Projects) at THSTI Delhi. He has been the Head at the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi. He earlier served as Sub Dean, AIIMS (1996 - 2001) and as the Director at Indian Institute of Toxicology Research (IITR, CSIR), Lucknow from 2003 to 2005. Dr Gupta has also been the President of Society of Toxicology, India and the Dean at Indian Society for Rational Pharmacotherapeutics. Ha has also served as the President of the Indian Pharmacological Society (2005- 2006).

HERWIG CHRISTOPH, a bioprocess engineer from RWTH Aachen and obtained a PhD in bioprocess identification at EPFL, Switzerland. From 2008 to 2023, he was full professor for biochemical engineering at the Vienna University of Technology. The research area focused on the development of data science methods for integrated and efficient bioprocess development along PAT and QbD principles for biopharmaceuticals. During his employment in various industries, such as with Lonza, he was deeply involved in the design and commissioning of large chemical and biopharmaceutical facilities. In 2013 he founded the company Exputec, which is now part of Körber Pharma, pioneering data science software solutions for the biopharma life cycle. Here, Christoph currently also acts as senior scientific advisor for Körber. In addition, Christoph is a serial entrepreneur, currently, as CPO at Fermify, he is focusing on the projection of precision fermentation on the commercialization of vegan cheese.

JAIN NITIN KUMAR, Secretary of The Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology (DBT), is a prominent figure in advancing biotechnology and ensuring regulatory and biosafety oversight for genetically engineered organisms. With expertise in molecular biology and biopharmaceutical development, he bridges research and practical applications to address critical challenges in healthcare, agriculture, and sustainability. Dr. Jain plays a pivotal role in fostering collaborations between academia, industry, and government, shaping national programs, and promoting interdisciplinary research. As a mentor and leader, he is dedicated to nurturing future scientists and strengthening India's global presence in biotechnology.

KADAM SANDIP is a biopharmaceutical process development and technical support specialist with over 10+ years' experience. I am a techno-commercial professional with a Doctor of Philosophy (Ph.D.-Tech, Bioprocess technology) and a Master of Technology (MTech- Bioprocess technology) degree focused on downstream processing of small and large molecules from Institute of Chemical Technology (ICT, formerly known as UDCT, Mumbai). Currently, I work with Thermo Fisher Scientific, as a product specialist for Purification. Providing strategic and technical guidance related to downstream process development for recombinant proteins, biosimilars, vaccines and CGT customer (Viral vector). Expertise in the downstream process development including early-stage and late-stage products development. Also, he has wide experience of handling the advanced and continuous process purification platforms including Simulated Moving Bed Chromatography (SMBC), True moving bed (TMB), fluidized moving bed etc. Prior, I was a part of Bio-Rad Laboratories (Product Specialist- Proteomics) and USV Pvt. Ltd (R&D). I have presented the posters and delivered the talks at several national and international conferences. I have received the awards and recognized for the outstanding performance on several occasions, including Fellowships from Department of biotechnology (DBT), Government of India for master and doctoral Studies.

LEE E. K. is a Professor Emeritus at the Department of Bionano Engineering of Hanyang University-ERICA, Korea. He obtained his B.S. degree from Hanyang University, Korea in 1975 and a Ph.D. from Drexel University, Philadelphia, PA, USA in 1985, both in Chemical Engineering. From January 1985 through July 1992, he worked for Miles Laboratories/Bayer and Pitman-Moore/Amgen in the US in the field of recombinant proteins processing technology and protein structure-function analyses. Since his return to Korea in 1992 as a Professor of Chemical Engineering at Hanyang University at Ansan, he has been active in the R&D activities focusing on applying biochemical engineering principles to the development of protein biopharmaceutics and analyses of protein interactions. Lee has published more than 60 SCI-grade original research articles as a corresponding author and has given numerous invited presentations at various international conferences. He is a member of the National Academy of Engineering in Korea and has served as a scientific and technical consultant to the Korean government and several biopharmaceutical industries globally. After the retirement in March 2018, he co-founded a bio startup, Immunoforge, Ltd., and works as a VP and CTO leading the MSAT and CMC team to develop long-acting therapeutic biobetters as orphan drugs. Besides, he consults biotech

companies on antibody CDMO establishment, and cell culture media and chromatography resin development.

MALIYIL JOBIN is a Bioprocess Application Specialist at 3M India for the Purification and Filtration Business. His responsibilities are focused on introducing and evaluating innovative purification technologies for the biopharmaceutical industry. Jobin's early experience has been as senior bioprocess engineer and worked extensively on qualification of bioprocess systems needed for recombinant proteins and vaccines. He is based out of Bangalore and holds a Master of Science in Biochemical Engineering from University College London.

MALLELA KRISHNA M.G. is currently a Professor in the Center for Pharmaceutical Biotechnology, and the Associate Director of the Pharmaceutical Sciences graduate program at the University of Colorado Anschutz Medical Campus. University of Colorado Center for Pharmaceutical Biotechnology is one of the first such centers established in the US in 1997 and has been supported by the US National Institutes of Health, US Department of Defense, FDA, NIIMBL, and the pharmaceutical industry. Mallela obtained his PhD from the Tata Institute of Fundamental Research in 1999, did his postdoctoral research in the University of Pennsylvania School of Medicine, and worked as a faculty at the University of Pennsylvania before joining the University of Colorado in 2007. Mallela is an expert in characterizing the biophysics, structure, stability, aggregation, and immunogenicity of protein therapeutics, biosimilars, and vaccines, using various techniques that include circular dichroism, fluorescence, multi-dimensional NMR, IR/Raman, differential scanning calorimetry, isothermal titration calorimetry, mass spectrometry, analytical ultracentrifugation, flow imaging, nanoparticle tracking, resonance mass measurement, mice models and whole human blood assays for immunogenicity. Mallela frequently collaborates with pharmaceutical companies on research projects, serves as a consultant in developing protein formulations and biosimilars, and his lab performs fee-for-service work for pharmaceutical companies. Mallela has published many peer-reviewed manuscripts in the field of pharmaceutical biotechnology, with many of them highlighted by the Journal of Pharmaceutical Sciences and the Pharmaceutical Research Journal as the most novel and most significant. He is also a frequently invited speaker at various conferences, Universities, and pharmaceutical companies in the US, and is a frequent organizer at the American Chemical Society Biochemical Technology (BIOT) annual meetings, biannual Colorado protein stability conferences, and annual International Symposia on Higher Order Structure of Protein Therapeutics. He serves on the editorial boards of the Journal of Pharmaceutical Sciences, Nature Scientific Reports, and PLoS One, and as a guest editor for a special issue of Pharmaceutical Research journal on protein biologics and biosimilars.

MEHTA KRUNAL received his bachelor's degree in chemical technology from Institute of Chemical Technology (ICT) Mumbai, and his Doctoral degree in Chemical and Biological Engineering from Rensselaer Polytechnic Institute, Troy, NY. He has over 10 years of experience in the field of bioprocessing with the primary focus on purification process development. At Amgen, Krunal has worked on commercial advancement of several late-stage clinical programs spanning a wide range of biologics such as mAbs, Fc-fusion protein, Bispecific T-cell engager, among the innovator drugs, and supported biosimilars development. Exploring the industrialization aspects of membrane affinity chromatography, novel harvest technologies, are among the various innovative bioprocessing technologies that Krunal has worked on and presented externally. In his current role at Merck, he is the head of the Bio separations Sciences within the Bioprocess Drug Substance Commercialization group, supporting the commercialization of biologics, including supporting the integration and launch of an externally acquired asset.

MISHRA AVINASH, a prominent figure in computational biology, holds a PhD from the Indian Institute of Technology Delhi (IITD), where he specialized in protein structure prediction. Before pursuing his doctoral studies, he gained valuable experience in the pharmaceutical industry through his work with AstraZeneca's research and development wing. Avinash's academic journey was further enriched by his postdoctoral fellowship, during which he received the prestigious Indo-Australian Gold Fellowship, allowing him to conduct two years of impactful research at Griffith University, Australia. His entrepreneurial spirit led him to establish a startup that bridged computational techniques and biological research, earning recognition such as the Biotechnology Ignition Grant (BIG) from BIRAC and the Newton Innovator Award in London. Currently, as the CEO of Growdea Tech, Avinash leads a team dedicated to advancing drug discovery through computational biology, designing and developing an in-silico drug discovery platform powered by machine learning and artificial intelligence to enhance prediction accuracy and accelerate research. His numerous accolades include the Leader in Innovation Award (2013, Newton Fund, London), Power of Ideas Award (2012, DST), Top Five Business Pitch at the Royal Academy of Engineering (2013, London), Indo-Australian Gold Fellowship (2016, DBT), Leave a Nest Award (2016, Japan), and the Australian Alumni Award (2023, Australian Consulate). Additionally, he holds an Indian patent (201711030494) on polypeptide sequences and compositions. Avinash's journey exemplifies his unwavering commitment to innovation, excellence, and the transformative potential of computational biology in drug discovery.

MULE ABHISHEK holds a doctorate in Microbiology from the University of Mumbai, India. He joined Eppendorf Asia Pacific China in 2015 as a Senior In-field Application Specialist, where he provides application support, troubleshooting, and both theoretical and practical training in fermentation, scale-up, and bioreactor optimization. Abhishek has extensive experience cultivating microorganisms and cells at scales ranging from a few milliliters to thousands of Liters. Prior to joining Eppendorf, Abhishek worked as a Research Scientist at ICT Mumbai, where he was actively involved in scaling aerobic and anaerobic cultures to thousand-liter bioreactors. He also completed postdoctoral research at IIT Bombay, focusing on using bioreactors for effluent treatment.

NUPUR NEH is an Assistant Professor in the Department of Biotechnology & Biopharmaceuticals at the National Institute of Pharmaceutical Education and Research (NIPER)-Guwahati. Before joining NIPER-G in 2024, she worked as a Research Associate at NIPER-Hajipur and as a Postdoctoral Researcher at IIT Delhi. She obtained her Ph.D in Chemical Engineering from IIT Delhi and her Masters in Biochemical Engineering from IIT BHU. Her area of interest principally encompasses a broad domain of biotherapeutic characterization. The current research endeavours at NIPER-G are focused on exploring cutting-edge analytical technologies for the development of safe and efficacious biotherapeutics. The research embodies (1) an in-depth characterization of critical quality attributes in biotherapeutics and (2) an understanding of physical and chemical instabilities in biotherapeutics and formulation studies. Neh Nupur has authored 13 publications and book chapters in peer-reviewed journals. She has been a recipient of several awards, including the IIT BHU medal for obtaining 1st position in master's degree, the Summer Research Fellowship from the Indian Academy of Sciences, and the International Travel Award from DST and CSIR. She has also presented at several National and International Conferences related to biopharmaceutical characterization.

P.S. CHANDRANAND is reputable scientist, Technocrat, avid researcher, subject matter expert with over Three decades of experience with important government organisations and prominent private sector entities. Expertise in dealing with innovations, startups, accreditation and regulatory testing for Biotechnology derived Therapeutic / rDNA products) and In-Vitro Diagnostic products. Expert in emerging technologies in areas of AI, IoMT, LIMS, QMS, and Regulatory Intelligence. He served as program coordinator for Support Cell WHO-PQ & WHO-CC at National Institute of Biologicals (NIB), for In-vitro Diagnostics. He contributed significantly in establishing various QC laboratories at NIB,

preparation of SOPs, QC test method development and validations engaging cutting edge technologies, leading to generation of pharmacopoeia monographs, dossier review, post approval changes as per prevailing regulatory guidance's. Man with a core strength in QC & QA of In-vitro Diagnostics, Biologics, Design & Development of Reference standards, application of relevant Data standards, Biobanking/Biorepository, cGMP, GLP, LIMS-ALCOA++, Quality Management Systems (QMS) ISO - 17025, 13485, 15189, 14971, 17043, 17034 & 33, OHSAS & QHSE. Moreover, he Served as project lead for Artificial Intelligence based in-house Laboratory Information Management System (LIMS) development at NIB.

PATANKAR DHANANJAY is an independent biopharmaceutical professional and freelance consultant, and is associated with several companies, startups and academic institutions in advisory roles. Previously he was the head of the biologics divisions of Syngene and Intas Pharmaceuticals and was senior scientist at Wockhardt. He has been intimately involved in the growth of the Indian biopharmaceutical industry since its early days. Over his career, he led teams that developed India's first biosimilar therapeutic product (EPO), India's first biosimilar approved for marketing in Europe (Filgrastim), India's first EU-GMP certified biologics manufacturing facility (Intas), and India's first commercial contract manufacturing of a novel biologic for the US market (Syngene). He has served in various national committees and biotechnology industry bodies in India and was Biologics Expert Committee member at the US Pharmacopeia from 2011 till 2020. By education he is a Chemical Engineer with bachelor's degree from IIT Mumbai and Ph.D. from University of Utah in the US.

PATTANAYEK SUDIP K broad research interest is the structure and dynamic behavior of macro-molecules like proteins and polymers near surfaces. He has been working on various on the development of (i) Microneedle based drug delivery (ii)Materials for Sensor application (iii) Surface of Materials required for biopharmaceuticals, the packaging of foods, etc. He has made a significant contribution to the characterization of proteins' structure and their properties near solid surfaces

PRASAD SAI is the CTO for IoT and Digital Engineering at TCS based in Bangalore. Sai is a bachelor's in engineering from Bangalore University and a PG Diploma in Design Thinking & Innovation from Emeritus, Singapore. Sai has over 30 years of experience in working with various technologies in Digital Engineering and IoT. He is also skilled in product development and product management and has built products in different areas such as Life Sciences, Retail and Manufacturing. He has filed 3 patents related to Digital Twins for logistics, manufacturing, and process industries. His areas of interest include Design Thinking and fostering an innovative culture. He is also a registered Patent Agent at the Indian Patent Office

RAMTEKE MANOJKUMAR is currently an Associate Professor in the Department of Chemical Engineering, Indian Institute of Technology, New Delhi, India. He did his B. Tech. from Babasaheb Ambedkar Technological University, Lonere (Maharashtra), India, and both M. Tech. and Ph. D. from the Indian Institute of Technology, Kanpur, India. Thereafter, he worked as a scientist 1 at Institute of Chemical and Engineering Sciences, Singapore. His research areas include modeling and multi-objective optimization of industrial processes; scheduling, planning, and control of process operations; sustainable energy production; advanced metaheuristic algorithms (adaptations of GA, DE, PSO, SA); machine learning and novel computing methods (DNA computing and bioelectronics). He has published several research papers in these areas and has also authored/co-authored a book on optimization and several book chapters in edited books.

RATHORE ANURAG S. is an Institute Chair Professor at the Department of Chemical Engineering, Indian Institute of Technology, Delhi, India. He is also the Coordinator for the DBT COE for Biopharmaceutical Technology. His previous roles included management positions at Amgen Inc., Thousand Oaks, California, and Pharmacia Corp., St. Louis, Missouri. His areas of interest include process development, scale-up, technology transfer, process validation, biosimilars, continuous processing, medical image analysis, process analytical technology, and quality by design. He has authored more than 600 publications and presentations in these areas. He is presently serving as the Editor-in-Chief of The AAPS Journal and Associate Editor for the Journal of Chemical Technology and Biotechnology. He also serves on the Editorial Advisory Boards for Biotechnology Progress, Biotechnology Journal, Electrophoresis, BioPharma International, Journal of Chromatography B, Journal of Chromatography Open, Pharmaceutical Technology Europe, and Separation and Purification Reviews. Rathore has edited books titled Process Validation (2023), Preparative Chromatography for Separation of Proteins and Peptides (2017), Quality by Design for Biopharmaceuticals: Perspectives and Case Studies (2009), Elements of Biopharmaceutical Production (2007), Process Validation (2005), Electrokinetic Phenomena (2004), and Scale-up and Optimization in Preparative Chromatography (2003). He has a Ph.D. in Chemical Engineering from Yale University.

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S M VIGNESH completed the Master's in Sports Engineering (Gold Medalist) from Tamil Nadu Physical Education and Sports University, Chennai and Bachelor's in Aeronautical Engineering. He is also working on his PhD, focusing on Natural Ventilation for the indoor stadiums. His area of interest is on Flight & Sports Aerodynamics, Wind Engineering and Biomechanics. In CADFEM India, he is an Application Engineer helping customer to adapt the Ansys Fluid technologies for their product development and service.

SAHA RAJIB is the Richard L. and Carol S. McNeel associate professor and chair of the graduate program of the Department of Chemical Engineering at University of Nebraska-Lincoln. He got his BS in Chemical Engineering from Bangladesh University of Engineering & Technology and MS and PhD from the Department of Chemical Engineering at Penn State and did his postdoctoral training at the Department of Biology at Washington University in St. Louis. Currently, he leads the Systems and Synthetic Biology Laboratory at UNL that focuses on studying non-model microbes, microbial communities, plants, and human diseases. His research work is funded by NIH, NSF, USDA, Nebraska Corn Board, and Nebraska Energy Center. He has been awarded the NIH Outstanding Early Career Investigator Award (MIRA) and NSF CAREER grant. He is also the recipient of 2024 UNL Dean's Award for Excellence in Graduate Education, 2022 UNL College of Engineering Edgerton Innovation Award, and 2020 Penn State Early Career Alumni Recognition Award.

SANGITRAO SAMIR is Bachelor of Veterinary Science and Animal Husbandry, India, Master of Science in Biotechnology Australia, & Regulatory Affairs Certified RAPS, USA. He has 27 years of experience in Regulatory Affairs and Developmental Quality Assurance along with expertise in Biologics project management. He has keen interest in Regulatory reforms and policy shaping and has worked on many national and international task forces for regulatory reforms for Pharma and Biotech. He has worked with world-class biopharmaceutical companies Wockhardt, Intas Pharmaceuticals, DSM Biologics Canada, Zydus Lifesciences, and Roche Pharmaceuticals India. Currently Samir Sangitrao is Vice President and Head of Regulatory Affairs and R&D Quality Assurance - Biologics at Zydus Lifesciences Limited

SARKAR JAYATI hold a Bachelor of Chemical Engineering degree from Jadavpur University, Kolkata (2000), an M.Tech in Chemical Engineering from IIT Kanpur (2001), and a Ph.D. in Chemical Engineering from IIT Kanpur (2005), where my research focused on instabilities in thin soft elastic films, exploring adhesion, debonding, dewetting, and pattern formation at soft interfaces—a critical field for fabricating nano-meso scale materials. My research interests span Interfacial Science, Computational Fluid Dynamics, Nanotechnology, Nanoparticle Self-Assembly, Complex Fluids, Solid Mechanics, and Energy, including hydrogen production, storage, and transport. Post-PhD, I worked as a lead CFD scientist in an MNC and an incubation center at IIT Bombay, contributing to dispersed phase flow, multiphase flow, electrokinetic, and parallelization. I completed postdoctoral research in Lattice Boltzmann Modeling at the Max Planck Institute for Dynamics and Self Organization, Germany (2008), before joining IIT Delhi's Chemical Engineering Department, where I currently serve as a professor. I have taught a wide array of UG and PG courses, supervised 19 PhD students, and mentored numerous M.Tech, Dual Degree, and B.Tech students. My research has been supported by DST, ICMR, DBT, UQIDAR, and several FIRP projects. I have contributed to departmental committees, including UG and faculty search committees, and served as M.Tech and Dual Degree coordinator. I have received prestigious awards, including University Medals, Kusuma Trust Outstanding Young Faculty Fellowship (2008), Amar Dye-Chem Award for excellence in research (2012), Outstanding Scientist Award (2015), Bharat Vikas Award (2017), and the Indo-U.S. WISTEMM-Women Overseas Fellowship (2018). I serve as a member of the Editorial Board for *Scientific Reports* (Nature) and as an Associate Editor for *Frontiers*. My first guided PhD thesis won the Shah-Schulman Award (IIChE, 2014), and our work on bioelectrodes received the Best Paper award at IICHE-CHEMCON (2023). Additionally, one of my students won prizes at "IPHE-MNRE 2024" for a quiz competition and poster presentation.

SAVINO MARIA holds a Ph.D. in Cellular and Molecular Biology and a master's in business administration. With over 10 years of experience as a sales manager for international biotechnology companies, she joined Beckman Coulter Life Sciences after the acquisition of Labcyte Inc. in 2019. Since then, she has held positions in marketing and business development. Currently, Maria focuses on biomanufacturing driving activities and developing workflow solutions that demonstrate the value of Beckman products in this field. Beckman teams are making significant efforts to establish a comprehensive list of solutions for vaccine development and biotherapeutics. These include low-volume gene editing solutions, mRNA construct optimization, strain optimization, monoclonal generation from mammalian cell culture, microbial cultures, and many other laboratory solutions.

SAXENA NIKITA is an Assistant Professor at IIT Kharagpur, specializing in the control and automation of manufacturing processes, leveraging nearly six years of extensive research experience. Her work focuses on multivariate data analytics for process monitoring and control, advancing Indian industries toward Industry 4.0. She has developed centralized distributed control systems for therapeutic production, integrating data acquisition through PLCs and LAN or RS232 connections. Saxena has designed Cyber-Physical Systems (CPS) to optimize resource use and adaptability in manufacturing, utilizing advanced machine learning techniques like reinforcement learning and supporting vector regression. Her research also highlights the role of soft sensors in real-time control and modeling, addressing challenges in commercial manufacturing. An accomplished scholar with numerous publications, she has received the Innovation Pride Award (2022) from TCS and the National Postdoctoral Fellowship (2019). During the COVID-19 pandemic, her data-driven studies provided insights into population dynamics and pandemic management.

SHAH MIHIR is Application manager at Solaris Biotech with specialization in bioprocessing solutions related to bioreactors, fermenters, and filtration systems from small to large scale. He obtained his PhD degree in Bioprocess engineering from Technical University Delft, The Netherlands and master's in biotechnology from Indian Institute of Technology Madras. Prior to current role, he worked as Bioprocess scientist with Chr. Hansen (now Novonesis) in probiotics and human milk oligosaccharides production related projects. He also worked as Scientist in Commonwealth Scientific and Industrial research organization (CSIRO), Canberra, Australia in metabolic engineering project. His areas of interest include biomanufacturing, high throughput process development, scale up, and innovative solutions for bioprocess control and optimization.

SHEKHAWAT LALITA KANWAR joined as Assistant Professor in the Department of Chemical and Biochemical Engineering at IIT Patna in August 2023. She holds a bachelor's degree in chemical engineering from Dayananda Sagar College of Engineering, Bangalore and a master's degree in chemical engineering from Indian Institute of Science Bangalore. She has a Ph.D. in Chemical Engineering from Indian Institute of Technology Delhi under the supervisor of Anurag S. Rathore. She did her industrial postdoctoral research from Cytiva Sweden AB, Uppsala and joined the same organization at the post of Scientist in R & D. In Cytiva, she has been the mechanistic modelling expert applying modelling on customer relevant therapeutic protein purification challenges. She also gained industrial experience from Dr. Reddy's Laboratories Ltd. after her master's degree where she was working on the crystallization process development, optimization, and process scale-up of novel polymorphs of Active Pharmaceutical Ingredients (APIs). Her areas of interest include Bioprocessing and Bioseparation: Downstream processing of therapeutic proteins; Development and optimization of chromatographic purification of monoclonal and bispecific antibodies; Quality by design: Design of Experiments and High-throughput process development, Mechanistic modeling of chromatographic separation process, Process analytical Tools (PATs), Computational fluid dynamics (CFD). She has authored publications and presentations in these areas.

SHIRUMALLA RAJ K is currently working as Mission Director in National Biopharma Mission in Biotechnology Industry Research Assistance Council (BIRAC), New Delhi. He received his M Pharm from Jamia Hamdard, and PhD from BITS, Pilani. He has over 28 years' experience as a scientist, academician, administrator. He has worked with Indian and Japanese Pharmaceutical Companies (Daiichi Sankyo), focusing on drug discovery. He has worked on and led teams to identify eight clinical drug candidates – three of them reached Phase II clinical trials. Dr. Shirumalla's primary research focus has been - respiratory diseases and Oncology. In addition, he has worked on Inflammatory diseases like - Rheumatoid arthritis, SLE, Multiple sclerosis, etc. He also worked with GlaxoSmithKline (GSK) in a collaborative project to identify one development candidate, reaching Phase II Trials for COPD. He has experience in translation research and worked on identifying novel biomarkers and developing QSP modelling for respiratory diseases. He has extensive experience in herbal research and was head of the operation of an herbal-

based company. He has several publications in peer-reviewed journals and has 30 international patents to his credit.

SINGH SUMIT KUMAR is an Assistant Professor in the School of Biochemical Engineering at the Indian Institute of Technology (Banaras Hindu University) Varanasi. Before joining IIT BHU, he worked as a postdoctoral researcher at the University of Delaware and obtained his PhD degree in Chemical Engineering from IIT Delhi. His areas of interest principally encompass the broad domain of therapeutic protein characterization and protein engineering. The current research endeavors of his group at IIT BHU are focused on developing novel biotechnologies aimed at clinical translation based on understanding of the underlying disease pathobiology involving glycan interactions. The research embodies a two-fold approach: (a) Identification of glycan biomarkers that are specific to a particular disease state; (b) utilization of the chosen biomarkers to develop therapeutics using data-driven protein engineering approaches. Sumit has authored 20 publications and several presentations in analytical characterization and development of safe and efficacious protein-based therapeutics. He has also been a recipient of several awards at various conferences, including the Young Scientist in Bioprocessing Award at the 6th Bioprocessing India Conference. He also serves as a reviewer of several journals, including Journal of Chromatography B, Biotechnology Progress, Bioanalysis, and Engineering in Life Sciences.

SMITH GREGORY (GREG) is the Director of the India Office in the FDA's Office of Global Policy and Strategy (OGPS). His FDA career spans over 12+ years working as the director of CDER's Special Projects Staff in the Office of Executive Programs and as a regulatory project manager in CVM's Office of New Animal Drug Evaluation. He specialized in complex and mission-critical scientific, regulatory, legislative, and operational issues including user-fee negotiation, supply chain assessment, legislative implementation, organization-wide governance, and portfolio management. His professional experience includes project management of clinical trials, risk evaluation and mitigation strategies, post marketing, and surveillance initiatives for a global contract research organization (CRO). Mr. Smith is a certified project and portfolio management professional and graduated from the University of Maryland, College Park.

SRIVASTAVA PREETI obtained PhD from Department of Biochemical Engineering and Biotechnology, Indian Institute of Technology, Delhi in corynebacterial plasmid biology. She did postdoctoral research work in chromosome dynamics in *Vibrio cholerae* from Laboratory of Biochemistry and molecular biology, National Cancer Institute (NCI), National Institutes of Health (NIH), Bethesda, Maryland, USA. She has worked as Senior Scientist in Environmental Biotechnology Division, Indian Institute of Toxicology Research (CSIR), Lucknow before joining IIT Delhi in 2011. Currently, she is working as Professor, Department of Biochemical Engineering and Biotechnology, IIT Delhi. Her present research interest is in Bacterial genetics and Environmental Biotechnology. She has published several papers in Internationally reputed journals and proceedings of National and International conferences. She has been granted 3 patents and has filed three patent applications. She is the recipient of the prestigious Innovative Young Biotechnologist Award from Department of Biotechnology, Ministry of Science and technology, Government of India.

TYAGI VIVEK is a Senior Consultant in CCSEA, Ministry of Fisheries, Animal Husbandry and Dairying, Government of India. Tyagi is a Senior Consultant with the Committee for the Control and Supervision of Experiments on Animals (CCSEA) under the Department of Animal Husbandry and Dairying. Based in Shadipur, Delhi plays a key role in promoting ethical practices in animal experimentation and ensuring compliance with CCSEA guidelines.

UPPAL ANNU, Director, Scientific Affairs and Strategy, leads a team of global scientists positioned across USP regions to advance USPs scientific priorities. Under her leadership, scientific affairs play a pivotal role in strengthening stakeholder engagement, fostering collaborations, and driving impactful scientific initiatives. Additionally, Annu leads key initiatives including USP's Science & Quality Framework and Knowledge Hubs for Multi-Attribute Methods, reflecting her commitment to promote advancements in science. Previously, Annu served as the global lead for mass spectrometry-based biopharma applications at SCIEX, where she specialized in the physiochemical characterization and impurity profiling of biologics. Her expertise includes glycosylation analysis, MAM, native mode, and host cell protein analysis. She holds a Ph.D. in Biotechnology from Aligarh Muslim University, India and has authored numerous peer-reviewed manuscripts and book chapters. Annu also serves as faculty for the USP biologics education program on method development and validation.

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Department of BioTechnology, Government of India

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