



Centre of Excellence Biopharmaceutical Technology

Dec 2023
**CBT
COURSE SERIES
BROCHURE**

Commercial Manufacturing
Mechanistic Modelling
Cell Line Development
Biologics Development
Good Manufacturing Practices (GMP)
Capillary Electrophoresis (CE)
Glycan Analysis of Biotherapeutics
Bioprocessing
Good Clinical Practices (GCP) Validation & Monitoring of Large Scale Biotherapeutics
Data Analytics & Statistics Characterization of mAbs
DOE
Viral Safety
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Centre of Excellence
Biopharmaceutical Technology

Welcome to Centre of Excellence for Biopharmaceutical Technology

The Center 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:

Cell Engineering for Expression of Recombinant Proteins for the Biopharmaceutical Industry

Medium Optimization for Microbial and Mammalian Cell Culture

Scale Up and Scale Down Approaches for Upstream Process Development

Continuous Downstream Processing for Production of Biotherapeutics

Real-Time Process Monitoring and Control of Downstream Processes

Post-translational Modification Characterization of Biotherapeutics

Characterization of Higher Order Structure of Biopharmaceuticals

Chemometrics for Analytical Characterization and Comparability

Preparing Regulatory Filing for a Biosimilar Product in India

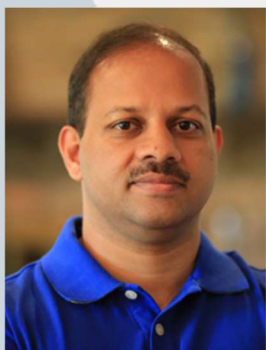
Preparing Regulatory Filing for a Biosimilar Product for FDA and EMA

Mastering DOE & QbD with JMP: Theory, Application, and Hands-On

Industry 4.0 in Biopharma Manufacturing

Data Analytics and Machine Learning in Bioprocessing Industry

Key Concepts of Drug Design, Clinical Trials and Regulatory Approval for Biopharmaceuticals



Prof. Anurag S Rathore
Coordinator, CBT, IIT Delhi



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

Registration Link: <https://forms.gle/Fh3sXpufwafBmZ3u5>

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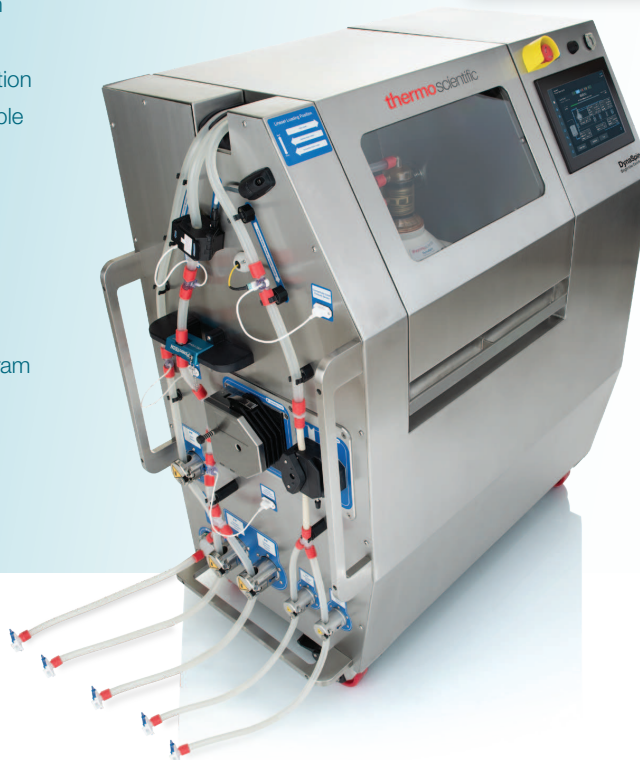
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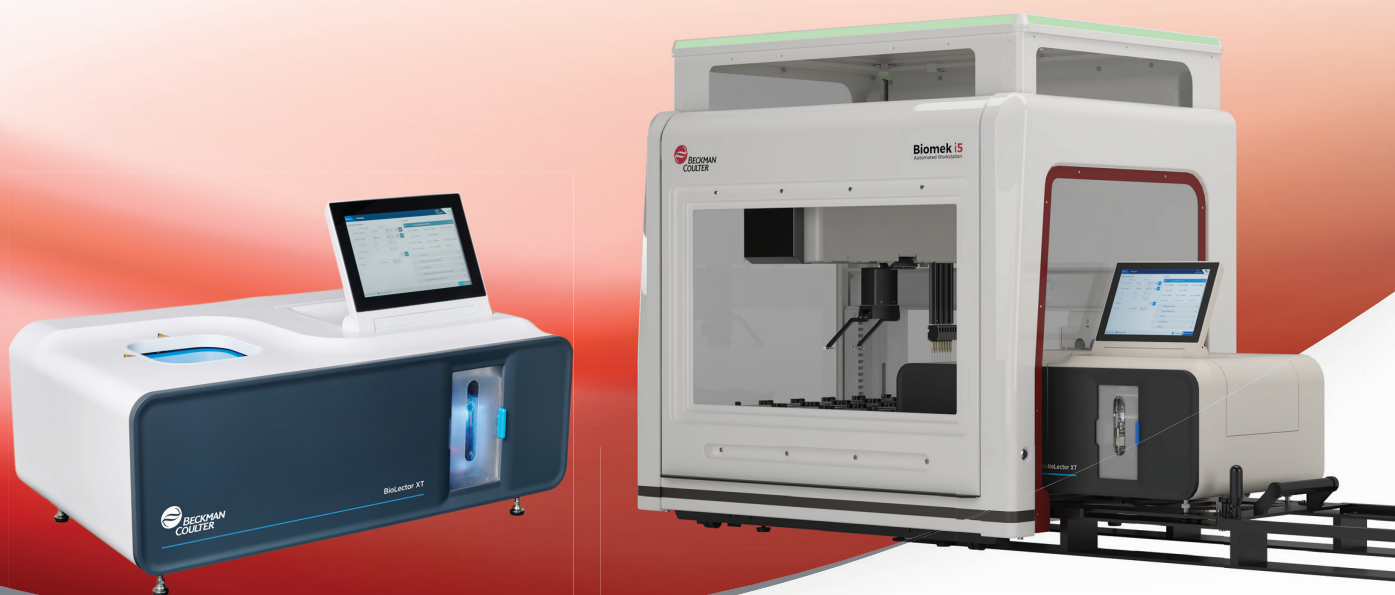




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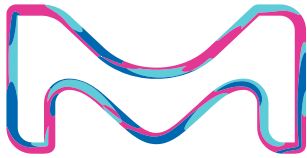
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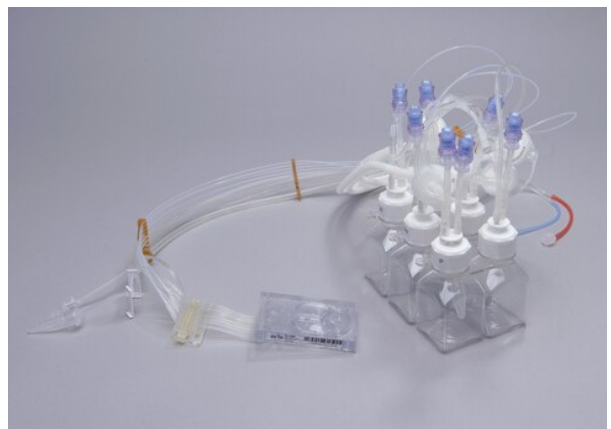
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- Reliable, high-quality product on demand
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For more details please contact
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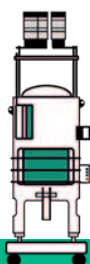
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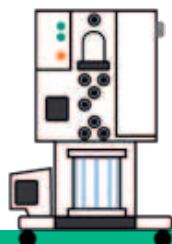
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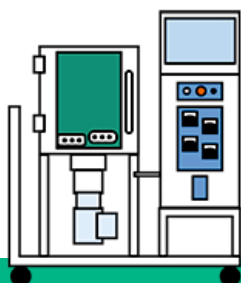
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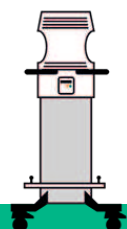
mAbs



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drug discovery**



Viral vectors



Cell therapy



**Training and
support**

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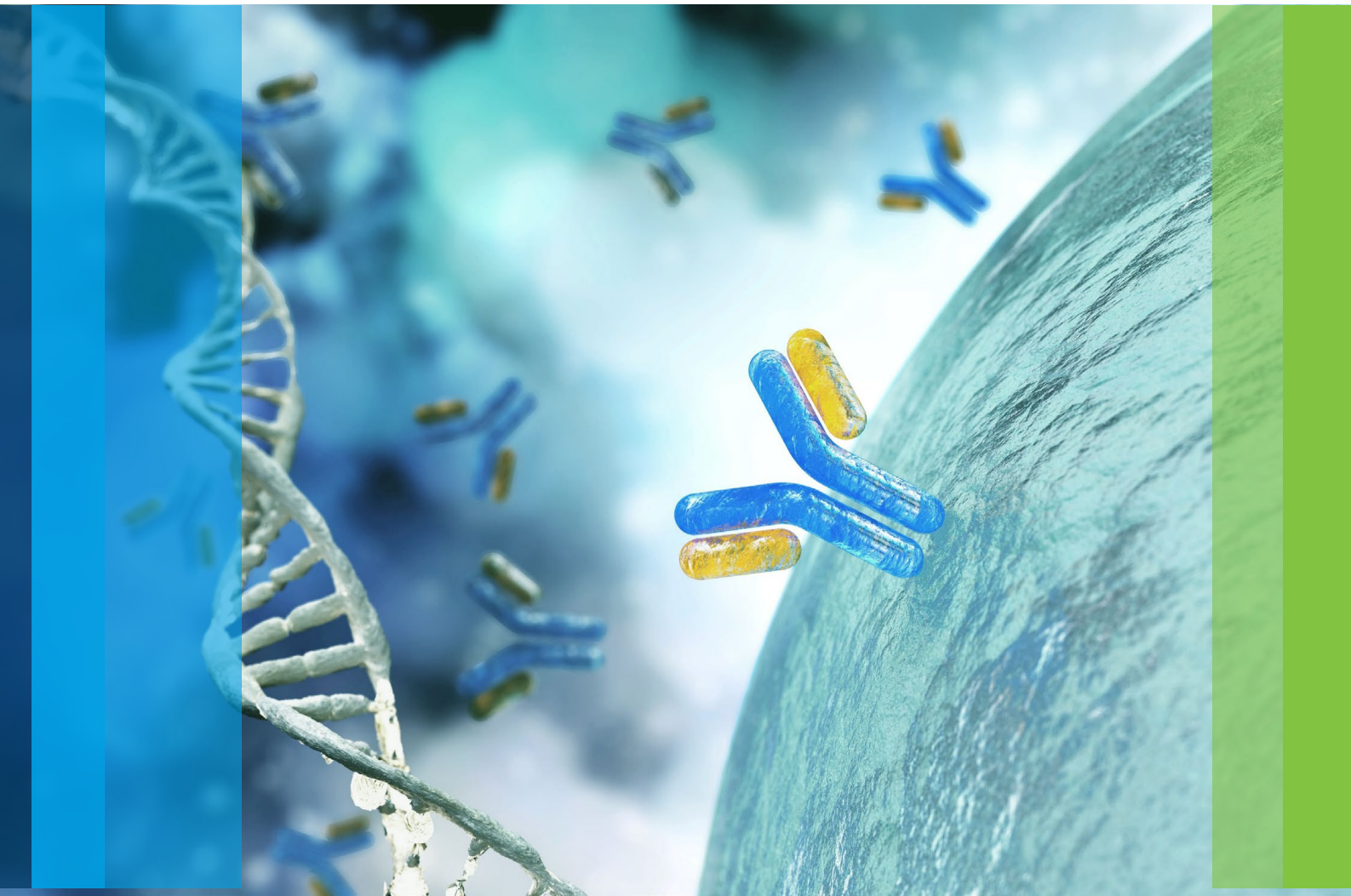
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Spent Media Analysis
Media Optimization

PROCESS

DEVELOPMENT

From Clone to Protein

SYSTEMATIC SCALE UP APPROACH

Scale I



Scale I :
High throughput
screening (10-15ml)

01 Accuracy by
Automization

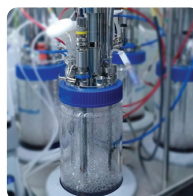
Scale II



Scale II :
Growth Factor
Optimization (50ml)

02 Top Down
Approach

Scale III



Scale III :
Lab scale bioreactors
(0.4L-1L)

03 Process
Optimization

Scale IV



Scale IV :
Complete Process
Optimization (10L)

04 Process
Validation

Scale V



Scale V :
In-situ Bioreactor
system (50L)

05 Pilot Scale
Plant

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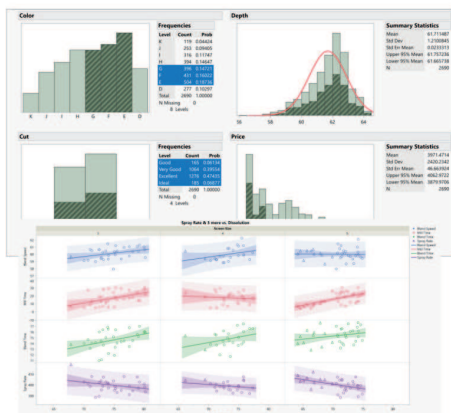
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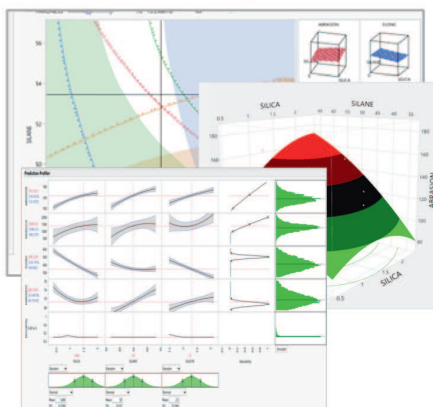
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JMP enables pharmaceutical processes and applications including Quality by Design (QbD), Design of Experiments (DOE), Data Visualization and Exploration, Chemometrics, Pharma Analytics and Machine Learning, Dissolution Testing, Pharmacokinetics, Enzyme Kinetics, Bioassays, and Regulatory Compliant Stability Testing.

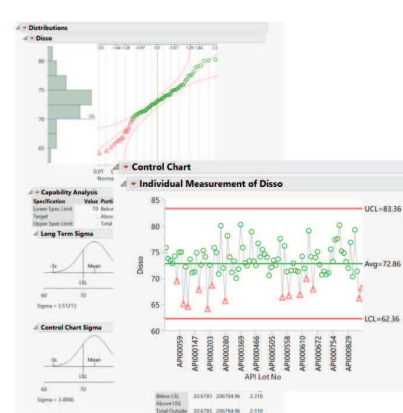
Data Visualization & Exploration



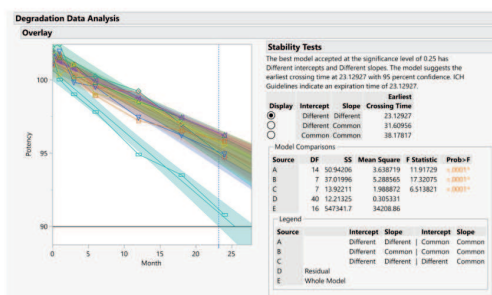
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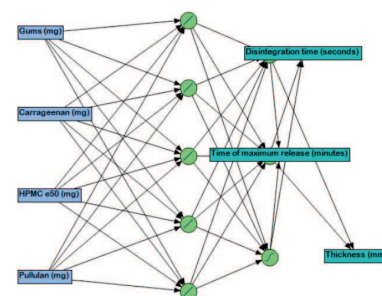
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Dissolution Testing



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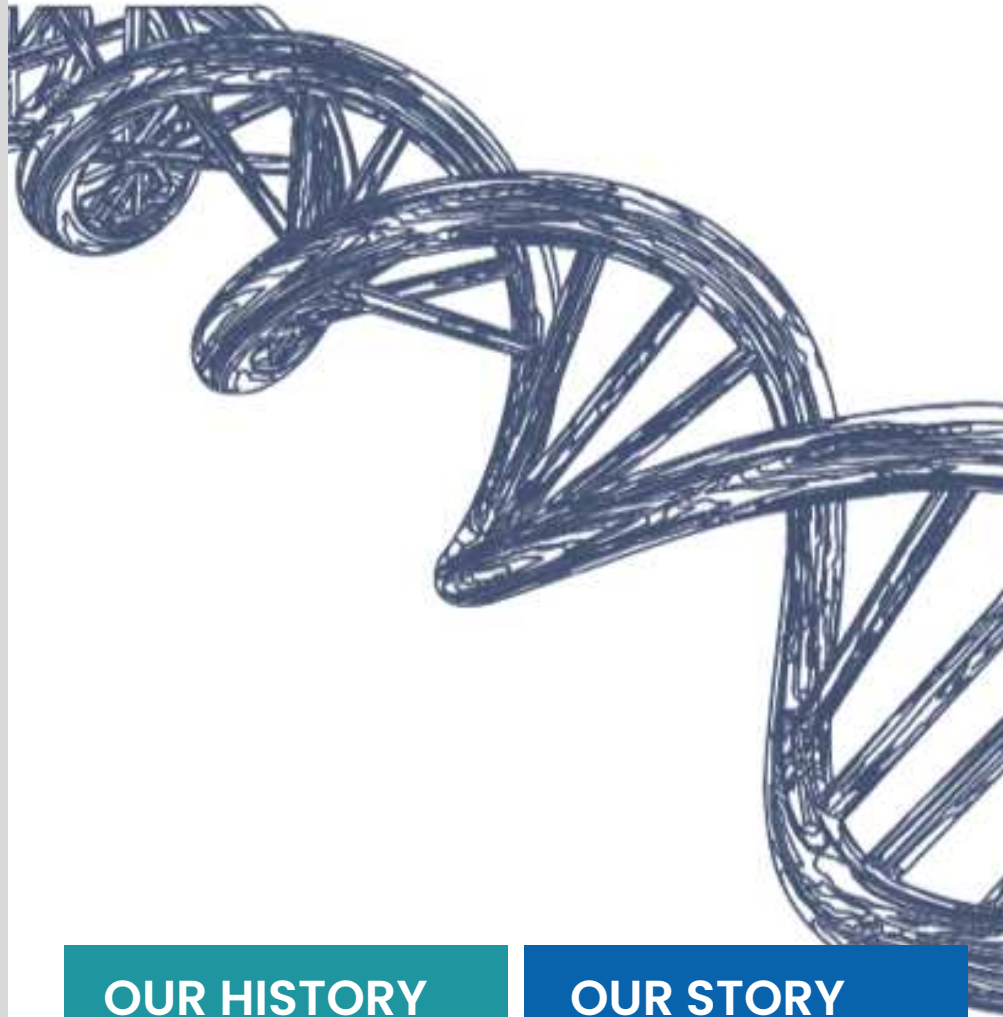


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- Proteomics
- Glycan Analysis

Speciality Reagents

- RNA Isolation & protecting Reagents
- Electrophoresis Reagents
- Cell Culture Reagents

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.

Here are the reasons why
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CBT Course Series 2023

11th December, 2023

All times are in Indian Standard Time (IST)



MODULE 1 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 of 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 audience will be able to gain deeper knowledge of techniques and learning strategies for upstream processing of biopharmaceutical development.

OUTLINE

08:30-09:00

Breakfast

09:00-09:45

Introduction to cell engineering and clone development in upstream processing (*Mark A. Blenner, University of Delaware, USA*)

09:45-10:45

Synthetic biology and systems biology approaches for biopharmaceutical production (*Mark A. Blenner, University of Delaware, USA*)

10:45-11:00

Tea Break

11:00-11:30

Upstream Process Intensification (*Abishek K, Merck*)

11:30-12:00

CRISPR/Cas9 cloning strategy for the production of humanized therapeutic proteins (*Venkateswara R. Naira, IIT Delhi*)

12:00-13:00

Impact of clone stability on biomanufacturing of therapeutic proteins (*Preeti Srivastava, IIT Delhi*)

13:00-14:00

Lunch

14:00-15:00

Data-driven cell line development and engineering (*Meiyappan Lakshmanan, IIT Madras*)

15:00-15:30

Tea Break

15:30-18:00

Industry Demo: Cellicon (cell retention device) / Biolector XT: Microbioreactors / NXTmix 50L Levitating Mixer for Media and Buffer preparation (*Merck / Beckmann Coulter / PharmNXT*)

18:30-20:00

Dinner

CBT Course Series 2023

12th December, 2023

All times are in Indian Standard Time (IST)



MODULE 2 **Description**

Medium Optimization for Microbial and Mammalian Cell Culture

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 micro-organisms 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

09:00-09:45

Introduction to early-stage upstream process development: Role of fermentation media (*Meiyappan Lakshmanan, IIT Madras*)

09:45-10:45

Computational model-driven design of upstream process and media (*Meiyappan Lakshmanan, IIT Madras*)

10:45-11:00

Tea Break

11:00-12:30

Recent advances and challenges in the fermentation media development (*Mark A. Blenner, University of Delaware, USA*)

12:30-13:00

Process and medium engineering for production of Fabs in microbial host systems (*Rucha S. Patil, IIT Delhi*)

13:00-14:00

Lunch

14:00-14:45

Virus-like particle (VLP) production *via* mammalian cell culture (*Abhilasha K Rani, IIT Delhi*)

14:45-15:00

Discussion + QA

15:00-15:30

Tea Break

15:30-18:00

Industry Demo: Cellicon (cell retention device) / Biolector XT: Microbioreactors / NXTmix 50L Levitating Mixer for Media and Buffer preparation (*Merck / Beckmann Coulter / PharmNXT*)

18:30-20:00

Dinner

CBT Course Series 2023

13th December, 2023

All times are in Indian Standard Time (IST)



Centre of Excellence
Biopharmaceutical Technology

MODULE 3 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 indispensable tool in biopharmaceutical process development which allows process developers and manufacturing associates to establish a range within which the process can be deemed to be optimal and in 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

09:00-09:45

Overview of scale-up and scale-down technologies in upstream process development (*Velu Mahalingam, Intas Pharmaceuticals*)

09:45-10:45

Challenges in biomanufacturing of AAV-based vaccine production (*Mark A. Blenner, University of Delaware, USA*)

10:45-11:00

Tea Break

11:00-12:00

Key considerations for upstream process scale-up and scale-down strategies (*Velu Mahalingam, Intas Pharmaceuticals*)

12:00-13:00

Monitoring and process control in bioreactor operations (*James Gomes, IIT Delhi*)

13:00-14:00

Lunch

14:00-14:30

Biolector XT | Microbioreactors: High Throughput Technology Platform in Upstream Processing (*Jagadish Bemmale, Beckman Coulter*)

14:30-15:15

Automated, Closed Loop Media and Buffer Preparation for Biologics Manufacturing using Innovative Single-Use Tech (*Sachin Joshi, PharmNXT*)

15:15-15:30

Tea Break

15:30-18:00

Industry Demo: Cellicon (cell retention device) / Biolector XT: Microbioreactors / NXTmix 50L Levitating Mixer for Media and Buffer preparation (*Merck / Beckmann Coulter / PharmNXT*)

18:30-20:00

Dinner

CBT Course Series 2023

14th December, 2023

All times are in Indian Standard Time (IST)



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Biopharmaceutical Technology

MODULE 4 Continuous Downstream Processing for Production of Biotherapeutics

Description This course series aims to highlight various aspects of the continuous processing of biotherapeutics molecules. The major focus will be on scale up and challenges in the implementation of continuous processing. Role of modelling and process analytical tools (PAT) in the context of continuous processing will also be elucidated.

OUTLINE

08:30-09:00

Breakfast

09:00-09:45

Continuous PCC and it's successful scale up operations (*Asis Singh, Cytiva*)

09:45-10:30

Introduction to continuous downstream processing

(*Alois Jungbauer, University of Natural Resources & Life Sciences, Austria*)

10:30-10:45

Tea Break

10:45-11:30

Integrated and controlled continuous processing of biotherapeutics

(*Anupa, IIT Delhi*)

11:30-12:30

Challenges in large scale preparative chromatography

(*Alois Jungbauer, University of Natural Resources & Life Sciences, Austria*)

12:30-13:00

Downstream processing for purification of VLPs

(*Lukas Gerstweiler, University of Adelaide, Australia*)

13:00-13:30

Lunch

13:30-14:15

Implementation of QbD in continuous downstream processing

(*Rahul Bhambure, CSIR-NCL*)

14:15-15:00

Mechanistic modelling in continuous downstream processing

(*Lalita Kanwar Shekhawat, IIT Patna*)

15:00-15:15

Discussion + QA

15:15-15:30

Tea Break

15:30-18:00

Demonstration of AKTA Avant (*Cytiva*)/ Demonstration of Automated Unit Operation (*ThermoFisher Scientific*)

18:30-20:00

Dinner

CBT Course Series 2023

15th December, 2023

All times are in Indian Standard Time (IST)



MODULE 5 Real-Time Process Monitoring and Control of Downstream Processes

Description This course aims to highlight aspects of real-time monitoring and control of in downstream processing of therapeutics. Aspects that will be covered include use of appropriate analyzers for real time monitoring of CPPs and CQAs, real time data analytics, and then finally real time control of processes. Case studies on various biotherapeutic modalities will be presented.

OUTLINE

08:30-09:00

Breakfast

09:00-09:45

Introduction to real-time process monitoring and control
(*Naveen G. Jesubalan, IIT Delhi*)

09:45-10:30

Real-time monitoring of CQAs in downstream processing of mAbs
(*Alois Jungbauer, University of Natural Resources & Life Sciences, Austria*)

10:30-10:45

Tea Break

10:45-11:30

Role of process monitoring and control in VLP production
(*Lukas Gerstweiler, University of Adelaide, Australia*)

11:30-12:15

Process control during production of Fabs (*Rahul Bhambure, CSIR-NCL*)

12:15-13:00

Process monitoring and data analytics for continuous processes
(*Nitika, IIT Delhi*)

13:00-13:45

Lunch

13:45-14:45

DynaSpin™ Single-Use Centrifuge-Simplified, Automated, Intensified processing (*Ramesh Vyasan, Thermofisher Scientific*)

14:45-15:15

Chemometrics and recent advances in prospects of DSP
(*Nikita Saxena, IIT Delhi*)

15:15-15:30

Tea Break

15:30-18:00

Demonstration of AKTA Avant (*Cytiva*)/ Demonstration of Automated Unit Operation (*Thermofisher Scientific*)

18:30-20:00

Dinner

CBT Course Series 2023

11th December, 2023

All times are in Indian Standard Time (IST)



MODULE 6 Post-translational Modification Characterization of Biotherapeutics

Description

Mass spectrometry (MS) stands out as a potent method that is extensively employed in the biopharmaceutical field for the purposes of identifying, quantifying, and comprehensively characterization of proteins. This versatile and prevalent analytical tool holds particular significance in the realm of biopharmaceutical product quality. It excels in tasks such as determining mass, unravelling the complexities of glycan structures, and pinpointing post-translational modifications in biotherapeutic proteins. The primary focus of this course is on delving into the realm of high-resolution analytical characterization and exploring the latest advancements that have emerged in recent years.

OUTLINE

08:30-09:00

Breakfast

09:00-09:45

Fundamentals of PTMs in biopharmaceuticals
(*Yonghyun (John) Kim, University of Alabama, USA*)

09:45-10:30

PTM characterization of biotherapeutics through MS
(*Yonghyun (John) Kim, University of Alabama, USA*)

10:30-10:45

Tea Break

10:45-11:15

N-glycan analysis of mAbs (*Saurabh Naagpal, Agilent*)

11:15-12:15

LC-MS Analysis of chemical-induced deamidation and oxidation of therapeutic mAbs (*Vadiraja B. Bhat, Agilent*)

12:15-12:45

Characterization of PTMs in mAbs using native mass spectrometry: case study
(*Sumil Kumar, IIT Delhi*)

12:45-13:00

Q&A

13:00-13:45

Lunch

13:45-14:30

Introduction to native mass spectrometry (*Sumit Singh, IIT BHU*)

14:30-15:00

PTM characterization of biotherapeutics through native MS
(*Sumit Singh, IIT BHU*)

15:00-15:15

Tea Break

15:15-18:00

Demo: Spectroscopy applications in biopharma (*Agilent Technologies*)

18:30-20:00

Dinner

CBT Course Series 2023

12th December, 2023

All times are in Indian Standard Time (IST)



Centre of Excellence
Biopharmaceutical Technology

MODULE 7 Characterization of Higher Order Structure of Biopharmaceuticals

Description

Higher order structure (HOS) of a protein is the collective term for secondary, tertiary, and quaternary structure. It is crucial to characterize the protein's HOS in order to comprehend its stability, folding, structure, and functional activity due to the complexity of protein therapeutics. For a complete understanding of the entire protein structure, HOS characterization should be carried out in conjunction with functional analysis and primary structure characterization. This course focuses on the application of spectroscopy analytical tools to study HOS of biotherapeutics.

OUTLINE

08:30-09:00

Breakfast

09:00-09:45

Fundamentals of HOS characterization

(Yonghyun (John) Kim, University of Alabama, USA)

09:45-10:30

Analytical tools for characterization of biopharmaceuticals

(Yonghyun (John) Kim, University of Alabama, USA)

10:30-10:45

Tea Break

10:45-11:30

Quality considerations: product and process related Impurity analysis.

(Annu Uppal, USP)

11:30-12:15

TEM for high order structure analysis of biotherapeutics

(Manidipa Banerjee, IIT Delhi)

12:15-12:45

FTIR for high order structure analysis of biotherapeutics

(Sudip Kumar Pattanayak, IIT Delhi)

12:45-13:00

Discussion + Q&A

13:00-13:45

Lunch

13:45-14:15

Case Study: High order structure analysis of biotherapeutics

(Deepika Sarin, IIT Delhi)

14:15-14:45

Case Study: Secondary structure analysis using FTIR spectroscopy

(Kunal Krishna, IIT Delhi)

14:45-15:15

High order structure analysis of mAbs charge variants: Case study

(Himanshu Malani, IIT Delhi)

15:15-15:30

Tea Break

15:30-18:00

Demo: Spectroscopy applications in biopharma *(Agilent Technologies)*

18:30-20:00

Dinner

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Centre of Excellence
Biopharmaceutical Technology

MODULE 8 **Description**

Chemometrics for Analytical Characterization and Comparability

This course aims to introduce and clarify chemometric concepts relevant to the analytical characterization and comparability of biopharmaceuticals and how to incorporate them in analytical development. This will be achieved via a sequence of lectures and case studies. Concepts discussed include biosimilarity exercise, critical quality attribute (CQA) comparability and orthogonality, spectroscopy and data analytics for biotherapeutic analysis, the audience will be able to explain what these concepts mean, the role they play in analytical characterization implementation and their relevant regulatory implications.

OUTLINE

08:30-09:00

Breakfast

09:00-09:45

The biosimilarity exercise: expectations and importance
(*Yonghyun (John) Kim, University of Alabama, USA*)

09:45-10:30

CQAs: comparability and orthogonality
(*Yonghyun (John) Kim, University of Alabama, USA*)

10:30-10:45

Tea Break

10:45-11:15

Biosimilarity scoring (*Srishti Joshi, IIT Delhi*)

11:45-12:15

Development and characterization of biosimilars (*Deepika Sarin, IIT Delhi*)

12:15-12:45

General: Data analytics for biotherapeutic analysis
(*Keerthiveena Balraj, IIT Delhi*)

12:45-13:00

Discussion + Q&A

13:00-13:45

Lunch

13:45-14:15

Case Study: NIR based analysis of aminoacids in cell culture
(*Shantanu Banerjee, IIT Delhi*)

14:15-14:45

Case Study: Raman-based chemometric analysis of biotherapeutics
(*Nitika, IIT Delhi*)

14:45-15:15

Case Study: Size heterogeneity analysis using DLS-ML
(*Anuj Shrivastava, IIT Delhi*)

15:15-15:30

Tea Break

15:30-18:00

Demo: Spectroscopy applications in biopharma (*Agilent Technologies*)

18:30-20:00

Dinner

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14th December, 2023

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MODULE 9 Preparing Regulatory Filing for a Biosimilar Product in India

Description Biologics are the fastest-growing class of medications. Biosimilars are therapeutic drugs that show extensive similarity to original biologic drugs. These biosimilar drugs are evaluated for approval based on the similarity data to the approved innovator drug. This course offers modules that provide in-depth knowledge about regulatory filing and also outlines the steps and challenges involved in filing biosimilars for regulatory approval in India according to CDSCO guidelines.

OUTLINE

08:30-09:00 Breakfast

09:00-09:40 Regulatory landscape of India and biosimilar application framework (*Samir Sangitrao, Zydus*)

09:40-10:20 Reference product selection, quality assessment, and characterization (*Samir Sangitrao, Zydus*)

10:20-10:30 Session Q & A

10:30-10:45 Tea Break

10:45-11:25 Manufacturing considerations: Host selection, upstream, and downstream process and control (*Samir Sangitrao, Zydus*)

11:25-12:10 Quality considerations: Analytical methods, product characterization, and specifications development (*Rahul Bhambure, CSIR-NCL*)

12:10-12:45 Quality and compliance considerations: Industry and regulatory perspective (*Samir Sangitrao, Zydus & Mamta Gautam-Basak, Bridge Bio*)

12:45-13:00 Session Q & A

13:00-13:45 Lunch

13:45-14:20 Pre-clinical studies: Data requirement, PK, PD and toxicological studies, animal model selection (*Narendra Chirmule, Symphony Technologies*)

14:20-15:00 Clinical studies: Data requirement, PK, PD and confirmatory safety and efficacy study, study waiver (*Sarika Deodhar, Biocon*)

15:00-15:15 Session Q & A

15:15-15:30 Tea Break

15:30-16:40 Market authorization- filing process and responses and pharmacovigilance plan (*Sarika Deodhar, Biocon*)

16:45-17:15 Preparing regulatory filing for a biosimilar product for CDSCO – through digital technology transfer (*Krishna A, Rockwell*)

17:15-18:00 Open Panel Discussion

18:30-20:00 Dinner

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15th December, 2023

All times are in Indian Standard Time (IST)



MODULE 10 Preparing Regulatory Filing for a Biosimilar Product for FDA and EMA

Description

Biosimilarity 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. To obtain approval, biosimilar manufacturers must conduct comprehensive studies that demonstrate the similarity of their product to the reference biologic. The goal is to establish that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety, purity, and potency. Hence, this course provides in-depth knowledge about regulatory filing and also outlines the steps and challenges involved in filing biosimilar for regulatory approval by US FDA and EMA guidelines.

OUTLINE

08:30-09:00

Breakfast

09:00-09:45

Regulatory landscape of biosimilarity: EMA, USFDA and India
(*Mamta Gautam-Basak, Bridge Bio*)

09:45-10:30

Biosimilar application framework and timelines (competent authorities, application forms) (*Mamta Gautam-Basak, Bridge Bio*)

10:30-10:45

Tea Break

10:45-11:25

Biosimilar product development strategy: India first and global next Vs. Global first and India next (*Dhananjay Patankar, Industry Expert*)

11:25-12:05

Manufacturing considerations: Product and process characterization
(*Dhananjay Patankar, Industry Expert*)

12:05-12:45

Quality and compliance considerations: Working with FDA and EMA
(*Mamta Gautam-Basak, Bridge Bio*)

12:45-13:00

Session Q & A

13:00-13:45

Lunch

13:45-14:20

Pre-clinical studies: Data requirement, animal model selection, non-clinical in vivo animal study waiver (*Narendra Chirmule, Symphony Technologies*)

14:20-15:00

Demonstrating clinical biosimilar comparability: PK, PD and clinical Safety and efficacy clinical trials (*Sarika Deodhar, Biocon*)

15:00-15:15

Session Q & A

15:15-15:30

Tea Break

15:30-16:40

Failures in regulatory filings: Lessons learned
(*Narendra Chirmule, Symphony Technologies*)

16:45-17:15

Pre-Approval Inspections, 483s and EIR (*Mamta Gautam-Basak, Bridge Bio*)

17:15-18:00

Open Panel Discussion

18:30-20:00

Dinner

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MODULE 11 Mastering DOE & QbD with JMP: Theory, Application, and Hands-On

Description

Design of Experiments (DOE) and Quality by Design (QbD) are powerful methodologies used in various industries, including pharmaceuticals, to systematically improve processes, products, and outcomes. The workshop's goal is to cultivate a strong grasp of the Quality by Design (QbD) approach, emphasizing regulatory compliance and the integrated workflow functionalities of JMP software. Attendees will be expertly led through risk assessment, experiment design, and process optimization stages, resulting in improved production process quality and efficiency.

OUTLINE

08:30-09:00

Breakfast

09:00-10:45

Introduction to DOE: Strategy of experimentation, terminologies in DOE. Screening designs: Factorial & fractional factorial experiments: Cases with hands-on exercises

10:45-11:00

Tea Break

11:00-12:45

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

14:00-15:30

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

15:30-15:45

Tea Break

15:45-17:45

Formulation/mixture designs, Mixture with process factors, Mixture with constraints: Cases with hands-on exercises

17:45-18:00

Resources for learning, Discussions and wrap up

18:30-20:00

Dinner

Workshop Facilitator: Muralidhara Anandamurthy, PhD | Global JMP Team

CBT Course Series 2023
11th and 12th December, 2023
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MODULE 12 Industry 4.0 in Biopharma Manufacturing

Description

A detailed learning module on implementing 4.0 in biopharmaceutical manufacturing will be presented. Biopharma 4.0 represents a transformative paradigm shift in the biopharmaceutical industry, integrating cutting-edge technologies into every facet of the drug development and manufacturing process. This revolutionary approach leverages the power of Industry 4.0, characterized by automation, data exchange, and artificial intelligence, to enhance efficiency, quality, and innovation. In this context, biopharmaceutical companies are adopting advanced analytics, Internet of Things (IoT), and machine learning to optimize processes, from drug discovery to production and beyond.

OUTLINE

11th Dec

Biopharma 4.0: Fundamentals and framework

08:30-09:00

Breakfast

09:00-09:45

Introduction: Biopharma Industry 4.0 (*Vinesh B. Yezhuvath, TCS*)

09:45-10:30

Next generation biomanufacturing (*Anurag S. Rathore, IIT Delhi*)

10:30-10:45

Tea Break

10:45-11:30

Digitalization of Biopharma Industry 4.0: Process development, manufacturing and quality assurance (*Shantanu Banerjee, IIT Delhi*)

11:30-12:15

Cyber physical systems (CPS) and cyber-physical production systems (CPPS): Concepts (*Nikita Saxena, IIT Delhi*)

12:15-13:00

Digital Twins (DT): Concepts (*Venkat Runkana, TCS*)

13:00-13:15

Discussion 1: QnA

13:15-14:15

Lunch

14:15-15:00

Digital Twins Industrial Applications and Challenges (*Venkat Runkana, TCS*)

15:00-15:45

Industrial Internet of Things (IIoT): Industry 4.0 framework (*Sai Prasad, TCS*)

15:45-16:15

Tea Break

16:15-17:00

Challenges and future prospects of moving towards Industry 4.0 and beyond (*Sai Prasad, TCS*)

17:00-18:00

Big data analytics framework for Industry 4.0 (*TCS*)

18:00-18:30

Discussion 2: QnA

18:30-20:00

Dinner

12th Dec	Enabling Biopharma 4.0: Case studies
08:30-09:00	Breakfast
09:00-09:45	Compliance and validation of Industry 4.0 (<i>TCS</i>)
09:45-10:30	Cyber security in Industry 4.0 (<i>Jitesh Vaishnav, TCS</i>)
10:30-10:45	Tea Break
10:45-11:30	Case study: CPS in Biopharma (<i>Nikita Saxena, IIT Delhi</i>)
11:30-12:15	Case study: Soft sensor application in integrated continuous manufacturing (<i>Venkata S. Buddhiraju, TCS</i>)
12:15-13:00	Case study: Multi objective optimization application (<i>Vishnu S. Masampally, TCS</i>)
13:00-13:15	Discussion 1: QnA
13:15-14:15	Lunch
14:15-15:00	Upstream processing case study: Enabling technologies for integrated continuous manufacturing (<i>Neelesh Gangwar, IIT Delhi</i>)
15:00-15:45	Downstream processing case study: Enabling technologies for integrated continuous manufacturing (<i>Anupa, IIT Delhi</i>)
15:45-16:00	Tea Break
16:00-16:45	DCS-driven continuous platform (<i>Naveen G. Jesubalan & Nitika, IIT Delhi</i>)
16:45-17:00	Discussion 2: QnA
17:00-18:30	Lab visit: Continuous downstream processing train
18:30-20:00	Dinner

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MODULE 13 Data Analytics and Machine Learning in Bioprocessing Industry

Description

Data analytics and machine learning has revolutionized sectors all over the world, and it has the potential to radically alter the field of biopharmaceutical technology. This dynamic field relies heavily on data-driven decision-making to optimize various facets of bioprocessing, encompassing everything from upstream cell cultivation to downstream purification processes. The wealth of data generated at each stage can be harnessed through data analytics, facilitating data collection, storage, and analysis to uncover critical insights. These insights empower process engineers to make real-time adjustments, reducing the risk of production discrepancies and ensuring product quality. The course offers hands-on modules on machine learning and deep learning techniques for bioprocessing.

OUTLINE

13th Dec

08:30-09:00

Explainable AI and its Application in Bioprocessing Industry

Breakfast

09:00-09:45

Data handling and introduction to artificial intelligence

(Hariprasad Kodamana, IIT Delhi)

09:45-10:30

Feature importance: Feature reduction and feature selection

(ManojKumar Ramteke, IIT Delhi)

10:30-10:45

Tea Break

10:45-11:45

Introduction to optimization techniques *(ManojKumar Ramteke, IIT Delhi)*

11:45-12:15

Explainable AI: LIME and SHAP *(ManojKumar Ramteke, IIT Delhi)*

12:15-13:00

Case study 1: Artificial intelligence and machine learning applications in biopharmaceutical manufacturing *(Nikita Saxena, IIT Delhi)*

13:00-14:00

Lunch

14:00-14:45

Case Study 2: Opportunities and challenges of machine learning in bioprocesses: Categorization from various perspectives and prospects for the future *(Mayank Garg, Biocon)*

14:45-15:15

Case study 3: AI/ML modeling applications in upstream and harvest unit operations *(Shantanu Banerjee, IIT Delhi)*

15:15-15:30

Tea Break

15:30-16:45

Python environment setup *(Keerthiveena Balraj, IIT Delhi)*

16:45-17:30

Hands-on session in explainable AI *(Keerthiveena Balraj, IIT Delhi)*

17:30-18:00

Discussion and Wrap-up

18:30-20:00

Dinner

14th Dec

08:30-09:00

09:00-09:45

09:45-10:30

10:30-10:45

10:45-11:30

11:30-12:15

12:15-13:00

13:00-13:45

13:45-14:30

14:30-15:00

15:00-15:15

15:30-16:45

16:45-17:30

17:30-18:00

18:30-20:00

Advanced Machine Learning in Bioprocessing

Breakfast

Statistical modeling and data processing (*Mayank Garg, Biocon*)

Introduction to deep learning and application in bioprocessing
(*Hariprasad Kodamana, IIT Delhi*)

Tea Break

Introduction to neural networks: DNN / CNN / RNN/ LSTM
(*Hariprasad Kodamana, IIT Delhi*)

Introduction to spectral data augmentation techniques
(*Keerthiveena Balraj, IIT Delhi*)

Case study 1: Machine learning application for identification and classification of subvisible particles in injectable formulations
(*Velu Mahalingam, Intas Pharmaceuticals*)

Lunch

Case study 2: Deep neural networks for prediction and control of permeability decline in single pass tangential flow ultrafiltration in continuous processing of monoclonal antibodies (*Naveen G. Jesubalan, IIT Delhi*)

Applications of advanced machine learning techniques in Bioprocessing
(*Sanjeet Patil, IIT Delhi*)

Tea Break

Python environment setup (*Sanjeet Patil, IIT Delhi*)

Hands-on session (*Sanjeet Patil, IIT Delhi*)

Discussion and Wrap-up

Dinner

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MODULE 14 Key Concepts of Drug Design, Clinical Trials and Regulatory Approval for Biopharmaceuticals

Description Regulatory approval is the cardinal necessity of all development and commercialization activities conducted in the biopharmaceutical industry. Global regulatory landscape has undergone major changes with respect to harmonization of technologies along with modifications in the requirements of Analytical Characterization, Preclinical, and Clinical Data. Biosimilar development relies heavily on analytical techniques to prove similarity necessitating the need for modified regulations. This proposed course aims to strengthen our regulators and the industry on some of the key aspects of biopharmaceutical product development and commercialization. The major focus of this proposed course relies on the Validation and Monitoring during Large Scale Manufacturing of Biotherapeutics, Good Manufacturing Practices (GMP), and Good Clinical Practices (GCP). The audience is expected to learn the key roles played by regulators and industries in the approval process.

OUTLINE

11th Dec

08:30-09:00

09:00-10:00

10:00-11:00

11:00-11:15

11:15-12:00

12:00-12:45

12:45-13:00

13:00-14:00

14:00-15:00

15:00-15:45

15:45-16:00

16:00-17:00

17:00-17:30

17:30-18:00

18:30-20:00

Basics of Drug Design

Breakfast

Introduction to drug development

(Narendra Chirmule, Symphony Technologies)

Workshop on drug development

(Narendra Chirmule, Symphony Technologies)

Tea Break

Introduction to process development

(Nikhil Kateja, Edna Biolabs/IIT Delhi)

DOE in process development *(Ravindra Khare, Symphony Technologies)*

Discussion + Q&A

Lunch Break

Introduction to early drug development & pharmacology

(Narendra Chirmule, Symphony Technologies)

Statistics for early drug development

(Ravindra Khare, Symphony Technologies)

Tea Break

Introduction to toxicology *(Narendra Chirmule, Symphony Technologies)*

Case Study of biologic regulations *(Himanshu Malani, IIT Delhi)*

Discussion + Q&A

Dinner

12th Dec

08:30-09:00

**Pre-clinical & Clinical Trial Phases I-IV Journey to Approval
Breakfast**

09:00-10:00

Manufacturing and quality of biopharmaceuticals for clinical trials
(*Narendra Chirmule, Symphony Technologies*)

10:00-11:00

Introduction to clinical trials (*Sarika Deodhar, Biocon*)

11:00-11:15

Tea Break

11:15-12:00

Statistical process control in manufacturing
(*Ravindra Khare, Symphony Technologies*)

12:00-12:45

Case study of biologic development
(*Narendra Chirmule, Symphony Technologies*)

12:45-13:00

Discussion + Q&A

13:00-14:00

Lunch Break

14:00-14:45

Statistical consideration in clinical trials
(*Ravindra Khare, Symphony Technologies*)

14:45-15:45

Introduction to pharmacovigilance (*Sarika Deodhar, Biocon*)

15:45-16:00

Tea Break

16:00-16:15

Case Study: Variability in Glycosylation of Biosimilars
(*Himanshu Malani, IIT Delhi*)

16:15-17:00

Regulatory overview of clinical process development
(*Narendra Chirmule, Symphony Technologies*)

17:00-17:30

Discussion + Q&A

18:30-20:00

Dinner

OUR SPEAKERS



ALOIS JUNGBAUER received his PhD in Food Technology and Biotechnology from BOKU. He is professor of Downstream Processing at the Institute of Bioprocess Science and Engineering at the University of Natural Resources. He is currently working in the field of bioprocess engineering of proteins, viruses and genetherapy vectors. He has published 390 papers on recombinant protein production, bioseparation and advanced materials for bioprocess engineering, 17 patents and 12 book contributions and a monograph entitled "Protein Chromatography, Process Development and Scale Up". He acts also as the vice president of the European Society of Biochemical Engineering Science.



ABISHEK K is a dedicated Biotechnologist with prior experience in facility design, qualification, process mapping & development, scale-up, and optimization of microbial and mammalian processes. As an expert at Merck, he specializes in delivering tailored solutions to clients for cell line selection, clone development, media screening and optimization. Abishek's academic background includes a Master's degree in Biotechnology, providing him with a solid foundation to drive innovation and achieve excellence in the field of biotechnology.



ANNU UPPAL is currently working as Director Scientific Affairs & Strategy at United States Pharmacopeia (USP), leading a global team of scientists responsible to drive and support organizational scientific priorities that advance the science of quality for medicines using USP's science and standards. She is also leading the USP's initiative of Knowledge hub for Multi Attribute Methods (MAM), scientific engagement activities and external collaborations. Before joining USP, she worked as a technical global lead for characterization and quantification of large biologics at SCIEX. She has experience in physiochemical characterization and impurity profiling of mAbs, peptides & other protein biotherapeutics. Her area of interest are glycosylation analysis, MAM, native mode and host cell protein analysis. She received her Ph.D. in Biotechnology from Aligarh Muslim University. Annu is the author of 30+ peer reviewed manuscripts and two book chapters. She is also faculty for USP biologics education program on method development and validation for biotherapeutics.



ANURAG S. RATHORE 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 Preparative Biochemistry and Biotechnology and Associate Editor for Journal of Chemical Technology and Biotechnology. He also serves on the Editorial Advisory Boards for Biotechnology Progress, Biotechnology Journal, Electrophoresis, BioPharm International, Journal of Chromatography B, Journal of Chromatography Open, Pharmaceutical Technology Europe, and Separation and Purification Reviews. Dr. Rathore has edited books titled 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.



ASIS SINGH has been with Cytiva for more than 4 years as application specialist for chromatography hardware and resin. He has been closely working with biopharma R&D and manufacturing companies, focused on Mab and recombinant biosimilar products, to provide chromatography resin and hardware solutions. Recently, started working as workflow specialist for Nucleic Acid Therapy of Genomic Medicine. Closely working with mRNA, Oligo and LNP customers across India to provide Cytiva solution and technologies in processes at early stage of the development and drive complete workflow for Nucleic Acids Therapy.



DHANANJAY PATANKAR is a Chemical Engineer with over 25 years' experience and has been intimately involved in the growth of the Indian biopharmaceutical industry. Most recently he was heading the Biologics CDMO business of Syngene International based in Bangalore, responsible for early and late stage development and GMP manufacturing of novel biologics for companies in US, Europe, India and elsewhere. Prior to Syngene, Dr. Patankar held leadership positions at Intas Biopharmaceuticals and the Biotech division of Wockhardt, and was responsible for the development and manufacturing of several biosimilars for the Indian and global markets, including India's first biosimilar approved for marketing in Europe and India's first EU-GMP certified biologics manufacturing facility. 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. Currently Dr. Patankar is an independent consultant supporting various aspects of biopharmaceutical development, manufacturing and business strategy.



HARIPRASAD KODAMANA is an associate professor in the Department of Chemical Engineering with a joint appointment in the Yardi School of Artificial Intelligence, IIT Delhi. His areas of interest include machine learning, Graphs, Optimization, Predictive control, Anomaly detection, and Sustainable systems. He has more than 60 international publications and a couple of patents to his credit.



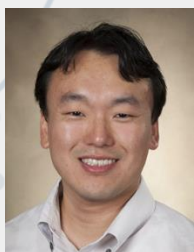
JAGADISH BENNALE is a Biotechnology Engineer, started his professional journey as a Lecturer at B.V.B C.E.T - Visvesvaraya Technological University (2006-2008), attended the Fifth Practical Summer Training in Biochemical Engineering and Biotechnology 2007 at IIT-Delhi and was trained on Design of Experiments in Upstream Bioprocessing. As a researcher he was introduced to practical aspects of Molecular Biology and Chromatography at Centre for Bioseparations Technology - VIT, Vellore with Prof. M A Vijayalakshmi (2008-2010), later joined The Biochemical Engineering Department - National Chemical Laboratory- Pune with Dr. Sanjay Nene and successfully executed a funded project "Integrated Bioprocess Engineering" | & "Koooperation International" initiative of Federal Ministry of Education and Research (BMBF)- Germany with the Department of Science and Technology- India (2010-2012). Embarked entrepreneurial journey and incubated at Venture Centre-Pune until 2014 later establishing complete factory setup at MIDC – Pune with core expertise in design & manufacturing special purpose bioprocess technology platforms. In 2018 Jagadish joined m2p-labs GmbH and introduced the first robotics enabled microfluidics based microbioreactor technology platform in India, upon acquisition of m2p-labs (Dec 2020) he is associated with Beckman Coulter Life Sciences – Danaher Corporation, India.



JAMES GOMES 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 the area of Systems and Network Biology. His group apply 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 gives 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.



JITESH VAISHNAV is Engineering Graduate in Instrumentation with 22+ years in Operational technology, Operational Technology Security & Industry 4.0. Jitesh heads the Operational Technology & Industrial 5G practice which is part of TCS's Digital Engineering business unit. He is MESA -Manufacturing Operation Management certified and Member of the International Society of Automation (ISA). He is also one of author for book "Manufacturing in the Future as a Cyber Physical System".



YONGHYUN (JOHN) KIM is an Associate Professor of Chemical and Biological Engineering at The University of Alabama. He received his B.S. in Chemical Engineering and B.A. in Biochemistry from Lafayette College (Easton, Pennsylvania, USA), his Ph.D. in Chemical and Biochemical Engineering from the University of Maryland Baltimore County (Baltimore, Maryland, USA), and his post-doctoral training in oncology from Samsung Biomedical Research Institute (Seoul, South Korea). He has over 65 peer-reviewed publications, and his cancer stem cell bioengineering research is funded by the U.S. National Science Foundation, the Department of Education, and the National Institutes of Health. He currently serves as chair-elect of the American Chemical Society Division of Biochemical Technology.



LALITA KANWAR SHEKHAWAT has recently joined as a faculty in the Department of Chemical and Biochemical Engineering. 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 Prof. 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 the 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.



KRISHNA has over seventeen years of experience in Industrial Control System engineering across different industry verticals and currently leading project delivery term for Life Science Industry Consultant at Rockwell.



LUKAS GERSTWEILER, a Lecturer at the School of Chemical Engineering, University of Adelaide, is dedicated to revolutionizing biopharmaceutical and vaccine manufacturing. His work aims to lower production costs and enhance drug accessibility. Dr. Gerstweiler leverages cutting-edge techniques including continuous manufacturing, model-based process optimization, and chromatography innovations. His expertise is driving advancements in pharmaceutical manufacturing for a more efficient and equitable future.



MAMTA GAUTAM-BASAK, alumna of IIT-Delhi (PhD, 1980), is a former senior FDA CMC policy advisor and recognized drug development expert with 24+ years of experience in global regulatory approval requirements (FDA/EMA/ICH/ISO) and FDA policy development process. She currently works as senior director, regulatory affairs CMC for BridgeBio, a publicly-traded biotechnology company designing transformative medicines for patients with rare genetic diseases and cancers with clear genetic drivers. Dr. Gautam-Basak has an extensive track record of advocating, articulating, and translating policy requirements, emerging trends, and regulatory requirements for drug manufacturers that mitigate risk and improve R&D efficiency across all phases of quality compliance through a nuanced understanding of FDA operations. She received her MSc and BSc in chemistry from University of Delhi, and her PhD in analytical chemistry from IIT-Delhi in 1980. Dr. Gautam-Basak also serves as a regulatory advisor to startups at entrepreneurship centers at Harvard University, University of California - Berkeley, and Carnegie Mellon University. She was also a former Entrepreneur in Residence at Columbia University in New York, an active angel investor and is passionate about advising and mentoring founders especially female entrepreneurs and scientists.



MANIDIPA BANERJEE 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 cryoelectron microscopy. Dr. 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.



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MARK A. BLENNER is the Thomas & Kipp Gutshall Career Development Professor of Chemical & Biomolecular Engineering at the University of Delaware. Prior to that, he was the McQueen Quattlebaum Associate Professor of Chemical and Biomolecular Engineering at Clemson University. He received his PhD in Chemical Engineering from Columbia University in 2009 and completed three years of postdoctoral training as an American Heart Association Postdoctoral Fellow and an NIH NRSA Postdoctoral Fellow at Harvard Medical School and Children's Hospital Boston. He has won numerous awards including the 2022 AIChE Food, Pharmaceutical, and Bioengineering Division Early Career Award, the 2022 Biochemical Engineering Journal Young Investigator Award, the 2021 ACS BIOT Young Investigator Award, and the 2019 Presidential Early Career Award for Scientists and Engineers (PECASE). His research is broadly focused on engineering biomolecular and cellular systems for the production of fuels, chemicals, enzymes, biopharmaceuticals and biosensors. He is interested in the use of synthetic biology in environments outside of the lab.



MAYANK GARG is currently working as Head of MSAT (mAbs DS) at Biocon Biologics Limited. With more than 21 years of experience in the Biotech industry, his areas of expertise are early & late-stage process development, tech-transfer, scale-up, regulatory approval, and data analytics for root cause investigation and process improvement. Prior to Biocon, he served in leadership role at Sanofi's Biologic unit at France where he successfully led many late-stage development projects of novel Mabs. He has also been associated with Shantha Biotechnics, Dr. Reddy's Laboratories, and Intas Pharmaceuticals. Mayank holds Masters of Technology degree in Biotechnology (major in bioprocess engineering) from Jadavpur University, Kolkata.



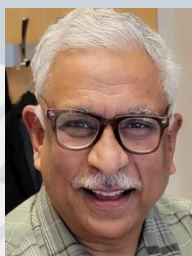
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RAVINDRA KHARE is the CEO and Director of Symphony Technologies Pvt Ltd. He is an acknowledged expert in Design, Manufacturing, Quality and applying Statistical analytics to Engineering and Life Sciences. He has papers published in international journals to his credit. He has worked as a visiting faculty and a member of the syllabus committee for the Board of Studies at VJTI Mumbai, Adjunct faculty and examiner for Graduate programs, and has served as the Chairman of the Industrial Advisory Board at VIT Pune.



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SACHIN JOSHI, a Bioprocess Technology M.Tech graduate from UDCT, Mumbai, possesses a 22-year career marked by close collaboration with industry scientists to develop processes now in commercial use. As Founder and Managing Director of PharmNXT Biotech, he oversees a cutting-edge PharmNXT Ekuse facility producing Single Use products for Biologics. Collaborating globally, Sachin, alongside PharmNXT Biotech's single-use line, partners with major global entities to deliver comprehensive end-to-end solutions worldwide. His significant tenure includes a role as Director of Process Engineering Biotech PASS, Asia at Pall, where he designed integrated manufacturing solutions. With expertise honed at GE Healthcare Lifesciences as General Manager, Bioprocess Division, Sachin is poised to share profound industry insights.



SAI PRASAD is the CTO for IoT and Digital Engineering at TCS based in Bangalore. Sai is a Bachelor 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 domains 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 interests include Design Thinking and fostering an innovation culture. He is also a registered Patent Agent at the Indian Patent Office.



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SAURABH NAAGPAL is working as Application Engineer in Centre of Excellence, Agilent technologies, Manesar. His area of interest is Biological Mass-spectrometry, Biopharma, Metabolomics. During his career-span of 20 years he has been involved in Lifesciences research at Indian Institute of Science (IISc) Bangalore and School of life-sciences (JNU, Delhi). Prior to joining Agilent, he was working as Scientist-Proteomics in Pall Life-sciences, Bangalore. He has authored 12 articles in reputed peer reviewed journals of and has presented several posters at international conferences (HUPO congress, Pittcon, AOHUPO, ASMS). He is an affiliate member of Human Proteome Organization (HUPO) and has been an invited speaker to several symposia and workshops. He enjoys creating awareness about Mass spectrometry among Biologists and training them on workflows.



SUDIP K. PATTANAYEK is a Professor in Department of Chemical Engineering at the Indian Institute of Technology Delhi. His 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 bio-pharmaceuticals, the packaging of foods, etc. He has made a significant contribution to the characterization of proteins' structure and their properties near solid surfaces.



SUMIT KUMAR SINGH 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 broad domain of therapeutic protein characterization and protein engineering. The current research endeavours 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 the area of 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.



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VELU MAHALINGAM is the Associate Vice President and Head of Process Science at Intas Pharmaceuticals Limited, Biopharma Division. With over 15 years of experience, he specializes in biopharmaceutical process development, scale-up, and validation across diverse categories such as monoclonal antibodies (mAbs), antibody-drug conjugates (ADCs), peptides, cytokines, and bispecific antibodies. Dr. Velu has provided technical and strategic leadership in global biosimilar projects, conducted technical due diligence, and led new product introductions. He holds a master's degree in chemical engineering and a Ph.D. in Bioprocess Engineering, making him a distinguished leader in large-scale biologics manufacturing.



VENKAT RUNKANA is Chief Scientist at TCS Research and leads the program on Research and Innovation for Manufacturing and Engineering. He is a chemical engineer by education and holds a Ph.D. from Columbia University. He has more than 32 years of experience in process modeling, simulation and optimization, advanced data analytics and digital twins, process development, scale-up and design, nanomaterials, and drug delivery systems.



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VINESH BALAKRISHNAN YEZHUVATH is part of the Strategic Capability Group within Life Sciences and Healthcare and is enabling customer in their business and IT transformation journey in areas of Manufacturing, Supply Chain, Quality and Regulatory. through transformation theme-based point of view, consulting, building assets, and driving business & growth. Vinesh comes with 31+ years of experience Pharma industry experience, large transformation programs, value engineering, digital transformation, advisory and innovation. Passionate and knowledge associate, who always eager to learn and contribute. He is also the co-principal investigator on the digitization of the Continuous Biopharma Manufacturing initiative, an academia. He combines process orientation and analytical abilities with an in-depth understanding of technology to develop IT solutions that drive productivity, efficiency, and digital maturity.



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