Centre of Excellence

Biopharmaceutical Technology

Dec 2022

CBT COURSE SERIES BROCHURE

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

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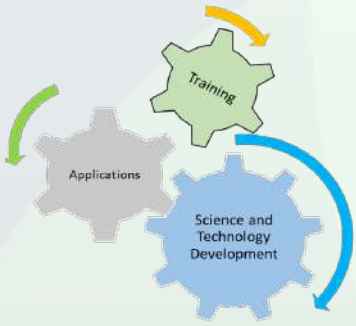
Welcome to Centre of Excellence for Biopharmaceutical Technology!!

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 of scientific and technology 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:

QbD and PAT Implementation for the Pharmaceutical Industry

Design of Experiments: Concepts and Case Studies

Multi-attribute Methods for CQA monitoring

Recent Advances in Filtration and Membrane Chromatography

Stability of Pharmaceutical Products

Mammalian Cell Culture based Production of Biotherapeutics

Drug Development and Risk Management: Regulatory Perspectives

Multivariate Data Analysis for Bioprocessing Data: Concepts and Case Studies

Mass Spec: A Powerful Tool in Biopharmaceutical Analysis

Chromatography Development for Biotherapeutics

Microbial Fermentation Based Production of Biotherapeutics

AI/ML for Bioprocessing

Prof. Anurag S Rathore
Coordinator, CBT, IIT Delhi

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

Registration Link: https://lnkd.in/duUdWVvv

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CBT Course Series 2022

12th and 13th December, 2022

All times are in Indian Standard Time (IST)

Prof. Anurag S. Rathore- Coordinator, CBT, IIT Delhi, India, and The National Institute for Pharmaceutical Technology & Education (NIPTE)

Prof. Carl Anderson–The National Institute for Pharmaceutical Technology & Education (NIPTE) and Duquesne University, USA

MODULE I–QbD and PAT Implementation for the Pharmaceutical Industry

Description: This course aims to clarify the key concepts that interplay in defining and implementing QbD and PAT towards development and manufacturing of biotech products. This will be achieved via a sequence of lectures and group work. Concepts discussed include: Critical Quality Attributes (CQA), Design Space, Risk Assessment, Process Characterization, Process Analytical Technology, Scale-up, and Technology Transfer. At the end of the course, the audience will be able to explain what these concepts mean, the role they play in QbD/PAT implementation and the interplays amongst them.

Outline:

12th Dec **QbD and PAT – Foundation (Part-I)**

08.30-09.00 : Breakfast
09.00-10.00 : Introduction to QbD, CQA and TPP (Anurag Rathore, IITD)
10.00-10.30 : Introduction to Process Analytical Technology (PAT) (Anurag Rathore, IITD)
10.30-10.45 : Discussion on QbD and PAT (Anurag Rathore, IITD)
10.45-11.00 : Tea Break
11.00-11.45 : Introduction to Multivariate Data Analysis (MVDA) (Anurag Rathore, IITD)
11.45-12.30 : Quality Risk Management (QRM) (Anurag Rathore, IITD)
12.30-13.00 : Discussion on PAT and MVDA (Anurag Rathore, IITD)
13.00-14.00 : Lunch Break

12th Dec **Analytical Tools for PAT – Pharmaceuticals (Part-I)**

14.00-15.00 : Introduction and Survey of Analytical Tools for PAT on Small Molecules (Carl Anderson, Duquesne University, USA)
15.00-15.30 : NIR Spectroscopy (Carl Anderson, Duquesne University, USA)
15.30-16.00 : Raman Spectroscopy (Carl Anderson, Duquesne University, USA)
16.00-16.30 : Tea Break
16.30-17.00 : Particle Size Determination (Carl Anderson, Duquesne University, USA)
17:00-17:30 : Chemical Imaging (Carl Anderson, Duquesne University, USA)
17:30-18:00 : New Tools for PAT (Carl Anderson, Duquesne University, USA)
18.00-18.30 : Discussion and Wrap-up (Carl Anderson, Duquesne University, USA)
18.30-20.00 : Dinner

13th Dec **Case Studies in Biopharma PAT Implementation (Part-II)**

08.30-09.00 : Breakfast
09.00-10.00 : Role of Modeling in Process Control (Anurag Rathore, IITD)
10.00-11.00 : PAT Application for Process Chromatography (Nitika, IITD)
11.00-11.30 : Tea Break
11.30-12.00 : PAT Application for Protein Refolding (Rashmi Sharma, IITD)
12.00-12.30 : PAT Application for UF DF Operations (Naveen Jesubalan, IITD)
12.30-13.00 : Panel Discussion on PAT (Anurag Rathore, IITD and Carl Anderson, Duquesne University, USA)
13.00- 14.00 : Lunch Break

13th Dec **Case Studies in Pharma PAT Implementation (Part-II)**

14.00-15.00 : Application of PAT to Blending (Carl Anderson, Duquesne University, USA)
15.00-15.30 : Application of PAT to Granulation (Carl Anderson, Duquesne University, USA)
15.30-16.00 : Tea Break
16.00-17.00 : Application of PAT at and for Tableting (Carl Anderson, Duquesne University, USA)
17.00-18.00 : Application of PAT to Continuous Manufacturing of Pharmaceuticals (Carl Anderson, Duquesne University, USA)
18.00-18.30 : Discussion
18.30-20.00 : Dinner

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12th December, 2022

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MODULE II – Recent Advances in Filtration and Membrane Chromatography

Description: This course series aims to highlight various aspects of downstream processing of industrially relevant biotherapeutics. This course will focus on advancements in filtration and membrane chromatography. Aspects that will be addressed include process development, process optimization, scaleup, process modeling, adaption of continuous processing in the industries as well as the process analytical tools (PAT) for monitoring and controlling the process throughout.

Outline:

12th Dec **Recent advances in Filtration and Membrane Chromatography**

08.30-09.00 **: Breakfast**

09.00-10.00 : Principle and Operation of Filtration Techniques ***(EK Lee, Hanyang University, South Korea)***

10.00-11.00 : Overview of Tangential Flow Filtration (TFF) and Recent Advances (SPTFF, ILC, ILDF) ***(Kiran Akhade/ Abhishek Gupta, Pall Corporation)***

11.00-11.15 **: Tea Break**

11.15-12.45 : Scale up and its Challenges with Filtration in Industrial Applications ***(Krunal Mehta, Merck, USA)***

12.45-14.00 **: Lunch Break**

14.00-14.45 : Modeling Approach in Filtration as a Preferred Control Tool ***(Naveen Jesubalan, IITD)***

14.45-15.15 : Application of Process Analytical Technology (PAT) tools in Filtration ***(Nitika, IITD)***

15.15-16.00 : Virus Removal Filtration- Current Trends & Challenges ***(Vineet Bhatnagar/ Kiran Akhade, Pall Corporation)***

16.00-16.15 **: Tea Break**

16.15-17.00 : Recent Advances & Implementation of Sterilizing Grade Filtration in Bioprocess ***(Abhishek Gupta / Vineet Bhatnagar, Pall Corporation)***

17.00-17.45 : Overview of Membrane Chromatography ***(Masilamani Selladurai/ Kiran Akhade, Pall Corporation)***

17.45-18.30 : Recent Advances in Membrane Chromatography ***(Krunal Mehta, Merck, USA)***

18.30-20.00 **: Dinner**

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12th and 13th December 2022

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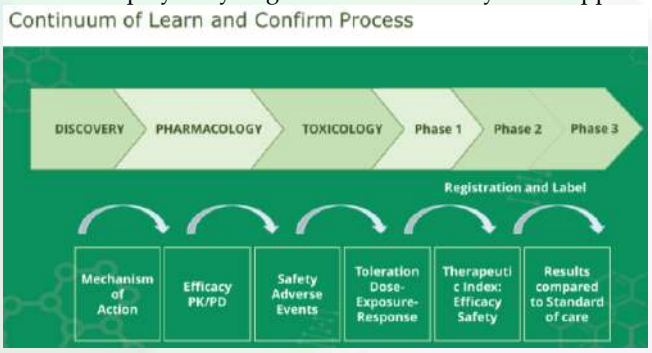
MODULE III – Drug development and Risk Management- Regulatory Perspectives

Description: Regulatory approval is the cardinal requirement of all development and commercialization activities in the biopharmaceutical industry. The regulatory landscape for biotherapeutics has seen many changes to requirements of preclinical and clinical subjects, reliance on analytical characterization studies, and the approval process. A critical aspect of biosimilar development is having comprehensive regulatory guidelines. This proposed course aims to strengthen our regulators and the industry on some of the key aspects of biopharmaceutical product development and commercialization. Validation and Monitoring during Large Scale Manufacturing of Bio therapeutics, Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) will be the focus of this course. The audience is expected to learn roles played by Regulators and industry in the approval process.



12th Dec Drug development – Overview

08:30-09:00: Breakfast
09.00-10.00: Introduction to Drug development ***(Naren Chirmule, SymphonyTech)***
10.00-11.00: Workshop on Drug development ***(Naren Chirmule, SymphonyTech)***
11.00-11.15: Tea Break
11.15-12.00: Introduction to process development ***(Nikhil Kateja, Edna Biolabs/IITD)***
12.00-12.45: DOE in process development ***(Ravi Khare, SymphonyTech)***
12.45-13.00: Discussion + Q&A
13.00-14.00: Lunch break

12th Dec Pharmacological process development

14.00-15.00: Introduction to Early drug development ***(Naren Chirmule, SymphonyTech)***
15.00-15.45: Statistics for Early drug development ***(Ravi Khare, SymphonyTech)***
15.45-16.00: Tea Break
16.00-16.45: Retrospective Analysis of Biologic Regulations ***(Himanshu Malani, IITD)***
16.45-17.30: Introduction to Pharmacology and Toxicology ***(Naren Chirmule, SymphonyTech)***
17.30-18.00: Discussion + Q&A

13th Dec Clinical stages of drug development

08.30-09.00: Breakfast
09.00-10.00: Manufacturing and Quality of Biopharmaceuticals for clinical trials (***Dhananjay Patankar, Industry expert)***
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 ***(Ravi Khare, SymphonyTech)***
12.00-12.45: Case study of Biologic development ***(Naren Chirmule, SymphonyTech)***
13.00-14.00: Lunch break

13th Dec Case Studies in drug development

14.00-14.45: Statistical consideration in clinical trials ***(Ravi Khare, SymphonyTech)***
14.45-15.45: Introduction to Pharmacovigilance ***(Sarika Deodhar, Biocon)***
15.45-16.00: Tea Break
16.00-17.00: Regulatory overview of clinical process development ***(Naren Chirmule, SymphonyTech)***
17.00-17.30: Discussion + Q&A

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13th December, 2022

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MODULE IV–Chromatography Development for Biotherapeutics

Description: This course series aims to highlight various aspects of downstream processing of industrially relevant biotherapeutics. The course will focus on development of chromatography-based purification of biotherapeutics. Aspects that will be addressed include process development, process optimization, scaleup, process modeling, adaption of continuous processing in the industries as well as the process analytical tools (PAT) for monitoring and controlling the process throughout.

Outline:

13th Dec **Chromatography Development for Biotherapeutics**

08:30-09.00 **: Breakfast**

09.00-10.00 : Principles and Commercial Aspects of Liquid Chromatography ***(Balaji Somasundaram, University of Queensland, Australia)***

10.00-11.00 : Development of Continuous Chromatography as Efficient Methods for Purification of Biotherapeutics ***(Krunal Mehta, Merck, USA)***

11.00-11.15 **: Tea Break**

11.15-12.00 : Enablers of Continuous Processing of Biotherapeutics Products ***(Anupa, IITD)***

12.00-12.45 : Scale up of Liquid Chromatography and its Challenges ***(Balaji Somasundaram, University of Queensland, Australia)***

12.45-13.45 **: Lunch Break**

13.45-14.45 : Process Data Analytics and Smart Process Monitoring in Biopharma Industry ***(Shitanshu Srivastava, Merck, USA)***

14.45-15.30 : Application of Spectroscopic PAT Tools in Downstream Processing ***(Anjali Ramakrishna, Biocon)***

15.30-15.45 **: Tea Break**

15.45-16.30 : Positioning of Chromatography Steps in Biopharmaceutics DSP ***(EK Lee, Hanyang University, South Korea)***

16.30-17.00 : Multi Flow Rate Loading Strategy for Process Intensification of Chromatography ***(Anjali Ramakrishna, Biocon)***

17.00-18.00 : Flow Through Polishing of Monoclonal Antibodies ***(Subhasis Banerjee, Merck, USA)***

18.30-20.00 **: Dinner**

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MODULE V– Design of Experiments: Concepts and Case Studies

Description: Quality by Design (QbD) and Design Space estimation, initiated by ICH, are moving to the phase of establishing standardized procedures and definitions within biopharmaceutical companies. The challenge is to extract a mathematically useful description that matches the flexibility and risk control described in the ICH Q8 guidelines. Design of Experiments (DOE) is required for a good and reliable Design Space description. However, most of the set-points derived from DOE are overoptimistic and do not consider risk of failure. A design space can be an irregular multidimensional region or a strict Proven Acceptable Range (PAR) for Critical Process Parameters (CPP's). This course will present the fundamentals of DOE and illustrate how to derive a multidimensional Design Space. Hands-on exercise is an integrated part of the course which let you experience how DOE and Design space estimation are carried out.

OUTLINE

13th Dec Design of Experiments: Concepts and Case Studies I

08.30-09.00 : Breakfast

09.00-10.00 : Data Analytics in Pharma/BioPharma Product Life Cycle: Introduction and Case Studies (***Vaibhav Patil, Sartorius Data Analytics***)

10.00-10.45 : Role of DOE in Pharma and Biopharma and its Applications (***Vinay Prathap, Sartorius Data Analytics***)

10.45-11.00 : Tea Break

11.00-11.45 : Process Parameter Screening with DoE and Hands-on Exercise (***Vaibhav Patil, Sartorius Data Analytics***)

11.45-12.45 : Process Parameter Optimization with DoE and Hands-on Exercise (***Vinay Prathap, Sartorius Data Analytics***)

12.45-13.45 : Lunch break

13th Dec Design of Experiments: Concepts and Case Studies II

13.45-14.45 : Upstream DoE: Cases with Hands-on Exercise (***Vaibhav Patil, Sartorius Data Analytics***)

14.45-15.30 : Downstream DoE: Cases with Hands-on Exercise (***Vinay Prathap, Sartorius Data Analytics***)

15.30-15.45 : Tea Break

15.45-16.15 : Formulation Stability Testing DoE: Cases with Hands-on Exercise (***Vaibhav Patil, Sartorius Data Analytics***)

16.15-17.15 : DOE for CPP Range Setting, Monte Carlo Simulations and Historical Data Analysis with Hands-on Exercise (***Vinay Prathap, Sartorius Data Analytics***)

17.15-17.45 : Case study: Application of DoE in Harvest Unit Operations. ***(Shantanu Banerjee, IITD)***

17.45-18.00 : Discussion and wrap up

18.30-20.00 : Dinner

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MODULE VI– Multivariate Data Analysis for Bioprocessing Data: Concepts and Case Studies

Description: Biopharma and biotech manufacturing today involves larger and larger masses of data. Correct management of these data can give us valuable insights to process development as well as production, help us understand the progress of a batch and also point us in the right direction to troubleshoot. By applying state-of-the art data analysis technologies in the biopharma production the time for fault detection and diagnosis in production can be significantly reduced. In one recent example, a company identified the cause of a cell culture problem about a month earlier than it otherwise might have. For that biologic product, making the fix early and not losing that month saved $2.4 million. The course will present fundamental theory and practice of Multivariate Data Analysis (MVDA) within the framework of PAT to improve quality and throughput, as well as hands-on exercises on how MVDA should be used in process development and production.

OUTLINE

14th Dec Multivariate Data Analysis for Bioprocessing Data: Concepts and Case Studies I

08.30-09.00 : Breakfast

09.00-09.45 : Role of MVDA in Pharma and Biopharma, Use cases, and Applications (***Vaibhav Patil, Sartorius Data Analytics***)

09.45-10.45 : Introduction to Tools, Practices, and Workflows in MVDA with Baseline Hands-on use Case on Healthcare Data (***Vinay Prathap, Sartorius Data Analytics***)

10.45-11.00 : Tea Break

11.00-11.40 : Accelerating Process Development and Predictive Model Building with Hands on Exercise (***Vaibhav Patil, Sartorius Data Analytics***)

11.40-12.00 : Deep Learning Approach for Automatic Peak Detection (***Keerthi Veena, IITD***)

12.00-12.45 : Classification Models with MVDA with Hands-on Exercise (***Vinay Prathap, Sartorius Data Analytics***)

12.45-13.45 : Lunch break

14th Dec Multivariate Data Analysis for Bioprocessing Data: Concepts and Case Studies II

13.45-14.45 : PAT and Model Building with Spectroscopy Data and Hands-on Exercise (***Vaibhav Patil, Sartorius Data Analytics***)

14.45-15.30 : Raw Material Qualification and Root Cause Investigation Use Cases using MVDA with a Hands-on Exercise (***Vinay Prathap, Sartorius Data Analytics***)

15.30-15.45 : Tea Break

15.45-16.15 : Application of Batch Evolution Models, Golden Tunnel for Process Monitoring and Early Detections of Drifts with a Hands-on Exercise (***Vaibhav Patil, Sartorius Data Analytics***)

16.15-17.15 : Application Batch Level Models for Investigating Causalities and Continuous Improvements in Bioprocess Manufacturing with a Hands-on Exercise (***Vinay Prathap, Sartorius Data Analytics***)

17.15-17.45 : Use of MVDA for Analysis of Spectroscopic Data. (***Naveen Jesubalan, IITD)***

17.45-18.00 : Discussion and wrap up

18.30-20.00 : Dinner

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Prof. Stephen W. Hoag – The National Institute for Pharmaceutical Technology & Education (NIPTE) and University of Maryland School of Pharmacy, USA

MODULE VII– Stability of Pharmaceutical Products

Description: The stability of any drug product is critical to product performance, product safety and the market success of any product. This module seeks to give a comprehensive overview of drug product stability and stability testing. A key aspect of drug product stability is the determination of the product shelf life, and in this module, we will cover the keys steps that are needed to assess a product's shelf life. The topics covered include:

- Common chemical reactions that affect stability (the big 5, temperature, pH, oxidation potential, light and moisture)
- Mathematical models of chemical reaction rates, including liquid and solid state
- The effect of temperature on reaction rates and the Arrhenius equation
- ICH guidelines for accelerated stability testing
- The critical role packaging plays in product stability
- Case study examining the stability testing of the combination product containing ivermectin and praziquantel

Upon completion of this module the student should have an overview of the background and key steps that are needed to determine a product's shelf life. Note this course will not cover the analytical assessment of drug substance and product stability.

Outline:

14th Dec Introduction to Stability

08.30-09.00 : Breakfast
09.00-10.00 : Introduction to Stability and Stability Testing
10.00-10.30 : Typical Chemical Reactions Affecting Product Stability
10.30-10.45 : Discussion
10.45-11.00 : Tea Break
11.00-12.00 : Chemical Kinetics
12.00-13.00 : Effect of Temperature on Reaction Rates
13.00-14.00 : Lunch Break

14th Dec Factors that Impact Stability

14.00-15.00 : Solid State Reactions, With and Without Moisture
15.00-15.30 : ICH Guidelines for Stability Testing
15.30-16.00 : Tea Break
16.00-17.00 : Critical Role Packaging Plays in Stability Testing
17.00-18.00 : Case Study Ivermectin and Praziquantel for Animal Health
18.00-18.30 : Discussion
18.30-20.00 : Dinner

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MODULE VIII – Microbial Fermentation Based Production of Biotherapeutics

Description: This course aims to clarify the core concepts in defining and implementing the upstream process development for manufacturing of biopharmaceutical products. The course will focus on recent developments in production of biotherapeutics via microbial fermentation. Aspects that will be covered include cloning strategies for recombinant strain development, media development, process optimization, scale-up, process control, monitoring, and modelling of bioprocesses. The audience will be able to gain deeper knowledge on microbial upstream processes and learn strategies for applying in fermentation technologies.

Outline

14th Dec Microbial Upstream Processing (Part-I)

08.30-09.00 : Breakfast

09.00-09.40 : An Overview of Industrial Fermentation Technologies
(Abhinav Jain, IGM Biosciences, USA)

09.40-10.20 : Cloning And Expression of Recombinant Proteins in Microbial Cells
(Preeti Srivastava, IITD)

10.20-11.00 : Points-to-consider for Biopharmaceutical Protein Expression from Recombinant Microbial Cells ***(E.K. Lee, Hanyang University, South Korea)***

11.00-11.15 : Tea Break

11.15-12.15 : Defining Critical Parameters for Optimization of Upstream Processing
(Komives Claire, San Jose State University USA)

12.15-13.00 : Media Development for High Product Titers of Recombinant Therapeutics
(Vishal G. Warke, Himedia Laboratories)

13.00-14.00 : Lunch Break

14th Dec Microbial Upstream Processing (Part-II)

14.00-14.45 : Process Development and Manufacturing of Biopharmaceutical Products
(Dhananjay Patankar, Industry Expert)

14.45-15.30 : Process Scale-Up for The Production of Biopharmaceuticals
(Velu Mahalingam, Intas Pharmaceuticals)

15.30-15.45 : Tea Break

15.45-16.30 : Modelling And Control Strategies for Upstream Process Development
(James Gomes, IITD)

16.30-17.00 : Monitoring And Process Integration for Biotherapeutics Production
(Sami Ullah Bhatt, IITD)

17.00-18.00 : Panel Discussion

18.30-20.00 : Dinner

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MODULE IX – Multi-Attribute Methods for Critical Quality Attribute Monitoring

Description: This course aims to introduce and clarify fundamental concepts relevant to contemporary analytical characterization of biopharmaceuticals and how to incorporate them in analytical method development. This will be achieved via a sequence of lectures and case studies. Concepts discussed include: Critical Quality Attributes (CQA), Analytical Quality by Design (AQbD) and multi attribute monitoring (MAM). At the end of the course, the audience will be able to explain what these concepts mean, the role they play in analytical characterization implementation and relevant regulatory implications.

OUTLINE

14th Dec MAM and CQA Monitoring

08.30-09.00 : Breakfast

09.00-09.45 : Biotherapeutics Characterization-Introduction to CQA's ***(Naren Chirmule, SymphonyTech)***

09.45-10.15 : Physical Chemistry Aspects in Various Biopharmaceutical Processes ***(Sudip K Pattanayak, IITD)***

10.15-11.00 : Primary Characterization-Analytical Tools and Techniques ***(Sumit Singh, IIT BHU)***

11.00-11.15 : Tea Break

11.15-13.00 : New Analytical workflows I: Overview of Analytical Quality by Design (AQbD) Considerations and Regulatory Implications ***(Amanda Guiraldelli Mahr, United States Pharmacopeia, US)***

13.00-14.00 : Lunch Break

14.00-14.50 : New Analytical Workflows II: Multi Attribute Methods: The Journey so far ***(Deepika Sarin, IITD)***

14.50-15.45 : New Analytical Workflows II: Multi Attribute Methods: Looking into the Future ***(Srishti Joshi, IITD)***

15.45-16.00 : Tea Break

16.00-16.40 : Multi Attribute Monitoring of Charge Heterogeneities in Recombinant Monoclonal Antibodies ***(Deepika Sarin, IITD)***

16.40-17.20 : Native Multi Attribute Monitoring Applied at The Critical Control Point Lends Perfectly to Disposition of In-Process Real Time Analysis of Samples ***(Sanghati Bhattacharya, IITD)***

17.20-18.00 : Titre and Aggregation Analysis of Monoclonal Antibody: A Case Study ***(Tushar Savane, IITD)***

18.30-20.00 : Dinner

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MODULE X – Mammalian Cell Culture Based Production of Biotherapeutics

Description: This course aims to clarify the core concepts in defining and implementing the upstream process development for manufacturing of biopharmaceutical products. This will be achieved via a sequence of lectures by renowned scientists from industry and academia. The course will cover important topics including Critical Quality Attributes (CQA), Media Development, Process Optimization, Scale-up, Monitoring, Control, modeling etc. along with recent advances and case-studies. At the end of this course, the participants will be able to explain what these concepts mean and learn how the mammalian upstream process is developed strategically for applying in industrial fermentation technologies.

Outline:

15th Dec Mammalian Upstream Processing - I

08:30-09.00 : Breakfast
09.00-10.00 : Cell Culture Media, Feeds and Buffers-HyClone Capabilities ***(Jitendra Kumar, Cytiva)***
10.00-11.00 : Mammalian Cell Culture-Based Biologics Production ***(Abhinav Jain, IGM Biosciences, USA)***
11:00-11.15 : Tea Break
11.15-12.00 : Process Intensification ***(Vasudevan, Cytiva)***
12.00-12.30 : Modulation of Critical Quality Attributes (CQAs) using Media Components: Case Study ***(Neelesh Gangwar, IITD)***
12.30-13.00 : Panel Discussion
13.00-14.00 : Lunch Break

15th Dec Mammalian Upstream Processing - II

14.00-15.00 : Root Cause Analysis, Productivity Improvement: Few Case Studies ***(Mayank Garg, Biocon)***
15.00-15.45 : Bioreactor Scaling ***(Vasudevan, Cytiva)***
15.45-16.00 : Tea Break
16.00-17.00 : Challenges with Cell Culture Scale-Up for the Production of Biologics ***(Abhinav Jain, IGM Biosciences, USA)***
17.00-17.30 : AI/ML Modeling Applications in Upstream and Harvest Unit Operations ***(Shantanu Banerjee, IITD)***
17.30-18.00 : Discussion and Wrap-up
18.30-20.00 : Dinner

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15th December, 2022

All times are in Indian Standard Time (IST)

MODULE XI – Mass Spectrometry: A powerful tool in Biopharmaceutical Analysis

Description: Mass spectrometry (MS) is a powerful technique for protein identification, quantification and characterization which is frequently applied in biopharmaceuticals. It is a versatile and widely used analytic tool for quality control of biopharmaceuticals, particularly in determine mass, elucidating glycan structure, and identifying post-translational modifications of biopharmaceutical proteins. This course focuses on high resolution analytical characterization as well as of novel approaches advancement in the recent few years.

OUTLINE:

08.30-09.00 : Breakfast

09.00-09.45 : Introduction to Intact Mass Analysis: Native and Non-Native Workflows ***(Sumit Singh, IIT BHU)***

09.45-10.30 : Introduction to N-Glycan Analysis: Biopharmaceuticals ***(Manoj Kumar Metta, United States Pharmacopeia)***

10.30-11.00 : Advances in Multi-dimensional LC-MS for Next Generation Protein Therapeutics ***(Vadiraja Bhat, Agilent Technologies)***

11.00-11.15 : Tea Break

11.15-12.00 : Chemometric Analysis for Bioanalytical Data (***Keerthiveena, IITD)***

12.00-13.00 : Characterization Through Peptide Mapping for Biopharmaceuticals ***(Sumit Singh, IIT BHU)***

13.00-14.00 : Lunch Break

14.00-15.00 : Rapid Analysis of N-Linked Glycan ***(Saurabh Nagpal, Agilent Technologies)***

15.00-16.00 : Process Related Biopharmaceutical Impurities Analysis: HCPs ***(Vadiraja Bhat, Agilent Technologies)***

16.00-16.15 : Tea Break

16.15-16.45 : Native Mass Analysis of Monoclonal Antibodies- A Case Study ***(Sunil Kumar, IITD)***

16.45-17.15 : CE-MS for Characterization of Biotherapeutics: A Case Study ***(Ramesh Kumar, IITD)***

17.15-18.00 : Elucidating Disulfide Scrambling in mAbs ***(Neh Nupur, IITD)***

18.30-20.00 : Dinner

Centre of Excellence
Biopharmaceutical
Technology

CBT Course Series 2022

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MODULE XII – AI/ML for Bioprocessing

Description: Artificial Intelligence (AI) has revolutionized sectors all over the world, and it has the potential to radically alter the field of biopharmaceutical technology. AI solutions are driving bioprocessing change, from alleviating the pressures of burnt-out professionals to streamlining administrative operations and speeding up clinical choices and diagnoses. Developing a revolutionary method coupled with data analysis for bioprocessing innovation may be both cheaper and faster by leveraging AI for cell line development and engineering, cell culture and media design, upstream process design and optimization, automation control, downstream processing and online monitoring of products and strains. The course offers modules on machine learning and deep learning techniques for bioprocessing.

OUTLINE

15th Dec Basics of Artificial Intelligence

08.30-09.00 : Breakfast
09.00-10.00 : Introduction to Machine Learning ***(Hariprasad Kodamana, IITD)***
10.00-10.30 : Scope of AI in Bioprocessing ***(Hariprasad Kodamana, IITD)***
10.30-11.00 : AI/ML Modeling Application in Downstream Processing ***(Naveen Jesubalan, IITD)***
11.00-11.15 : Tea Break
11.15-12.30 : Introduction to Optimization Techniques ***(Manojkumar Ramteke, IITD)***
12.30-13.00 : Application of Optimization Techniques in Bioprocessing ***(Manojkumar Ramteke, IITD)***
13.00-14.00 : Lunch Break

15th Dec Case studies in Bioprocessing

14.00-15.15 : Machine Learning Application for Identification and Classification of Subvisible Particles in Injectable Formulations ***(Velu Mahalingam, Intas)***
15.15-15.45 : AI/ML Modeling Applications in Upstream and Harvest unit operations ***(Shantanu Banerjee, IITD)***
15.45-16.00 : Tea Break
16.00-17.15 : Introduction to MVDA and Data Handling ***(Mayank Garg, Biocon)***
17:15-17:45 : Introduction to Deep Learning and its application in Bioprocessing ***(Keerthiveena, IITD)***
17.45-18.00 : Discussion and Wrap-up
18.30-20.00 : Dinner

CARL A. ANDERSON joined the Duquesne University faculty in 2002 as an assistant professor of pharmaceutical sciences. He is a founding member and director of the Duquesne University Center for Pharmaceutical Technology (DCPT). During his time at Duquesne, he has built a research group focusing on exploration of new and existing analytical technologies for pharmaceutical manufacturing. In addition to exploring process analytical tools, his group uses these tools to enhance the understanding of the chemistry and physics of pharmaceutical technology. He has served for two years as a Division Head for the Pharmaceutical, Administrative and Social Sciences division and is currently the Associate Dean of Research and Graduate programs. Prior to joining Duquesne, he spent seven years working for Aventis pharmaceuticals. While there, he led the team that developed, validated, and implemented Aventis' first PAT based methods.

KIRAN AKHADE is currently working as Team Manager at Pall Corporation & has an overall industry experience of 13+ years in Process development & scale up of biopharmaceutical and pharmaceutical products. Kiran holds a Master's degree in Bioprocess Technology from Institute of Chemical Technology, Mumbai. Kiran specializes in Process development, scale up & troubleshooting of various unit operations involved in downstream processing of biopharmaceuticals & vaccines. He supports Biotech and pharmaceutical organizations on filtration optimization, scale up and troubleshooting of Pall technologies like Tangential flow filtration, Direct flow filtration, Filter integrity testing, Single use, Virus filtration and validation.

VADIRAJA B. BHAT, Ph.D., Biopharma Business Development Manager at Agilent Technologies, India. Vadi Bhat received his Ph.D. in Chemical Biology from JNCASR/IISc and did his post-doctoral research in the Department of Bioengineering at the Massachusetts Institute of Technology. Prior to join Agilent, he was associate director for mass spec core facility at the Baylor Scott & White Hospital/ Texas A&M University, Temple, TX. Vadi Bhat joined Agilent Technologies in 2008 as LC-MS applications scientist out of the Wilmington, Delaware, Center of Excellence. Since then he has been focusing on developing novel LC-MS based workflows for proteomics and biopharma applications and delivering these solutions to the customers. From 2015, he also worked as proteomics market specialist in "Agilent North America Field Team" where he was responsible for customer collaborations and business development. In this role, he published several peer-reviewed journal articles and presented in many scientific conferences. From 2017, he is working as Biopharma Business Development Manager in India where he was responsible for biopharma customer collaborations and business development for Agilent Technologies.

SUBHASIS BANERJEE is the Principal Application Expert for Asia Pacific (APAC) in Merck Life Sciences based out of Bangalore, India. Subhasis supports technical consultation for downstream processing for the APAC region. Previously he was heading the Manufacturing Sciences and Technology group; team of Scientists and Engineers for Singapore, Southeast Asia and Oceania supporting in optimizing downstream unit operations and providing scale up solutions to biological manufacturers. He is a Ph.D. in Biochemistry with a post-doctoral experience from The Ohio State University, Columbus, Ohio, USA. Dr. Banerjee has several publications in international peer reviewed journals and presentations in several national and International Conferences.

VINEET BHATNAGAR is working as Senior Manager Scientific and Laboratory services at Pall Corporation Bangalore. He has an overall industry experience of 19 years in Downstream Process development & scale up of biopharmaceutical and convectional pharma. With Masters in Biotechnology, and carrier in upstream process development of bacterial fermentation based product to downstream process development for biopharmaceuticals he currently is responsible for technical and process development team (SLS) supporting customers on optimization and troubleshooting studies for Pall's product line.

NARENDRA CHIRMULE is the co-founder and CEO of SymphonyTech Biologics, a data analytics company focused on engineering solutions for biology. 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, and gene therapy for several rare diseases. Dr. Chirmule is on the NIH advisory committee for HIV vaccines. He is a TEDx speaker and recently published a book "Good Genes Gone Bad" by Penguin Press, both of which describe lessons learned from colossal failures in drug development.

SARIKA S DEODHAR, MBBS and MD in Pharmacology from K.E.M Hospital Mumbai. Served as Physician in Primary Health Care centres, lecturer in Medical college, trainer for medical representatives training programs and as a Senior Scientific Manager in Medical affairs and clinical research in Ranbaxy . In Biocon, worked for global clinical trials as Medical Monitor and Medical Lead in Clinical development; as a drug safety physician and clinical safety lead in pharmacovigilance. Managed end to end global clinical trial activities from conception of clinical trial, protocol writing, study start and execution till study report writing on medical and safety grounds for several key projects for oncology, immunology and diabetes products. Established several operating procedures in medical and safety during the tenure. Faced several MOH/ RA inspections and partner Audits, due-diligences in clinical safety and pharmacovigilance. Health

conscious, keen in sports, yoga and a student of Bharatnatyam dance form, very well describes me. Being blessed with 16 years son and 8 years old daughter, I strongly believe in maintaining the work and personal life balance.

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.

ABHISHEK GUPTA is currently working as Senior Scientist at Pall Corporation & has an overall industry experience of 15+ years in Pharmaceutical & Biotech sector. Abhishek holds degree in Chemical Engineering from Rajiv Gandhi Technical University, Bhopal along with Certificate in Project Management from IIT Delhi. He supports customers in performing various technology trials: Direct Flow Filtration (DFF) - Filterability Studies (Vmax, Pmax) for Sterile, Clarification, Buffer Sizing, Depth Filtration, Virus filtration and Tangential Flow Filtration (TFF) Selection, Sizing & Optimization, Scale up support, Troubleshooting, Integrity Testing, Technical Consultancy including Pall Single Use Technology (SUT) related Process development & scale up runs for biopharmaceutical and pharmaceutical processes. Abhishek also heavily involved in Internal and external customer trainings for knowledge sharing and feels equally enthusiast while solving customer’s complex challenges. He specialized in downstream unit operations and have extensive experience in Sterile Filtration & Single Use Technology.

AMANDA GUIRALDELLI has been with USP since 2012 and holds the position of scientific affairs manager and scientific liaison in the compendial science group-general chapters. She is the scientific liaison for the USP general chapters <1220> Analytical Procedure Life Cycle and <1039> Chemometrics. Previously, Amanda worked as senior scientist for 8 years at the USP reference standard laboratory focused on characterization of compendial standards. She is also visiting professor at the University of Campinas (UNICAMP) at the Institute of Chemistry in Brazil and is a frequent speaker and instructor on topics related to analytical procedure life cycle and Analytical Quality by Design (AQbD). Amanda is specialist in chromatography, mass spectrometry and chemometrics and has more than 14 years of experience in pharmaceutical R&D areas. Prior to joining USP, she was R&D scientist in a brazilian pharmaceutical industry and visiting scientist at TU Berlin in Germany and Leiden University in Netherlands (Center for Proteomics and Metabolomics) working on proteins characterization by LC-HRMS and bioanalytical procedure

development using UHPLC-HRMS. Amanda is graduated in pharmacy biochemistry and holds a Ph.D. in analytical chemistry from the University of São Paulo (metabolomics by UHPLC-HRMS, GC-MS and 1H NMR and chemometrics).

JAMES GOMES received his Bachelors' degree in Chemical Engineering from Jadavpur University and his M.S. and Ph.D from Tulane University, New Orleans, USA. He worked for Process Services Inc., Baton Rouge and L&T, Powai, Mumbai, before joining IIT Delhi. His current research interest is in the area of Systems and Network Biology. His group focusses on the application of mathematical and computational methods to study disease networks, understand disease progression and determine new drug targets, followed by directed experiments. Particular areas include neurodegenerative diseases and virus-host interaction networks. In the area of Biochemical Engineering, he uses differential geometry methods and neural networks to design process control strategies for bioprocesses. James also has interest in emergent properties arising in complex systems and a growing interest in the mind and cognition problem.

STEPHEN W. HOAG is a professor at the University of Maryland, Baltimore School of Pharmacy. His primary research interests are in oral delivery systems, controlled release polymers, excipient functionality, stability testing, excipient testing, pediatric formulations and the use of Raman and NIR spectroscopy in PAT applications. Dr. Hoag is the Director of the School of Pharmacy GMP facility and a member of NIPTE, Steering Committee for the Handbook of Pharmaceutical Excipients, the editorial board of the journal of Pharmaceutical Development Technology and an AAPS Fellow.

ABHINAV JAIN is at the forefront for development of upstream manufacturing process of a new class of medicines, the engineered IgM antibodies. Researchers have long appreciated the potential for IgM antibody-based medicines but have been stymied by the technical challenges of efficiently creating and manufacturing highly specific IgM antibodies. IGM Biosciences is currently the first and only company that can efficiently produce engineered antibodies at scale. In his other role at IGM, Dr. Jain is a leader of a CMC group that's actively working on bringing a new IgM molecule to the clinic to treat cancer patients. Before joining IgM Biosciences, Dr. Jain completed his Ph. D. at Tulane University where he worked on improving the "functionally-active" expression of "difficult-to-produce" membrane proteins. Dr. Jain has more than twelve years of research experience in solving technical and scientific problems by designing, performing, and analyzing genomics, proteomics, and transcriptomics experiments in bacterial, yeast, and mammalian systems. In his spare time, Dr. Jain volunteers for the communication committee for the Biochemical Technology (BIOT) division of ACS and has hosted webinars and moderated panel discussions for the organization.

RAVINDRA KHARE is the CSO and Director of SymphonyTech Biologics Pvt Ltd. He is an internationally acknowledged expert in Design, Manufacturing and Quality and applying statistical analytics to Engineering. 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. He holds a Master's degree in Data Science & Engineering from BITS Pilani, India.

CLAIRE KOMIVES obtained a Ph.D. in chemical engineering at the University of Pittsburgh and did postdoctoral research at the ETH Zurich in Switzerland with Professor James E. Bailey. Since returning to the US, she held positions at the US Agency for International Development with a focus on Child Health Research, DuPont, Genencor (now also DuPont), IIT Delhi as a visiting scholar and as a Professor of Chemical Engineering at San Jose State University (SJSU). She has completed a Fulbright-Nehru fellowship award to pursue her current research interest towards the expression and purification of a snake antivenom peptide from the American opossum in bacteria. She completed a second Fulbright-Nehru award to deliver workshops to faculty in India on various aspects of engineering education. She has graduated 22 Master's students, has received over one million USD in grants since joining SJSU.

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.

JITENDRA KUMAR works as an Upstream Application Specialist, in Cytiva, APAC. In this role, Jitendra is responsible for Cell Culture Media and Upstream Applications support for India / Asia. For the past 14 yrs, he has worked in various BioPharma industries mainly Lupin, Intas Pharmaceuticals, Bioneeds, Ipca laboratories as scientist, Sr. scientist & Manger and developed commercially viable cell lines and done the Process Development in a small-scale Bioreactor for Biosimilar therapeutic molecules. So far, developed 10 recombinant molecules of which three Biosimilar products have been launched in the Indian market and rest are in different clinical phase development. Jitendra have received the Postgraduate in 2007 from SRM University Chennai, India in Biotechnology & Bioinformatics and Postgraduate in PMIR from Patna University in 2013. He has also contributed to patent generation and scientific publication in peer reviewed journals. He is a co-author for four articles and co-inventor of the two patents application.

E. K. LEE 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. Prof. 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 National Academy of Engineering in Korea, and serves as a scientific and technical consultant to the Korean government and several biopharmaceutical industries globally. After the retirement in March 2018, he co-founded and works as a VP and CTO of a biostartup, Immunoforge, Inc., to develop a therapeutic biobetter as an orphan drug. Besides, he consults biotech companies on antibody CDMO establishment, and cell culture media and chromatography resin development.

VASUDEVAN M has 15+ years of experience in bioprocess industry and he is currently working as Techical Leader Upstream for Asia in Cytiva Lifesciences. Vasudevan supports upstream technical, project consultancy/adaptation, scaling, and single use technologies. He is specialized in process development to scaling and manufacturing. Previously, he was a process development specialist for upstream in Sartorius Stedim India. He was also the part of Shantha, Inverness and Cadila. His key skill include Upstream Process Development, Process Scaling, and Process analytics.

VELU MAHALINGAM, Ph.D., Associate Vice President, and Head of Process Science with Intas Pharmaceuticals limited, Biopharma Division, has over 15 years' experience in process development, scale-up, technology transfer and validation of biopharmaceutical products using multiple host platforms with strong background in end-to-end understanding of CMC processes (vial to vial) and deep expertise in applying engineering fundamentals during the development and deployment of large-scale biologics manufacturing processes. Previously he held positions of increasing responsibility in process development and manufacturing sciences and technology at Viatris (formerly Mylan) and Dr. Reddy's. Where, he has been involved providing technical and strategic leadership to CMC project teams from early development through post-commercial phase in developing multiple biosimilar products for global markets. He has participated in several technical due diligences for in-licensing, implementing new technology initiatives and alliance projects. Held technical leadership roles for several new product introductions to commercial manufacturing sites including five new drug substance and two drug product facility start-up projects. Dr. Velu holds a master's degree in

chemical engineering from Anna University, A.C. College of Technology, and a Ph.D. in the Bioprocess Engineering from Indian Institute of technology, Madras.

KRUNAL MEHTA has a Bachelor's in Chemical Technology from Institute of Chemical technology, Mumbai, India, and has received his Ph.D. in Chemical and Biological Engineering from Rensselaer Polytechnic Institute, Troy, New York. Before joining as the Director of Biologics Drug Substance Commercialization group at Merck, Dr. Mehta has several years of experience working in the late stage process development groups at Bristol-Myers Squibb and Amgen. His contributions in the filed of bioprocessing span from supporting the development and implementation of emerging technologies in next-generation biologics manufacturing facility, making process improvements or developing second generation processes for commercial biologics, to advancing the development of biosimilars through commercialization.

MANOJ KUMAR METTA is a renowned Biological Scientist with 17 plus years combinational experience in Biologics Quality assessment, and Compendial sciences. Subject matter expert in therapeutic proteins, monoclonals, and peptides process from starting material to the drug product. He has rich hands-on experience in implementing an effective quality management system includes biopharmaceutical development, and commercial manufacturing. His experience also engrossed on commercial development of biologics, with emphasis on physicochemical and functional characterization, analytical control strategies, quality risk management and reviewing CMC regulatory documentation to support product licensure in global markets. He has also sound knowledge in handling USFDA and WHO audits. Academically, he received Ph.D. in Biotechnology from Gandhi Institute of Technology and Management, where his work focused on the "Development of novel mammalian expression systems by using polyomaviral elements in CHO cell line" for monoclonal antibody production". Dr. Manoj has been associated with USP–India since December 2011 as Science and Standards Liaison, Global Biologics. Currently, his work is focused on the development of USP-NF monographs and Reference Standards associated with Therapeutic proteins, Monoclonals and Synthetic peptides. He conducted several hands-on Pharmacopeial Education (PE) courses on "Glycan Analysis" at USP and customer sites. Globally, he has delivered keynote speeches and engaged in projects on RS development and advance analytical technology.

SAURABH NAGPAL 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.

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.

VAIBHAV PATIL is a Manager of Data Science, APAC at Sartorius Data Analytics. Master of Bioprocess Technology with ~15 yrs. of industrial exp. with a multidisciplinary role in Process R&D, Manufacturing, and Data analytics spanning across Pharma, Chemical, and FMCG sectors. I gradually moved from R&D heavy role to DoE/QbD/PAT and data analytics, pre-sales, ROI, and technical role. I have experience working as an individual contributor as well as a managing team. He have extensive hands-on exposure to various ML/AI algorithms, Mechanistic / Hybrid Models, Data visualization, and data wrangling platforms along with in-depth functional knowledge about the process/manufacturing industry. Before joining Sartorius Data Analytics in 2018, he was a Manager of Statistics at Pfizer. Prior experiences include Associate Investigator at DuPont and Jr Scientist at Dr. Reddy's Lab. His major focus areas are applying advanced data analytics tools for pharma applications, data-driven decision making, process monitoring, predictive analytics, Continuous improvement, and QbD/PAT.

SUDIP K. PATTANAYEK's 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.

VINAY PRATHAP is Bioprocess Data Scientist at Sartorius Stedim India Pvt Ltd. In his current role he focuses on building customer applications in QbD, PAT and data analytics, delivering trainings and consultancy. He has over 10 years' experience in Monoclonal antibody purification/separation techniques including filtration and chromatography. During this period, he has contributed towards development of purification platforms, scale up and process characterization for multiple biosimilar projects. He has extensive exposure in developing and validating various statistical and mechanistic models as well as utilizing machine learning and mathematical tools in decision making and causal investigations. Before joining Sartorius Data Analytics in 2022, he had been serving Biocon Biologics in various capacities. His areas of interest include Multivariate Data analysis, Statistical modeling, and Mechanistic modeling. Vinay has completed his Masters degree in Industrial and Commercial Biotechnology.

ANJALI RAMAKRISHNA has 9 years' experience in the Biopharma industry and holds expertise in Downstream processing of Biologics. She is currently leading end to end of development, tech transfer, process characterisation, viral validation and other CMC activities for 2 Biosimilar programs at Biocon Biologics Limited. She has been involved in the successful filing and approvals of Biocon's key Biosimilar drugs across developed and developing markets, during her tenure. She is also pursuing PhD in Chemical engineering at IIT Delhi with focus on development of PAT tools and integrated operations for process improvement and COGs reduction in Biologics manufacturing.

ANURAG 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, 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. Prof. Rathore is presently serving as Dean, Corporate Relations, at IIT Delhi.

MANOJ KUMAR RAMTEKE is currently an Associate Professor in the Department of Chemical Engineering, Indian Institute of Technology, New Delhi, India. He did his B. Tech. from Dr. 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.

MASILAMANI SELLADURAI, Ph.D. is responsible for high throughput process development, application development on Pall membrane chromatography products on Gene Therapy applications. He has worked on several chromatography customer projects related to downstream processing. Prior to Pall, Dr. Masilamani has worked as post-doctoral scientist at Pohang University of Science and Technology, South Korea, where he had worked few projects on signal transduction and purification of peptides and proteins. Dr. Masilamani has published 30 research papers on reputed journals. Dr. Masilamani holds Ph.D. in Life Sciences from University of Madras and worked as a senior scientist at Southern Petro Chemical and Industrial Corporation, Chennai. He was a lecturer in Bharat Engineering & Biotechnology – Deemed University, Chennai.

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.

BALAJI SOMASUNDARAM, with a PhD in in Chemical and Process Engineering, has 12 years research experience in the areas of protein expression, recovery and characterisation. He has delivered on industry-relevant projects including human enterovirus-like particle vaccine development, biosimilars, development of continuous chromatography and membrane-based protein separation. As the Strategy and Operations Manager at the Protein Expression Facility, housed at the University of Queensland, Dr Somasundaram has established several national and international partnerships and provided strategic research leadership in a multi-stakeholder environment that includes academia, industry, and government. Dr Somasundaram holds a joint appointment with Denteric Pty Ltd as Senior CMC Project Manager directly overseeing vaccine scale-up production for GLP tox studies and Phase-1 clinical studies.

PREETI SRIVASTAVA obtained PhD from Department of Biochemical Engineering and Biotechnology, Indian Institute of Technology, Delhi in the area of corynebacterial plasmid biology. She did postdoctoral research work in the area of 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.

SHITANSHU SRIVASTAVA, Lead Customer Excellence Expert, Process Solution. Merck Life Science. Shitanshu Srivastava has 11+ years of Bioprocess industry experience of cGMP manufacturing and technical support. He has spent last 5 years developing and implementing data analysis and monitoring platform at various customers across the globe. Shitanshu’ s key strength lies in data science, applied statics, and provide user's perspective for Continuous Product Improvement. He is a key member of Merck's customer interaction team and lead the efforts on customer training and implementation of data analysis platform at customers. He also plays a vital role on internal product improvement initiative by providing valuable insight on customer perspective, assisting in product design and software validation efforts.

VISHAL G WARKE is a reputed Scientist and Director of Research & Development within Cell Culture & Immunology division at HiMedia Laboratories Private Limited. After graduating as a Medical Doctor (M.B.B.S) from the University of Mumbai, he completed his doctoral research in Cell Biology and Molecular Genetics from the University of Maryland, USA. He has been awarded with the Medical Research Fellowship of The Walter Reed Army Institute of Research (June 2002), Silver Spring, MD, USA. As the gen-next leader of HiMedia, he has diversified into other areas of biosciences, broadening the portfolio of the organization. He has successfully established the Animal Tissue Culture, Plant Tissue Culture, and Hydroponics business divisions and, has worked on design and development of media for biosimilar production. He has developed many products including Serum Free Media, Lymphocyte Separation Media, Viral Transport Media, Primary Cell Media etc. for the global market. He has been an active member of several reputed scientific bodies and a PI for many collaborative translatable projects.

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