DBT Center 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**.

Centre of Excellence Biopharmaceutical Technology

AFOB Asian Federation of Biotechnology

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.

Together with the Asian Federation of Biotechnology (AFOB), 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:

Downstream processing	**Upstream processing**	**Computational design**
Computational fluid dynamics	**Continuous processing**	**Analytical characterization**
Quality by Design	**Process scheduling**	**Process analytical technology**

We look forward to welcome you at IIT Delhi.

Prof. Anurag S. Rathore
Coordinator, CBT, IIT Delhi

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

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UPSTREAM PROCESSING (12th December 2016)

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TITLE: **Upstream Processing for Production of Biopharmaceuticals: Theory, Practice and Case Studies**

DESCRIPTION: Upstream processing primarily involves operation of the bioreactor for expression of the biopharmaceutical in a suitable microbial or mammalian host. The complexity of this step comes from the fact that the single bioreactor step involves interaction amongst multiple process variables (10-20) and involve use of numerous raw materials (20-50), some of which may be partially or poorly characterized (such as soy hydrolysate). Of all the unit operations that typically comprise a bioprocess, the bioreactor is known to impact the maximum number of critical quality attributes, some of which such as glycosylation are not impacted by the rest of the process. This course will present the fundamental theory of bioreactor operations as well as present case studies that highlight the challenges faced by the practitioners as well as showcase the industry best practices.

OUTLINE:

8.30-9.00: Breakfast

9.00-10.00: Introduction to microbial fermentation
(***Prof. Fengwu Bai, Shanghai Jiao Tong University, China***)

10.00-10.45: Introduction to mammalian cell culture (***Ankur Bhatnagar, Biocon Ltd.***)

10.45-11.00: Break

11.00-11.45: Introduction to fermenter design
(***Prof. Fengwu Bai, Shanghai Jiao Tong University, China***)

11.45-12.30: Scale-up of bioreactor for microbial and mammalian cell cultures
(***Dr. Velu Mahalingam, Mylan***)

12.30-1.30: Lunch

1.30-2.30: Control of bioreactors (***Prof. James Gomes, IITD***)

2.30-3.00: Case Study 1: Development of a mammalian cell culture process for production of a biotherapeutic (***Ankur Bhatnagar, Biocon Ltd.)***

3.00-3.30: Case Study 2: DIOLC based control of a bioreactor (***Prof. James Gomes, IITD***)

3.30-4.00: Break

4.00-4.30: Case Study 3: Scale-up of a bioreactor (***Dr. Velu Mahalingam, Mylan***)

4.30-5.00: Case Study 4: QbD based media development for Lucentis
(***Dr. Deepak Kumar, IITD***)

5.00-5.30: Case Study 5: Multivariate data analysis for correlating media components to mAb CQA
(***Sumit Kumar Singh, IITD***)

5.30-6.00: Discussion and Wrap-up


Prof. Fengwu Bai


Prof. James Gomes


Ankur Bhatnagar

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DOWNSTREAM PROCESSING (12th December 2016)

TITLE: **Downstream Processing for Production of Biopharmaceuticals: Theory, Practice and Case Studies**

DESCRIPTION: Protein therapeutics, as a class of products, are required to meet high quality standards as per the regulations. When a therapeutic product is expressed *via* microbial fermentation or mammalian cell culture, it coexists in the bioreactor together with a myriad of species including product related variants, product related impurities, process related impurities, and host cell related impurities. Downstream processing aims to meet the challenge of achieving the required purification by utilizing a combination of high resolution and orthogonal unit operations. This course will present the fundamental theory behind key downstream unit operations as well as present case studies that highlight the challenges faced by the practitioners as well as showcase the industry best practices.

OUTLINE:

8.30-9.00: Breakfast

9.00-10.00: Introduction to process chromatography (***Prof. Anurag S. Rathore, IITD***)

10.00-10.30: Introduction to ultrafiltration and diafiltration processes (***Prof. Anupam Shukla, IITD***)

10.30-10.45: Break

10.45-11.45: Modeling and process optimization of liquid chromatography (***Prof. Shuichi Yamamoto, Yamaguchi University, Japan***)

11.45-12.30: Scale-up of downstream unit operations (***Prof. Anurag S. Rathore, IITD***)

12.30-1.30: Lunch

1.30-2.00: Role of process integration in process development (***Prof. Daniel Bracewell, UCL***)

2.00-2.30: Case Study 1: Chromatographic process development for production of a biotherapeutic (***Dr. Nitin Patil, Biocon Ltd.)***

2.30-3.00: Case Study 2: Purification of pegylated proteins (***Prof. Shuichi Yamamoto, Yamaguchi University, Japan***)

3.00-3.30: Break

3.30-4.00: Case Study 3: Model based development of chromatographic steps (***Lalita Kanwar, IITD***)

4.00-4.30: Case Study 4: High throughput process development (***Prof. Daniel Bracewell, UCL***)

4.30-5.00: Case Study 5: Modeling of filtration processes (***Prof. Anupam Shukla, IITD***)

5.00-5.30: Case Study 6: Application of moments and transition analysis (***Dr. Scott Rudge, RCM Pharmaceutical Solutions, USA***)

5.30-6.00: Discussion and Wrap-up


Prof. Shuichi Yamamoto


Prof. Daniel Bracewell


Prof. Anurag S. Rathore


Prof. Anupam Shukla


Dr. Scott Rudge

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PROCESS SCHEDULING (12th December 2016)

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TITLE: **Production Planning & Scheduling Operations in Chemical & Biotech Industries**

DESCRIPTION: The workshop is aimed at providing state-of-the-art technology in modeling and solution of process operations in chemical & biotech industries. The workshop will cover development of production planning & scheduling models based on different process and time representations along with recent advances in batch manufacturing. Several applications including petrochemicals, refineries, biopharmaceuticals, and other fast moving consumer goods (FMCG) industries will be discussed. A couple of hands-on sessions are also included on using GAMS software for solving these models.

OUTLINE:

8.00-8.30: Breakfast

8.30-9.30: From planning and scheduling to supply chain management (***Prof. Raj Srinivasan, IIT Gandhinagar & IIT Madras***)

9.30-10.30: Short-term scheduling of batch plants: discrete & continuous time models (***Prof. M.A. Shaik, IIT Delhi***)

10.30-10.45: Break

10.45-11.45: Advances in batch manufacturing (***Prof. Ravi Gudi, IIT Bombay***)

11.45-12.45: Scheduling of multiproduct manufacturing facility for biotech products (***Prof. M.A. Shaik, IIT Delhi***)

12.45-1.30: Lunch

1.30-2.30: Production planning in petrochemical industry (***Prof. Prakash Kotecha, IIT Guwahati)***

2.30-3.30: Scheduling of continuous fast moving consumer goods (FMCG) Manufacturing (***Prof. M.A. Shaik, IIT Delhi***)

3.30-3.45: Break

3.45-4.45: Hands-on session I: 'Optimization using GAMS software' (***Prof. M.A. Shaik, IIT Delhi***)

4.45-5.45: Hands on session II: 'Scheduling of biotech products using GAMS' (***Prof. M.A. Shaik, IIT Delhi***)

5.45-6.15: Discussion and Wrap-up


Prof. Raj Srinivasan


Prof. M.A. Shaik


Prof Ravi Gudi


Prof. Prakash Kotecha

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ANALYTICAL CHARACTERIZATION (13th December 2016)

TITLE: **Characterization of Biopharmaceuticals: Advanced Analytical Tools and Case Studies**

DESCRIPTION: Analytical characterization is the backbone of establishing comparability, which is arguably the most critical step in development and commercialization of biosimilars. Major advancements have occurred in the past few years with respect to both development of novel, high resolution analytical tools as well as development of novel approaches. This course will address both of these objects. Novel technologies that can facilitate analytical characterization will be presented together with case studies that highlight approaches towards achieving the above mentioned objective.

OUTLINE:

8.00-8.30: Breakfast

8.30-9.00: Role of analytical characterization in development of biosimilars (***Prof. Anurag Rathore, IITD***)

9.00-10.00: Characterization of biotherapeutics (***Dr. Ravindra Gudihal, Agilent***)

10.00-10.30: ITC as an analytical tool for analysis of biotherapeutic molecules (***Prof. Sudip Pattanayek, IITD***)

10.30-11.00: Break

11.00-11.30: TEM as an analytical tool for analysis of biotherapeutic molecules (***Prof. Manidipa Banerjee, IITD***)

11.30-12.00: Case study 1: Characterization of a biopharmaceutical product (***Dr. Nitin Patil, Biocon***)

12.00-12.30: Case Study 2: Analysis of aggregation of monoclonal antibody products using multiple, orthogonal tools (***Rohit Bansal, IITD***)

12.30-1.30: Lunch

1.30-2.00: Case Study 3: Characterization of mAb glycosylation (***Neh Nupur, IITD***)

2.00-2.30: Case Study 4: Use of LC-MS-MS for characterization of Protein A fouled resin (***Dr. Katherine Lintern, UC***L)

2.30-3.00: Case Study 5: Use of modeling for optimization of liquid chromatography analysis (***Dr. Varsha Joshi, IITD***)

3.00-3.30: Break

3.30-4.00: Case Study 6: Should charge variants of monoclonal antibodies be considered CQA? (***Sumit Kumar Singh, IITD***)

4.00-4.30: Case Study 7: Characterization of host cell proteins (***Prof. Daniel Bracewell, UCL***)

4.30-5.30: Demonstration on data analysis workflows (***Dr. Ashish Pargaonkar, Agilent***)

5.30-6.00: Discussion and Wrap-up


Prof. Manidipa Banerjee


Prof. Sudip Pattanayek


Dr. Ravindra Gudihal


Prof. Daniel Bracewell

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CONTINUOUS PROCESSING (13th December 2016)

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TITLE: **Continuous Processing for Production of Biopharmaceuticals: Basic Concepts and Case Studies**

DESCRIPTION: The merits of continuous processing over batch processing are well known in the manufacturing industry. Continuous operation results in shorter process times due to omission of hold steps, higher productivity due to reduced shut down costs and lowers labor requirement. Over the past decade, there has been an increasing interest in continuous processing within the bioprocessing community, specifically those involved in production of biotherapeutics. This course will address the topic of continuous processing with a focus on production of biotech therapeutics. Basic concepts that provide a foundation for this exercise will be presented together with a few case studies that demonstrate process integration.

OUTLINE:

8.30-9.00: Breakfast

9.00-9.30: Continuous processing (***Prof. Anurag Rathore, IITD***)

9.30-10.00: Enabling Technologies: Continuous clarification (***Dr. Holly Haughney, Pall Corporation***)

10.00-10.30: Enabling Technologies: Single pass TFF (***Dr. Venkat Ramana, Pall Corporation***)

10.30-11.00: Break

11.00-11.45: Enabling Technologies: Multicolumn chromatography (***Dr. Masilamani, Pall Corporation***)

11.45-12.30: Process integration in continuous processing (***Dr. Marc Bisschops, Pall Corporation***)

12.30-1.30: Lunch

1.30-2.15: Case Study 1: Use of continuous flow inverted reactor for continuous protein refolding and protein precipitation (***Nikhil Kateja, IIT Delhi***)

2.15-2.45: Case Study 2: Virus filtration (***Dr. Holly Haughney, Pall Corporation***)

2.45-3.15: Case Study 3: BioSMB (***Dr. Marc Bisschops, Pall Corporation***)

3.15-3.45: Break

3.45-4.15: Case Study 4: Continuous downstream process for production of GCSF (***Nikhil Kateja, IIT Delhi***)

4.15-5.00: Regulatory considerations in continuous processing (***Dr. Marc Bisschops, Pall Corporation***)

5.00-5.30: Discussion and Wrap-up


Dr. Holly Haughney


Dr. Marc Bisschops


Dr. Masilamani


Prof. Anurag S. Rathore


Dr. Venkat Ramana

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COMPUTATIONAL DESIGN (13th December 2016)

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TITLE: **In-Silico Design of Stable Biotherapeutic Formulations**

DESCRIPTION: Therapeutic proteins can aggregate during drug manufacture, shipping and storage. It has been recognized as a key quality attribute by the manufacturers and the regulatory agencies. In this course we will share our understanding of aggregation pathways and risk factors that can induce aggregation, right from the start of the drug development process. This is an essential aspect concerning the design of mitigation strategies and alignment of manufacturing processes. Significant strides in processor speed and development of new algorithms have made possible the use of compute in making meaningful interventions in biotherapeutical product development, allowing for significant cost and man-hour savings. We will discuss algorithms/software for free energy as well as equilibrium structure determination and present select case studies where this knowledge guided experimentalists in improving the solubility of therapeutic proteins.

OUTLINE:

8.30-9.00: Breakfast

9.00-9.45: Use of compute to elucidate molecule level origins of aggregation and its impact on product development (***Prof. Gaurav Goel, IITD***)

9.45-10.30: Protein aggregation in solution: free energy calculations (***Prof. K. Ganapathy Ayappa, IISc-Bangalore***)


Prof. K. Ganapathy Ayappa

10.30-11.00: Break

11.00-11.45: Effect of surface on protein aggregation and mitigating strategies (***Prof. Sudip Pattanayek, IITD***)

11.45-12.30: Recent advances in computational biology in biologics designing (***Dr. R. Raghu, Schrodinger***)


Prof. Gaurav Goel

12.30-1.30: Lunch

1.30-2.00: Case Study 1: Mitigating solvent effects (***Prof. K. Ganapathy Ayappa***)

2.00-2.30: Case study 2: Knowledge based peptide design to inhibit insulin aggregation (***Richa Rathore and Dr. Avinash Mishra, IITD***)

2.30-3.00: Case Study 3: Dependence of insulin aggregation on surface type (***Prof. Sudip Pattanayek, IITD***)


Prof. Sudip Pattanayek

3.00-3.30: Break

3.30-4.00: Case Study 4: Application of Computational methods in biopharmaceutical drug discovery (***Dr. M. Ravikumar, Schrodinger***)

4.00-5.30: Demo of Schrodinger Biologics suite (***Dr. M. Ravikumar, Schrodinger***)

5.30-6.00: Discussion and wrap-up

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COMPUTATIONAL FLUID DYNAMICS (13th December 2016)

TITLE: **Computational Fluid Dynamics simulations for biotech processes and medical devices**

DESCRIPTION: Biotech and Medical Devices industry faces challenges with increased market globalization, tougher regulation and ever increasing demand to reduce time-to-market. This directly impact process development in biotech industry and product development in medical device industry. Engineering simulations are becoming popular due to ability of CFD and other simulation methods to provide greater insights into processes and product performance. Simulation not only helps improving products, but can also help accelerating regulatory approvals.

OUTLINE:

8.30-9.00: Breakfast

9.00-9.30: Application of CFD simulation in engineering (***Prof. Jayati Sarkar, IITD***)

9.30-10.30: CFD Fundamentals: Governing equations in fluid flow and finite volume methods (***Prof. Jayati Sarkar, IITD***)

10.30-11.00: Break

11.00-12.00: Case Study 1: Modeling bioreactor and centrifuge using CFD methods (***Lalita Kanwar, IITD***)

12.00-12.30: Case Study 2: Use of CFD in medical device modeling (***Shital Joshi, Ansys***)

12.30-1.30: Lunch

1.30-3.00: Hands on work-shop (two tracks):

Track 1: Simulation of flow inside mixing tank (***Prof. Jayati Sarkar, IITD***)

Track 2: Simulation of fluid flow inside medical device (***Shital Joshi, Ansys***)

3.00-3.30: Break

3.30-4.00: Modeling of downstream processes using CFD (***Shital Joshi, Ansys***)

4.00-4.30: Introduction to multiphysics simulations (***Prof. Jayati Sarkar, IITD***)

4.30 -5.00: Role of simulation in regulatory (FDA) approvals (***Shital Joshi, Ansys***)

5.00-5.30: Discussion and Wrap-up


Prof. Jayati Sarkar


Shital Joshi

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QUALITY BY DESIGN & PROCESS ANALYTICAL TECHNOLOGY (14th December 2016)

TITLE: **Quality by Design (QbD) and Process Analytical Technology (PAT) for Biopharmaceuticals: Concepts and Applications in Development and Commercialization**

DESCRIPTION: Successful implementation of Quality by Design (QbD) and Process Analytical Technology (PAT) concepts requires that the concepts are put in place when the first activities around designing the product are initiated and then continue to be incorporated into the designing of the process that is used to make the product and other activities associated with the lifecycle of a pharmaceutical product. This course will allow the participants to better understand how their job responsibilities will evolve in the QbD/PAT paradigm, what is the big picture and the role they play in ensuring successful implementation of QbD/PAT.

OUTLINE:

8.30-9.00: Breakfast

9.00-9.45: Introduction to Quality by Design (***Prof. Anurag S. Rathore, IITD***)

9.45-10.30: Quality Risk Management
(***Dr. Scott Rudge, RCM Pharmaceutical Solutions, USA***)

10.30-11.15: Introduction to process analytical technology
(***Prof. Anurag S. Rathore, IITD***)

11.15-11.45: Break

11.45-12.15: Case Study 1: Role of modeling in QbD implementation
(***Prof. Shuichi Yamamoto, Yamaguchi University, Japan***)

12.15-12.45: Case Study 2: Model based PAT implementation towards process chromatography (***Lalita Kanwar, IITD***)

12.45-1.15: Case Study 3: Creation of PAT based control for a UF DF step
(***Vishwanath Hebbi, IITD***)

1.15-1.45: Case Study 4: Multivariate data analysis as a tool for QbD implementation
(***Sumit Kumar Singh, IITD***)

1.45-2:10: Discussion and Wrap-up

2.10-3.10: Lunch


Prof. Anurag S. Rathore


Dr. Scott Rudge


Prof. Shuichi Yamamoto

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REGISTRATION DETAILS

REGISTRATION FEES:

	Indian academic	Indian industry participant	Foreign academic	Foreign industry participant
One day	3000 INR	5000 INR	100 USD	200 USD
Three days	7000 INR	12000 INR	250 USD	500 USD

Discounts: ***Additional discount (10%) available before 15th November 2016***

LODGING AND BOARDING: Accommodation can be booked in nearby hotels/ guesthouses directly. For information please email: **coe.biopharma.course@gmail.com**

MODE OF PAYMENT FOR REGISTRATION: The registration fee should be paid only by NEFT transfer to one of the accounts mentioned below. The scanned registration form along with registration fee receipt should be sent by e-mail to Course Coordinator Prof. Anurag S. Rathore (IIT Delhi), at **coe.biopharma.course@gmail.com**

INDIAN PARTICIPANTS	FOREIGN PARTICIPANTS
Beneficiary Name: Foundation for Innovation and Technology **Bank Name:** State Bank of India **Account #:**10773571968 **Branch Name**: SBI, IIT Delhi Hauz Khas, New Delhi-110016 **IFS Code**: SBIN0001077 **MICR:** 110002156	**Beneficiary Name**: Foundation for Innovation and Technology **Bank Name:** State Bank of India **Account #:**1077 357 2123 **Branch Name**: SBI, IIT Delhi, Hauz Khas, New Delhi-110016 **Swift No.** SBI NIN BB 547 **Bank Code:** 1077

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Designation: …… Department: ……...

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Signature of the Applicant: …….

For further details, please contact **coe.biopharma.course@gmail.com**