

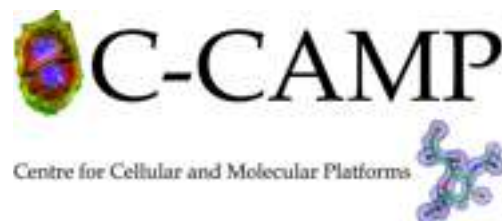


**BIOSIMILAR**  
WORKSHOP 2018

ICT, MUMBAI  
Nov. 29-Dec. 1



*In Partnership with*



# BIOSIMILAR-WORKSHOP-2018

**HANDS ON TRAINING FOR BIOSIMILAR/BIOLOGICS  
CHARACTERISATION, Nov.29-Dec.1-2018**



The Objective of this workshop is to provide hands on training to candidates from academia and Industry towards better understanding of biologics

- A. Experimental design and data interpretation of higher order structure and binding kinetics by ligand tracer (ICT)
- B. Experimental design and data interpretation of Glycan analysis (USP)

**Techniques: DLS, AUC, Q-TOF, CAP ELECTROPHORESIS, LIGAND TRACER , HILIC**

**Participation/Sponsorship Interest: [rd.jain@ictmumbai.edu.in](mailto:rd.jain@ictmumbai.edu.in) Web: [www.biosimilarindia.com](http://www.biosimilarindia.com)**



# About Institute of Chemical Technology



- Set Up in 1933 to help the Indian Chemical Industry: Autonomous-Elite Institute of the State of Maharashtra
- Imparts graduate and postgraduate (MS/PhD) education in Chemical Engineering and Applied Chemical Technology
  - Best Chemical Engineering program in India
  - Amongst the Best Biotechnology Programs in India
- Unparalleled Impact to Indian Society
  - 500+ First generation 'chemical' entrepreneurs
  - Scientific advisors to Indian governments
  - Head of National Research Labs
- Significant International Impact
  - International academies (eg. FRS) and societies



Mukesh Ambani  
Reliance



Anji Reddy  
Dr. Reddy's



Kishor Mariwala  
Marico



Nilesh Gupta  
Lupin



NiKhil Meswani  
Reliance



N. Sekhsaria  
Gujrat Ambuja



Ashwin Dani  
Asian Paints



MB Parekh  
Pidilite

## International Scientific Impact

### Civilian Honours



Prof. MM Sharma  
Padma Vibhushan  
Padma Bhushan



DR. RA Mashelkar  
Padma Bhushan  
Padma Shri



Prof. JB Joshi  
Padma Bhushan



Prof. GD Yadav  
Padma Shri

## About BIRAC



Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-profit Section 8, Schedule B, Public Sector Enterprise, set up by Department of Biotechnology (DBT), Government of India as an Interface Agency to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs.

BIRAC is a new industry-academia interface and implements its mandate through a wide range of **impact initiatives**, be it providing access to risk capital through targeted funding, technology transfer, IP management and handholding schemes that help bring **innovation excellence** to the biotech firms and make them globally competitive. In its five years of existence, BIRAC has initiated several schemes, networks and platforms that help to **bridge the existing gaps** in the industry-academia Innovation research and facilitate novel, high quality affordable products development through cutting edge technologies. BIRAC has initiated partnerships with several national and global partners to collaborate and deliver the salient features of its mandate.

### Vision

"To Stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry, particularly start-ups and SME's, for creation of affordable products addressing the needs of the largest section of society"



## USP: Glycan Training Course (Chapter <212>)

**Date: 29.11.2018**

9.00 AM to 5.00 PM

- Introduction
- Presentation on “USP Compendial Procedures for N-Glycan Analysis”
- Tea Break
- Presentation on “USP Compendial Procedures for N-Glycan Analysis” – contd.
- Hands-on (Group demonstration) - Glycan sample preparation as per USP <212>, HILIC-1
- Lunch
- Presentation on “USP Compendial Procedures for N-Glycan Analysis” – contd.
- Tea Break
- Hands -on (Group demonstration) - “Glycan sample preparation as per USP <212>, HILIC -1 & CE-LIF analysis – contd.
- Wrap-up for the day

**Date: 30.11.2018**

9.00 AM to 5.00 PM

- Hands -on (Group demonstration) - Glycan analysis as per USP GC <212>, HILIC-1 & CE-LIF
- Tea Break
- QA & Discussion
- Lunch
- Case studies on USP <212> HILIC -2 & HPAEC analysis
- Tea Break
- Data review & discussion on HILIC-1 & CE-LIF analysis
- Wrap-up

### End of Program

**Registration Fees: Rs. 10,000 (Students) Rs. 15,000 (Academics) Rs. 25,000 (Industry)**

**\*BIRAC Grantee Will Receive 10% Discount**

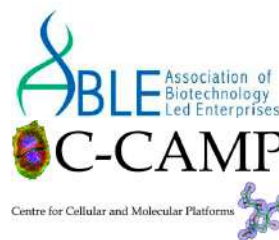
Trainer:

1. Ms. Anjali Chillara, USP
2. Dr. Manoj Metta, USP

<http://www.nano-medicine.co.in/biosimilar-workshop-2018.html>



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## Workshop on Protein Aggregation and Higher Order Structure Analysis

Date: 29.11.2018

9.00 AM to 5.00 PM

### **Global Methods: Sedimentation Velocity Analytical UltraCentrifuge, Theoretical and Experimental Sessions**

AUC Sample Preparation: Key to generate “right” data  
Principle of sedimentation boundary modeling (Lamm equation)  
Apparent sedimentation coefficient distribution  $g^*(s)$  analysis  
Sedimentation coefficient distribution  $c(s)$  analysis

**Faculty: Marianne Saldanha, ICT**

**Nanda Rohra, ICT**

**Prasad Satyamurthy, Lupin Limited**

**Pramod Madoori, Wockhardt**

### **Global Methods: Dynamic Light Scattering, Theoretical and Experimental Sessions**

Understanding Rayleigh scattering intensity, Diffusivity Concept  
Sample Preparation: Key to generate “right” data  
Experimentation and Recording of Data

**Faculty: Aditya Narvekar, ICT**

**Sharwari Ghodke, ICT**

**Dr. PA Hassan, BARC**

**Dr. Anand Tadas, Malvern**

Date: 30.11.2018

9.00 AM to 5.00 PM

### **Global Methods: Sedimentation Velocity Analytical UltraCentrifuge, Theoretical and Experimental Sessions**

AUC Data Fitting  
Data Analysis using SEDFIT

**Faculty: Marianne Saldanha, ICT**

**Nanda Rohra, ICT**

**Prasad Satyamurthy, Lupin Limited**

***Pramod Madoori, Wockhardt***

**Global Methods: Dynamic Light Scattering, Theoretical and Experimental Sessions**

Data Fitting and Calculations

Data Analysis and interpretation

***Faculty: Aditya Narvekar, ICT***

***Sharwari Ghodke, ICT***

***Dr. PA Hassan, BARC***

***Dr. Anand Tadas, Malvern***

**Secondary and Tertiary Structural Analysis**

Case Studies for Secondary and Tertiary Structure Analysis using NMR, CD, DSC, Mass Spectroscopy

**Faculty**

**Navratna Vajpai, Biocon**

**Amarnath Chatterjee, Wockhardt**

**Dipak Thakur, ACRNS Analytical**

**Ashutosh Kumar, IIT-B**

**Sankaranarayanan Srinivasan, Intas Biopharma**

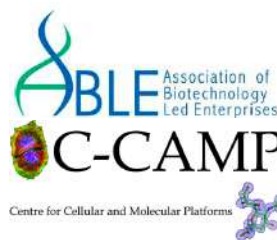
**End of Program**

**Registration Fees: Rs. 10,000 (Students) Rs. 15,000 (Academics) Rs. 25,000 (Industry)**

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## Workshop on Upstream Bioprocessing

Date: 29.11.2018

9.00 AM to 5.00 PM

### Bioreactor: System Operation

- How to prepare fermentor/bioreactor to reduce chance of contamination in cell culture
- Control strategies for reactor operation

### Bioprocess Scale-Up From Small Scale to Pilot/Production Scale

#### Scale Up Consideration

- Tip speed (calculation)
- Hands-on for OTR/kLa determination (Gassing Out Methods)
- Sulphite Method

**Faculty: Kritika Gupta, ICT**

**Nagendra Gowda, ICT**

**Kaamil Bhavsar, Adello Biologics**

**Abhishek Mule, Eppendorf**

**Lay Koon Goh, Eppendorf**

Date: 30.11.2018

9.00 AM to 5.00 PM

### Bioprocess Scale-Up from Small Scale to Pilot/Production Scale

#### Scale Up Consideration

- Hands-on for OTR/kLa determination (Gassing Out Methods)
- Sulphite Method

**Faculty: Kritika Gupta, ICT**

**Nagendra Gowda, ICT**

**Kaamil Bhavsar, Adello Biologics**

**Abhishek Mule, Eppendorf**

**Lay Koon Goh, Eppendorf**

### **Advances in Upstream Bioprocessing**

Rahul Bhambure, NCL, Pune: High cell density E. coli fermentation for antibody fragments production: rHu Ranibizumab a case study.

Debojyoti Chakraborty, IGIB, New Delhi: CRISPR case studies and Gene Editing

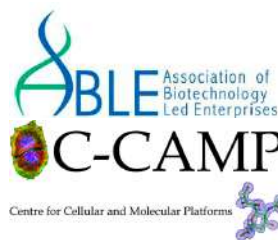
### **End of Program**

**Registration Fees: Rs. 2,500 (Students) Rs. 5,000 (Academics) Rs. 10,000 (Industry)**

**\*BIRAC Grantee Will Receive 10% Discount**



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## Workshop on Binding Kinetics Using Ligand Tracer

Date: 30.11.2018

9.00 AM to 5.00 PM

**LigandTracer introduction/welcome, brief presentation**

**(lab): Explain principle, baseline, 1<sup>st</sup> concentration (cetuximab)**

**Introduction, basic kinetics, application examples**

**(lab): 2<sup>nd</sup> concentration, explain cell seeding & fluorescent labeling**

**Computer exercise (LigandTracer Learning)**

**(lab): dissociation & comment on binding data**

**Intro to data evaluation in TraceDrawer, Q&A session**

**End of Program**

**Registration Fees: Rs. 2,000 (Students) Rs. 5,000 (Academics) Rs. 10,000 (Industry)**





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## Workshop on Entrepreneurship for Biopharmaceuticals (BIRAC Day)

Date: 01.12.2018

8.00 AM to 9.00 AM | Registration

### Tentative Program

9.00 AM to 9.15 AM	Inaugural Address (VC, ICT) <b>Session Chair: Prof. Arvind Lali, ICT</b>
9.15 AM to 9.45 AM	National Biopharma Mission Speaker: Kavita Singh/TBD, BIRAC
9.45 AM to 10.15 AM	BIRAC Scheme (e.g. Early Stage Funds, Late Stage Funds, ACE Funds) Speaker: Manish Diwan/PKS Sarma/TBD, BIRAC
10.15 AM to 10.30 AM	Motivational Talk: Innovation and Entrepreneurship: Dr. R. Ramanan, Atal Innovation Mission, NITI Aayog
10.30 AM to 11.00 AM	<b>Tea, Breakfast and Networking</b> <b>Session Chair: Prof. Rohit Srivastava, IIT-B</b>
11.00 AM to 11.10 AM	Incubation Opportunities in Mumbai: SINE, IITB, Mumbai
11.10 AM to 11.20 AM	Incubation Opportunities in Mumbai: NMIMS, Mumbai
11.20 AM to 11.30 AM	Incubation Opportunities in Mumbai: KJ Somaiya, Mumbai
11.30 AM to 11.45 AM	<b>Session Chair: Dr. Samir Kulkarni, Founder, inBiocognate</b> Dr. Anand Khedkar, Sekkei Bio Pvt Ltd, Bengaluru
11.45 AM to 12.00 PM	Dr. Pankaj Sharma, Lead Invent, New Delhi
12.00 PM to 12.15 PM	Shantani Biotech, Pune
12.15 PM to 12.30 PM	Narasimha Rao Nedunuri, Clonz Biotech, Hyderabad
12.30 PM to 12.40 PM	Conclusion

### End of Program

**Audience: Students, Academician, Young Entrepreneurs, Investors, Govt. Officials, Journalist**

**Registration Fees: Rs. 500 (Students) Rs. 1000 (Academics) Rs. 2000 (Industry)**

Website: <http://www.nano-medicine.co.in/biosimilar-workshop-2018.html>



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## Biosimilar Workshop: Leadership Conclave

**Date: 01.12.2018**

2.00 PM to 2.30 PM

Inauguration and Setting the Pitch of Discussion (Chief Guest and Ratnesh Jain)

### Tentative Program

2.30 PM to 3.15 PM

Panel 1: Need and Challenges of Skilled Workforce for Biopharmaceutical Industry  
Moderator: Dr. Ranjit Madan, CEO, LSSSDC  
Panel Members: Leadership from Biopharma Industry, Academia and Government

3.15 PM to 3.30 AM

Q&A and Summary of Panel Discussion by Moderator

3.30 PM to 4.15 PM

Panel 2: Entrepreneurship model needed for the growth of biopharmaceutical industry  
Moderator: Mr. Narayanan Suresh, COO, ABLE  
Panel Members: Leadership from Biopharma Industry, Academia and Government

4.15 PM to 4.30 PM

Q&A and Summary of Panel Discussion by Moderator

4.30 PM to 5.00 PM

**Tea, Snacks and Networking**

5.00 PM to 5.45 PM

Panel 3: Development of Shared Infrastructure/Biopharmaceutical Institute under PPP model for Biopharmaceutical Industry  
Moderator: TBD  
Panel Members: Leadership from Biopharma Industry, Academia and Government

5.45 PM to 6.00 PM

Q&A and Summary of Panel Discussion by Moderator

6.00 PM to 6.15 PM

Conclusion and Vote of Thanks

6.15 PM to 8.30 PM

Networking, Dinner and Departure

*\*Participation in Leadership Conclave is by Invitation Only. Please contact Dr. Ratnesh Jain (rd.jain@ictmumbai.edu.in) for more information.*

## PAST PARTICIPANTS PROFILE



## REGISTRATION

REGISTRATION DEADLINE	November 25, 2018
REGISTRATION FEES	₹ 25,000 (Industry)
(Per Workshop)	₹ 15,000 (Academic, Faculty, Scientist)
	₹ 10,000 (PhD Students, Postdoc. Fellow)

\*BIRAC Grantee will receive 10% Discount

Contact :

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Email: [biosimilarworkshop2018@nano-medicine.co.in](mailto:biosimilarworkshop2018@nano-medicine.co.in)

Website: [www.biosimilarworkshop.com](http://www.biosimilarworkshop.com)

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