



## Downstream Processing for Production of Biologicals

**Overview:** Bio-therapeutics form an important part of modern medicines. Complexity of bio-therapeutics molecules necessitates elaborate purification processes involving a number of unit operations like chromatography, refolding, precipitation, filtration to target process and product related impurities. Selection of such unit operation depends on the expression system and specific purification requirements of the molecule. For example- refolding is required for proteins expressed as inclusion bodies whereas precipitation for removal of process related impurities like host cell proteins and DNA precipitation. Majority of purification processes, however, involves one or more chromatography steps because of its unmatched selectivity, robustness and scalability. Purification processes may also include conditioning of process streams in terms of concentration and buffer exchange which can be carried out in tangential flow filtration. Each unit operation demands a large number of parameters to be fine-tuned. This has led to the widespread adoption of high-throughput screening (HTS) technologies, which are characterized by miniaturization, automation and parallelization. The four-day course work organized by GIAN at IIT Delhi will broadly cover important bio-pharma topics including high-throughput techniques, chromatography, filtration and refolding for purification of therapeutic proteins and will also include hands on training.

<b>Dates</b>	11 <sup>th</sup> December to 14 <sup>th</sup> December 2018
<b>Host Institute / Venue</b>	Indian Institute of Technology (IIT), Delhi Lecture Hall Complex (LHC), IIT Delhi
<b>Participants</b>	Limited to 20
<b>Who Should Attend</b>	<ul style="list-style-type: none"><li>❖ Executives, engineers involved in chemical engineering / Life-sciences from academia and manufacturing, service and government organizations including R&amp;D laboratories.</li><li>❖ Students at all levels (B.Tech/MSc/M.Tech/PhD) or Faculty Members/Scientists from reputed academic institutions and technical institutions.</li></ul>
<b>Course Registration Fees</b>	The participation fees for taking the course is as follows: <ul style="list-style-type: none"><li>✚ <b>Research Scholars/Students:</b> Rs.5000/-</li><li>✚ <b>Faculty:</b> Rs.10000/-</li><li>✚ <b>Working Professionals:</b> Rs.15000/-</li><li>✚ <b>Participants from Abroad:</b> US \$ 500</li></ul> The above fees ( <b>inclusive of GST</b> ) and includes the use of all instructional materials assigned for the course and laboratory equipment usage charges.
<b>Registration Process</b>	<p><b>Step 1: GIAN web Portal Registration:</b> Register in the GIAN portal i.e. <a href="http://www.gian.iitkgp.ac.in/GREGN/index">http://www.gian.iitkgp.ac.in/GREGN/index</a> by paying Rs. 500/- online. Registration to this portal is the one-time affair and will be valid for the lifetime of GIAN. Please note that course fee is separate.</p> <p><b>Step 2:</b> Login to the GIAN portal with the registered User ID and Password. Choose for the Course registration option. Select the course titled "Downstream Processing for Production of Biologicals" from the list and click the "Save" option. Confirm your registration by clicking the suitable option.</p> <p><b>Step 3: Course Shortlisting:</b> Candidates will be intimated through email regarding their selection.</p> <p><b>Step 4: Course Fee Remittance:</b> Once you receive the intimation from the Course Coordinator, the fee (as</p>

applicable) need to be paid. The participants will be provided with accommodation (if available) on payment basis.

**Step 5: Mode of payment:** The details of fee payment by Electronic Clearing Service/ RTGS/ Demand Draft in the name of **"IITD CEP ACCOUNT"**. The bank details are as follows:

1	Bank Account No.	36819334799
2	Bank Address	State Bank of India, IIT Delhi, Hauz Khas New Delhi-16
3	MICR Code	110002156
4	Beneficiary	IITD CEP ACCOUNTS
5	IFSC Code	SBIN0001077
6	MICR Code	110002156
7	SWIFT Code	SBININBB547
8	IITD PAN No.	AAATI0393L
9	Account Type	Saving

The participants are required to send the Demand Draft for the registration fee to the Coordinator:

**Prof. Anurag S Rathore**  
**Department of Chemical Engineering**  
**Room no 94, Block 2, Indian Institute of Technology, Delhi**  
**Hauz Khas, New Delhi-110016**

**Step 5:** Fill up the registration form (Given in Page no. 5 of this brochure), by providing details of the bank transaction. Send the scanned copy of registration form to the Course coordinator at [coe.biopharma.course@gmail.com](mailto:coe.biopharma.course@gmail.com) before **30<sup>th</sup> November 2018**

**Tentative Lecture Schedule**

<b>Day 1 (11<sup>th</sup> December 2018)</b>			
<b>Timing</b>	<b>Session 1</b>	<b>Duration</b>	<b>Teaching faculty</b>
9:00 am to 10:00 am	Lecture: Introduction to Downstream Processing	1.0 hrs	Prof. Anurag S Rathore
10:00 am to 10:20 am	Tea break		
10:20 am to 11:20 am	Lecture: Introduction to Chromatography and Filtration	2.1 hrs	
11:20 am to 12:30 pm	Lecture: Introduction to Refolding and Precipitation		
<b>Timing</b>	<b>Session 2</b>	<b>Duration</b>	
12:30 pm to 1:30 pm	Lunch break		
1:30 pm to 5:30 pm	<ul style="list-style-type: none"> <li>Group 1 (5 members): Refolding</li> <li>Group 2 (5 members): Precipitation</li> <li>Group 3 (5 members): Chromatography</li> <li>Group 4 (5 members): Filtration</li> </ul>	4 hrs	Prof. Shuichi Yamamoto
<b>Day 2 (12<sup>th</sup> December 2018)</b>			
<b>Timing</b>	<b>Session 1</b>	<b>Duration</b>	<b>Teaching faculty</b>
9:00 am to 10:00 am	Lecture: PEG precipitation	2 hrs	Prof. Shuichi Yamamoto
10:00 am to 10:20 am	Tea break		
10:20 am to 11:20 am	Lecture: High throughput experimental methods on PEG precipitation		
11:20 am to 12:30 pm	Tutorial	1.17 hr	
<b>Timing</b>	<b>Session 2</b>	<b>Duration</b>	
12:30 pm to 1:30 pm	Lunch break		

	1:30 pm to 5:30 pm	Hands on training <ul style="list-style-type: none"> <li>Group 1 (5 members): Precipitation</li> <li>Group 2 (5 members): Chromatography</li> <li>Group 3 (5 members): Filtration</li> <li>Group 4 (5 members): Refolding</li> </ul>	4 hrs	Prof. Shuichi Yamamoto
	<b>Day 3 (13<sup>th</sup> December 2018)</b>			
	<b>Timing</b>	<b>Session 1</b>	<b>Duration</b>	<b>Teaching faculty</b>
	9:00 am to 10:00 am	Lecture: Stability of proteins	1 hr	Prof. Shuichi Yamamoto
	10:00 am to 10:20 am	Tea break		
	10:20 am to 11:20 am	Lecture: Fundamentals on bio-separation	1 hr	Prof. Shuichi Yamamoto
	11:20 am -12:00 pm	Monitoring of Protein A column Breakthrough	45 mins	Dr. Richard Willson
	12:00 pm to 12:45 pm	Tutorial	1 hr	Prof. Shuichi Yamamoto
	<b>Timing</b>	<b>Session 2</b>	<b>Duration</b>	
	12:45 pm to 1:30 pm	Lunch break		
	1:30 pm to 5:30 pm	Hands on training <ul style="list-style-type: none"> <li>Group 1 (5 members): Chromatography</li> <li>Group 2 (5 members): Filtration</li> <li>Group 3 (5 members): Refolding</li> <li>Group 4 (5 members): Precipitation</li> </ul>	4 hrs	Prof. Shuichi Yamamoto
<b>Day 4 (14<sup>th</sup> December 2018)</b>				
	<b>Timing</b>	<b>Session 1</b>	<b>Duration</b>	<b>Teaching faculty</b>
	9:00 am to 10:30 am	Lecture: Bioprocess integration	3.17 hrs	Prof. Shuichi Yamamoto
	10:30 am to 10:50 am	Tea break		
	10:50 am to 12:00 pm	Lecture: Bioprocess optimization		
	<b>Timing</b>	<b>Session 2</b>	<b>Duration</b>	
	12:00 pm to 1:00 pm	Lunch break	1 hr	
	1:00 pm to 5:00 pm	Hands on training <ul style="list-style-type: none"> <li>Group 1 (5 members): Filtration</li> <li>Group 2 (5 members): Refolding</li> <li>Group 3 (5 members): Precipitation</li> <li>Group 4 (5 members): Chromatography</li> </ul>	4 hrs	Prof. Shuichi Yamamoto
	5:00 pm to 5:30 pm	Valedictory Session		
<b>Accommodation</b>	<p>The participants (students) may be provided with hostel accommodation, depending on the availability, on payment basis.</p> <p>The faculty &amp; working professional may be provided with faculty guest house accommodation, depending on the availability, on payment basis.</p>			



## The Faculty



Prof. Shuichi Yamamoto is Professor of Bioprocess Engineering at School of Engineering & Graduate School of Medicine, Yamaguchi University, Japan. His research interests are in the field of biochemical engineering, food engineering and mass transfer. He has published more than 100 scientific papers. Among them, his monograph published in 1988 by Marcel Dekker (Now Taylor & Francis) "Ion-Exchange Chromatography of Proteins" is well-known. His chromatography model better known as "Yamamoto Model" and "Yamamoto number" has been employed by various biotech companies as well as by academic researchers. Recently, he published a book chapter, in which various application of these models are explained (Preparative chromatography for separation of proteins, edited by A. Staby, A. S. Rathore, S. Ahuja, Chapter 4, pp, 111- 157, Wiley, 2017). Currently, he is president of Asian-Pacific Confederation of Chemical Engineering.



Prof. Anurag S Rathore is Professor at the Department of Chemical Engineering, Indian Institute of Technology, Delhi, India. 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, process analytical technology and quality by design. He has authored more than 400 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* and *PDA Journal of Science and Technology*. He also serves on the Editorial Advisory Boards for *Biotechnology Progress*, *BioPharm International*, *Pharmaceutical Technology Europe* and *Separation and Purification Reviews*. Dr. Rathore has edited books titled *Novel Bioprocessing Technology for Production of Biopharmaceuticals and Bioproducts*, *Preparative Chromatography for Separation of Proteins and Peptides*, *Quality by Design for Biopharmaceuticals: Perspectives and Case*

## Course Coordinator

Prof. Anurag S Rathore  
Department of Chemical Engineering  
Indian Institute of Technology (IIT Delhi)  
Mobile: +91-9650770650  
Landline: +91-11-26591098  
Fax: +91-1126596279  
E-mail: [asrathore@biotechcmz.com](mailto:asrathore@biotechcmz.com)  
Website: [www.biotechcmz.com](http://www.biotechcmz.com)

<http://www.gian.iitkgp.ac.in/GR>  
EGN

*Studies (2009), Elements of Biopharmaceutical Production (2007), Process Validation (2005), Electro kinetic Phenomena (2004) and Scale-up and Optimization in Preparative Chromatography (2003). He has a Ph.D. in Chemical Engineering from Yale University.*



**GIAN COURSE REGISTRATION FORM**

**(11<sup>th</sup> December 2018 to 14<sup>th</sup> December 2018)**

**NAME:** .....

**DESIGNATION:**.....

**ORGANIZATION:** .....

**ADDRESS:** .....

.....

.....

**EMAIL ID:** .....

**MOBILE NO.** .....

**COURSE NAME:**.....

**Fees payable to "IITD CEP ACCOUNT" , SBI , IIT DELHI**

**TRANSACTION NO. (e-transfer/RTGS/NEFT) .....**

**DEMAND DRAFT NO.(If paid by Demand Draft).....**

**Place :** .....

**Date :** .....

**Signature of the Applicant:** .....