



# Critical Quality Attributes of Biologics and Biosimilar

3-7 February 2020 | Institute of Chemical Technology, Mumbai

In spite of recent advancements in analytical technologies, it remains challenging and time-consuming to fully characterize all variants of mAb products. Although mAb molecular heterogeneities are usually well characterized, their correlations among each other, such as glycosylation and charge heterogeneities, are often less understood. Glycosylation and charge variant understanding is critical for development of protein therapeutics. Ion exchange chromatography, isoelectric focusing, and capillary electrophoresis are commonly employed for charge profiling, whereas liquid chromatography–mass spectrometry (LC–MS) is often limited to structural characterization of isolated charge variants due to its technical complexity. The module shall highlight the understanding of PTMs and glycosylation process, factors affecting glycosylation, fundamentals of mass spectroscopy, capillary electrophoresis and data interpretation.

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Organising Partner



Management Partner



Time	Activity Details	Speaker/Expert	Junior Expert	Location
<b>Day 1: 03.02.2020</b>				
08:00 am – 08:30 am	Breakfast			Pidilite Pavillion
08:00 am – 09:00 am	Registration			Marble Hall
09:00 am – 11:30 am	Inauguration, Welcome address, Introduction - Participants	<b>Prof. A.B. Pandit</b> , Vice Chancellor, ICT Mumbai <b>Dr. Ratnesh Jain</b> , UGC Assistant Professor, ICT Mumbai <b>Dr. Hardeep Vora</b> , Program Manager, BIRAC <b>Dr. Shreerang Joshi</b> , HOD, Department of Pharmaceutical Sciences and Technology <b>Dr. A.W. Patwardhan</b> , HOD, Department of Chemical Engineering <b>Dr. Purnima Sharma</b> , Managing Director, BCIL <b>Dr. Narendra Chirmule</b> , CEO, Symphonytech Biologics <b>Dr. Dhananjay Patankar</b> , Vice-President, Syngene <b>Dr. Prajakta Dandekar Jain</b> , ICT UGC Assistant Professor, ICT Mumbai	--	KV Auditorium
11:30 am – 12:00 pm	Tea Break			Pidilite Pavillion
12:00 pm – 12:30 pm	Key note lecture: CQA in biologics	<b>Dr. Jyoti Iyer</b> , Biocon		CE conference Room
12:30 pm – 01:00 pm	Keynote Lecture: Importance of “Critical Quality Attributes” in development of Therapeutic proteins	<b>Dr. Venkat Yetaru</b> , Lupin		CE conference Room
01:00 pm – 01:30 pm	Keynote lecture: Identification and Characterization of Critical Quality Attributes in Biologics: Biophysics to the rescue!	<b>Dr. Amarnath Chatterjee</b> , Wockhardt	--	CE conference Room
01:30 pm – 02:30 pm	Lunch Break			Pidilite Pavillion
02:30 pm – 03:00 pm	Lecture: Basics of Data analysis and interpretation of N-Glycan Analysis and Peptide mapping data obtained by LCMS	<b>Dr. Babu Ponnusamy</b> , Intas	--	Pharma conference room
03:00 pm – 06:00 pm	2D-LC Introductory Lecture and Experimental setup	<b>Dr. Debdip Ghosh</b> , <b>Dr. Ashish Pargaonkar</b> and <b>Ms. Paramjeet Khandpur</b> , Agilent Technologies	Ms. Amita Puranik, Mr. Lalit Khare	Pharma conference room and Pharm Biotech Lab
<b>Day 2: 04.02.2020</b>				
08:30 am – 09:00 am	Breakfast			Pidilite Pavillion
09:00 am – 09:30 am	Lecture: Strategic applications of ion-mobility mass spectrometry for the characterization of Biopharmaceuticals	<b>Dr. Jayaprakash Natarajan</b> , Stelis Pharma		Pharma conference room
09:30 am – 01:30 pm	Glycan Analysis and LC-MS setup	<b>Dr. Debdip Ghosh</b> , <b>Dr. Ashish Pargaonkar</b> and <b>Ms. Paramjeet Khandpur</b> , Agilent Technologies	Ms. Amita Puranik, Mr. Lalit Khare	Pharma conference room and Pharm Biotech Lab
01:30 pm – 02:30 pm	Lunch			Pidilite Pavillion
02:30 pm – 06:00 pm	LC-MS Experiment: Intact and Peptide Mapping	<b>Dr. Debdip Ghosh</b> , <b>Dr. Ashish Pargaonkar</b> and <b>Ms. Paramjeet Khandpur</b> , Agilent Technologies	Ms. Amita Puranik, Mr. Lalit Khare	Pharma conference room and Pharm Biotech Lab

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<b>Day 3: 05.02.2020</b>				
08:30 am – 09:00 am	Breakfast			Pidilite Pavillion
09:00 am – 11:00 am	2D-LC Data Interpretation	<b>Dr. Ashish Pargaonkar</b> , Agilent Technologies <b>Dr. Paramjeet Khandpur</b> , Agilent Technologies	Ms. Amita Puranik, Mr. Lalit Khare	Pharma Conferece Room
11:00 am – 11:30 am	Tea Break			
11:30 am – 01:30 pm	Capillary Electrophoresis: Lecture and Data Analysis	<b>Dr. Prashant Dour</b> and <b>Mr. Sagar Amberkar</b> , Sciex; <b>Dr. Manish Singh</b> and <b>Mr. Hitesh Sharma</b> , Bio-Techne	Ms. Amita Puranik, Ms. Nanda Rohra	Analytical Instruments Lab-II, CE & Pharma Conference Room
01:30 pm – 02:30 pm	Lunch Break			
02:30 pm – 06:00 pm	Capillary Electrophoresis: Lecture and Data Analysis	<b>Dr. Prashant Dour</b> and <b>Mr. Sagar Amberkar</b> , Sciex; <b>Dr. Manish Singh</b> and <b>Mr. Hitesh Sharma</b> , Bio-Techne	Ms. Amita Puranik, Ms. Nanda Rohra	Analytical Instruments Lab-II, CE & Pharma Conference Room
<b>Day 4: 06.02.2020</b>				
08:30 am – 09:00 am	Breakfast			Pidilite Pavillion
09:00 am – 09:30 am	Lecture : Protein Metrics Byos Host Cell Protein Workflow for Comprehensive Characterization of Host Cell Proteins in biopharmaceutical products	<b>Dr. Dipak Thakur</b> , ACRNS Analytical Technologies		Pharma Conference Room
09:30 am – 10:00 am	Lecture: Controlling N-glycosylation in the manufacture of biosimilars	<b>Dr. Narasimha Krishnakumar</b> , Senior Lead Investigator, Syngene International Limited		Pharma Conference Room
10:00 am – 10:30 am	Lecture: Sweet Talk on Glycan analysis for Antibody Characterization	<b>Dr. Wang Tian Hua</b> , Product Specialsit, Shimadzu		Pharma Conference Room
10:30 am – 11:00 am	Tea Break			
11:00 am – 01:30 pm	Method Set-up for Cell Culture Profiling and Protein Characterization on Q-ToF LCMS	<b>Dr. Wang Tian Hua, Dr. Deepti Bhandarkar</b> , Shimadzu	Ms. Amita Puranik, Ms. Marianne Saldanha	Textile Department Lab
01:30 pm – 02:30 pm	Lunch Break			
02:30 pm – 03:00 pm	Key note lecture: Biosimilar/ Biotherapeutic protein and peptide characterization by mass spectrometry	<b>Prof. Utpal Tatu</b> , IISC Bangalore		CE conference Room
03:00 pm – 03:30 pm	Keynote lecture: Critical Quality Attributes for a therapuetic biologic	<b>Dr. M.S. Ramakrishnan</b> , Biocon		CE conference Room
03:30 pm – 06:30 pm	MS Data Analysis Session	<b>Dr. Wang Tian Hua, Dr. Deepti Bhandarkar</b> , Shimadzu	Ms. Amita Puranik, Ms. Marianne Saldanha	Pharma Conference Room

Time	Activity Details	Speaker/Expert	Junior Expert	Location
Day 5: 07.02.2020				
08:30 am – 09:00 am	Breakfast			
09:00 am – 11:30 am	Lecture: Impact and need of data analytics across lifecycle of biopharmaceuticals	<b>Mr. Vaibhav Patil</b> , Sartorius Stedim	--	KV Auditorium
	Lecture: Design of Experiments	<b>Mr. Vinay Babu</b> , Biocon		
11:30 am – 12:00 pm	Keynote Lecture: Impact and Importance of Standards on Biotherapeutic Development	<b>Dr. Kevin Carrick</b> , Director, USP-RKV	--	KV Auditorium
12:00 pm – 12:30 pm	Keynote Lecture: Data Integrity and Ethics for Biopharmaceutical Product Development	<b>Dr. Francis Crawley</b> , Executive Director, GCPA		KV Auditorium
12:30 pm – 01:15 pm	Keynote Lecture: Innovative technologies for the expression of next generation biotherapeutics	<b>Dr. Amita Goel</b> , CEO, Cell theon Corporation	--	KV Auditorium
01:15-02:00	Lunch Break			
02:00-02:30	Inauguration of Job Mela	<b>Dr. Meenakshi Munshi</b> , DBT, Govt. of India	--	Pidilite Pavillion
02:30-04:30	HR Talks: Biopharmaceutical Industry		--	Pidilite Pavillion