Title: Hands-on-training program on CQA of biologics/biosimilar

Venue: Institute of Chemical Technology, Mumbai

Dates: 3rd Feb – 7th Feb, 2020

Keynote Speakers

Dr. Jyoti Iyer, General Manager, Biocon Dr. Venkata Yeturu, Head R&D Analytical, Lupin Dr. Dipak Thakur, Director, ACRNS Analytical Technologies Prof. Utpal Tatu, IISC Bangalore

Speaker (Senior Expert)

Dr. Navratna Vajpai , Biocon
Dr. Ashish Pargaonkar, Application Specialist, Agilent Technologies
Dr. Debdip Ghosh, Agilent Technologies
Dr. Amarnath Chatterjee, Wockhardt

Junior Expert

Deepti Bhandarkar, Shimadzu
Prashnat Dour, Application Specialist, Sciex
Marianne Saldanha, ICT
Amita Puranik, ICT
Jayprakash Natrajan, Stelis Biopharma

Day-1: 3 rd Feb, 2020						
Sr. No.	Time	Activity				
1	09:30 – 11:00Am	Classroom Session: Introduction to Mass Spectrometry & its importance in CQA analysis of biopharmaceuticals				
		Lab Session: Introduction to MS Hardware & brief overview of software part				
2	11:15Am – 1:00 pm	Sample preparation initiation – Desalting using centrifugal ultrafilters				
3	2:00 pm – 3:00 pm	Lab Session: PNGase enzyme treatment for deglycosylation& incubation for over night				
4	3:00pm – 4:00pm	Classroom Session: Introduction to Capillary Electrophoresis &itscrucial role in CQA analysis				
5	4:30pm– 6:00 pm	Lab Session: Introduction to hardware & software of Capillary Electrophoresis				

Day-2: 4 th Feb, 2020							
		Lab Session: PNGase enzyme removal and sample purification by using cartridges					
1	9:30Am – 11:00 Am	Initiation of Glycan labelling & incubation					
2	11:30 Am – 1:00 pm	Lab Session: Introduction to Mass Spectroscopy based method development for glycan analysis & guidelines for method validation					
2		Mobile phase preparation					
		Initiation of HILIC column Cleaning					
3	2:00pm – 4:00 pm	Lab Session: Glycan Analysis on Mass Spectroscopy					
4	4:30pm – 6:00pm	Lab Session: Data Analysis & discussion session					
Day-3: 5 th Feb, 2020							
1	09:30 Am – 11:00 Am	Lab Session: Capillary electrophoresis based glycan analysis					
2	11:30 – 1:00 pm	Classroom Session: Introduction to LC-MS based charge variants analysis & Capillary electrophoresis based Charge variants analysis					
		Lab Session: LC-MS & Column Cleaning, Mobile phase preparation					
3	2:00pm – 4:00pm	Sample preparation (Desalting)					
4	4:30 – 6:00pm	Lab Session: LC-MS Based Charge variants analysis					
Day-4: 6 th Feb, 2020							
1	9:30 – 11:00 Am	Lab Session: Capillary Electrophoresis based charge variants analysis					
2	11:30 - 1:00pm	Classroom Session: Introduction to 2D LC MS					
3	2:00 – 4:00 pm	Lab Session: 2D LC-MS based glycan & Charge variants analysis					
4	4:30 – 6:00pm	Lab Session: 2D LC-MS based glycan & Charge variants analysis					
Day-5: 7 th Feb, 2020							
1	9:30 – 11:00Am	Lab Session: Data analysis & discussion session 2D LC-MS based sample analysis					
2	11:30 – 1:00pm	Classroom Session: Introduction to Protein Matrix Software for biopharmaceuticals characterization					
3	2:00 - 4:30 pm	Lab Session: Demo on application of Protein Matrix Software using previous MS based analysis data					