Centre of Excellence
Biopharmaceutical
Technology

CBT Course Series 2021

13th to 17th December, 2021

All times are in Indian Standard Time (IST)

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

MODULE 1- Analytical and Functional Characterization of Biotherapeutic Products
13th-16th December, 2021

Description: Development of protein-based medicines is the current burgeoning segment of the global pharmaceutical industry. India has successfully placed itself as a leader in "generic" segment and is now steadily working its way up to make a global mark in the "biotherapeutic" segment as well. Unlike a "generic" drug that is a chemically synthesized identical copy of the innovator drug, production of biotherapeutics is a complex process as it involves recombinant expression of the specific protein/ peptide in a biological host. Therefore, the amount and type of permissible structural and functional variations have to be strictly controlled to avoid adverse immunogenic responses arising from the different proteoforms. This requires extensive physiochemical characterization of the structure, structural variation and impurities that may arise from the manufacturing process itself or the host used for the protein production. The potential for the presence of multiple variants in protein-based pharmaceuticals highlights the indispensability of state-of-the-art analytical techniques that can measure these variants in a reliable and accurate manner. As no one technique can capture all possible structural variants of a protein in a high-throughput manner, multiple methods are used to study the different characteristics of each protein. This two-day course work organized by the DBT Center for Biopharmaceutical Technology and National Biopharma Mission at IIT Delhi broadly cover the various aspects of Analytical Characterization of Biotherapeutics including hands-on-training on the cutting-edge techniques used in the industry as well as academia.

OUTLINE

13th Dec. Mass Spectrometry in Biosimilar Characterization- Primary Structure & Glycosylation

2.00-2.45 PM: Keynote Lecture- Fundamentals of Mass Spectrometry ***(Ashish Pargaonkar, Agilent Technologies)***
2.45-3.00 PM: Q&A ***(Ashish Pargaonkar, Agilent Technologies)***
3.00-3.45 PM: Keynote Lecture- Application of MS in Biosimilar Characterization ***(Ashish Pargaonkar, Agilent Technologies)***
3.45-4.00 PM: Q&A ***(Ashish Pargaonkar, Agilent Technologies)***
4.00-4.30 PM: CE as an Orthogonal Separation Technique - Case Studies (***Ramesh Kumar, IIT Delhi)***
4.30-5.00 PM: Quantifying Glycan Through MS ***(Saurabh Nagpal, Agilent Technologies)***
5.00-5.30 PM: Characterization of Primary Structure Characterization and PTMs (***Sumit K. Singh, IIT BHU)***
5.30-6.00 PM: Panel Discussion

14th Dec. Higher Order Structure Characterization

9.00-10.00 AM: Keynote Lecture- Challenges in Characterization of Biosimilars ***(Anurag S. Rathore, IIT Delhi)***
10.00-11.00 AM: Keynote Lecture- NMR-HOS: ***(Ashutosh Kumar, IIT Bombay)***
11.00-11.30 AM: Aggregate Analysis- Analytical Platform: ***(Surbhi Gupta, IIT Delhi)***
11.30-12.00 PM: Assessment of Biosimilarity of Insulin Glargine- A Case Study ***(Neh Nupur, IIT Delhi)***
12.00-12.30 PM: Orthogonality- Recent Advances in HOS Assessment ***(Srishti Joshi, IIT Delhi)***
12.30-1.00 PM: Panel Discussion

15th Dec. Emerging Technologies in Biosimilar Characterization

2.00-3.00 PM: Keynote Lecture- Application of 2D-LC in Biopharma
(Davy Guillarme, University of Geneva)
3.00-3.15 PM: Q&A ***(Davy Guillarme, University of Geneva)***
3.15-4.00 PM: Keynote Lecture- Recent Advances in MS Applications for Biosimilar Characterization
(Vadi Bhat, Agilent Technologies)
4.00-5.00 PM: Case Studies in MS Based Characterization of Biotherapeutic Products
(Sumit K. Singh, IIT BHU)
5.00-5.30 PM: Panel Discussion

16th Dec. Functional Characterization and Similarity Assessment- Case Studies

9.00-10.00 AM: Keynote Lecture- Immunogenicity of Monoclonal Antibodies
(Narendra Chirmule, SymphonyTech Biologics)
10.00-11.00 AM: Keynote Lecture- Statistical Concepts for Drug Development
(Ravi Khare, SymphonyTech Biologics)
11.00-11.30 AM: Variability in Glycan Distribution of Biosimilars ***(Himanshu Malani, IIT Delhi)***
11.30-12.00 PM: Cell-based and Binding Assays for Functional Characterization
(Rozaleen Dash, IIT Delhi)
12.00-12.30 PM: Role of Interfacial Stress in Aggregation Analysis ***(Shravan Sreenivasan, IIT Delhi)***
12.30-1.00 PM: Panel Discussion

MODULE 2- Continuous Processing for Production of Biotherapeutic Products
14th-17th December, 2021

Description: Despite the technological advances, affordability of biotherapeutics continues to be poor not only for developing and underdeveloped nations but also for many others around the world. Biotherapeutics on average cost more than 20 times their pharmaceutical counterparts. Majority of these biotherapeutics act as a vital tool for treatment of a number of life-threatening diseases like cancer. With the number of cancer patients increasing drastically, the need for cheaper therapeutics has gained more relevance. This requires advancements in manufacturing that can offer higher productivity and better economics without sacrificing product quality. In this regard, continuous bioprocessing holds great promise. In comparison to traditional batch processes, continuous processes offer a number of benefits such as improved productivity, product homogeneity, superior quality assurance reduced cost of manufacturing, easy accessibility and affordability of biotherapeutic. Biotherapeutics industry presently is undergoing a transition from batch to continuous processing by investing in novel continuous processing technologies for different unit operations starting from clarification and going all the way till filtration. Multiple approaches including mechanistic, statistical and hybrid techniques are implemented for creating digital twin of the process and devising control strategies for real time control. A number of machine learning techniques are also developed for monitoring, fault detection, modelling and control. Furthermore, in the present era of digitization, bioprocessing 4.0 has gained lot of interest from researchers and manufacturers. This includes integration of unit operations and monitoring tools with machine learning and statistical approaches, developing data analysis and control logics and establishing data communication between unit operation across the channel. Here, advanced analytical tools and soft sensors plays an important role for data acquisition. The course also discusses the development of end-to-end integrated continuous manufacturing platform for microbial and mammalian products with the different process control strategies and data analytics.

OUTLINE

14th Dec. Continuous Manufacturing- Enablers

2.00-2.45 PM: Keynote Lecture- Continuous Processing Overview and Current Status quo ***(Alois Jungbauer, University of Natural Resources and Life Sciences-Vienna)***
2.45-3.00 PM: Q&A ***(Alois Jungbauer, University of Natural Resources and Life Sciences- Vienna)***
3.00-3.45 PM: Keynote Lecture- Enablers for Continuous Processing ***(Anurag S. Rathore, IIT Delhi)***
3.45-4.15 PM: Continuous Clarification (ATF & AWS) (***Shantanu Banerjee, IIT Delhi)***
4.15-4.45 PM: Continuous Refolding and Precipitation (***Nitika, IIT Delhi)***
4.45-5.15 PM: Continuous Chromatography (***Anamika Tiwari, IIT Delhi)***
5.15-5.45 PM: Continuous Filtration ***(Garima Thakur, IIT Delhi)***
5.45-6.15 PM: Panel Discussion

15th Dec. Continuous Manufacturing- Modeling and Control

9.00-9.45 AM: Modelling and Control of Bioreactor - Case Studies ***(Somesh Mishra, IIT Delhi)***
9.45-10.30 AM: Modelling and Control of AWS - Case Studies ***(Shantanu Banerjee, IIT Delhi)***
10.30-11.15 AM: Modelling and Control of Chromatography- Case Studies ***(Anamika Tiwari, IIT Delhi)***
11.15-12.00 PM: Modelling and Control of UF DF - Case Studies ***(Garima Thakur, IIT Delhi)***
12.00-12.30 PM: Role of AI/ ML in Process Control ***(Nikita Saxena, IIT Delhi)***
12.30-1.00 PM: Panel Discussion

16th Dec. Continuous Manufacturing- Process Analytics

2.00-3.00 PM: Keynote Lecture- Advanced Analytical Tools for Continuous Manufacturing ***(Mark Smales, University of Kent)***

3.00-3.15 PM: Q&A ***(Mark Smales, University of Kent)***

3.15-4.00 PM: Keynote Lecture- Process Analytical tools for Continuous Manufacturing ***(Anurag S. Rathore, IIT Delhi)***

4.00-4.30 PM: Use of HPLC for PAT Implementation – Case Study ***(Anamika Tiwari, IIT Delhi)***

4.30-5.00 PM: Use of NIR as PAT Analyzer for BioSMB and SP TFF – Case Study ***(Garima Thakur, IIT Delhi)***

5.00-5.30 PM: SPC as PAT Analyzer – Case Study ***(Nikita Saxena, IIT Delhi)***

5.30-6.00 PM: Panel Discussion

17th Dec. Continuous Manufacturing- End-to-End Platforms

9.00-10.15 AM: Keynote Lecture- Development of Integrated Continuous Manufacturing Platform for Biotherapeutic Productions ***(Rahul Bhambure, NCL Pune)***

10.15-10.30 AM: Q&A ***(Rahul Bhambure, NCL Pune)***

10.30-11.00 AM: End-to-end Integrated Platform for Microbial Products– Lucentis ***(Anupa Pahuja, IIT Delhi)***

11.00-11.30 AM: End-to-end Integrated Platform for Mammalian Products– Trastuzumab ***(Nikhil Kateja, IIT Delhi)***

11.30-12.00 PM: Process Control and Integration for end-to-end Integrated Platform ***(Garima Thakur, IIT Delhi)***

12.00-12.30 PM: Data Analytics for Continuous Processing ***(Nikita Saxena, IIT Delhi)***

12.30-1.00 PM: Panel Discussion

MODULE 3- Hands-on Training on Advanced Data Analytics Solutions with DoE for Bioprocess Development and Manufacturing
13th-14th December, 2021

Description: Over the past three decades, development of biotherapeutics has revolutionized innovation in medicines. The field has made major advances in developing recombinant technologies for clone development, cell culture and purification technologies, formulation and devices, pre-clinical pharmacology and clinical trial designs. The industry encompasses various aspects of approaches, including proteins, cells and genes as drugs. Drug development is at a turning point in human medicine. Efficiency and Quality compliance are critical to achieve innovation and affordability. This comprehensive course will provide an in-depth overview of the basics and multi-dimensional nature of drug development utilizing technology, statistical and quality considerations. The course also provides the current trends and future challenges in the field with case studies.

OUTLINE

13th Dec. Design of Experiments (DOE) for Bioprocess Development and Manufacturing with Hands-on (1)

9.00-9.50 AM: Lecture 1- Introduction to DOE ***(Vaibhav Patil, Sartorius Data Analytics)***
9.50-10.00 AM: Lecture 1- Q&A ***(Vaibhav Patil, Sartorius Data Analytics)***
10.00-10.50 AM: Lecture 2: DoE Designs/Workflow and Screening ***(Vaibhav Patil, Sartorius Data Analytics)***
10.50-11.00 AM: Lecture 2- Q&A ***(Vaibhav Patil, Sartorius Data Analytics)***
11.00-11.15 AM: Break
11.15-1.15 PM: Hands-on Session
1. Dug Product Formulation Screening study
2. Cell Culture Upstream Process DoE

(Vaibhav Patil, Sartorius Data Analytics)

14th Dec. Design of Experiments (DOE) for Bioprocess Development and Manufacturing with Hands-on (2)

9.00-9.50 AM: Lecture 1- Optimization DOE design ***(Vaibhav Patil, Sartorius Data Analytics)***
9.50-10.00 AM: Lecture 1- Q&A ***(Vaibhav Patil, Sartorius Data Analytics)***
10.00-10.50 AM: Lecture 2: Robustness Testing DoE Designs ***(Vaibhav Patil, Sartorius Data Analytics)***
10.50-11.00 AM: Lecture 2- Q&A ***(Vaibhav Patil, Sartorius Data Analytics)***
11.00-11.15 AM: Break
11.15-1.15 PM: Hands-on session
1. API Mfg.-Pilot Plant Optimization
2. mAb Downstream Process DoE

(Vaibhav Patil, Sartorius Data Analytics)

MODULE 4- Hands-on Training on Advanced Data Analytics Solutions with MVDA for Bioprocess Development and Manufacturing
15th-16th December, 2021

Description: Biopharma and biotech manufacturing today involves larger and larger masses of data. Correct management of these data can give us valuable insights to process development as well as production, help us understand the progress of a batch and also point us in the right direction to troubleshoot. By applying state-of-the art data analysis technologies in the biopharma production the time for fault detection and diagnosis in production can be significantly reduced. In one recent example, a company identified the cause of a cell culture problem about a month earlier than it otherwise might have. For that biologic product, making the fix early and not losing that month saved $2.4 million. The course will present fundamental theory and practice of Multivariate Data Analysis (MVDA) within the framework of PAT to improve quality and throughput, as well as hands-on exercises on how MVDA should be used in process development and production.

OUTLINE

15th Dec. Multivariate Data Analysis for Production of Biopharmaceuticals: Basics, Practice and Case Studies (1)

9.00-9.50 AM: Lecture 1- Introduction to MVDA ***(David Wang, Sartorius Data Analytics)***
9.50-10.00 AM: Lecture 1- Q&A ***(David Wang, Sartorius Data Analytics)***
10.00-10.50 AM: Lecture 2: Principal Component Analysis (PCA)
(David Wang, Sartorius Data Analytics)
10.50-11.00 AM: Lecture 2- Q&A ***(David Wang, Sartorius Data Analytics)***
11.00-11.15 AM: Break
11.15-1.15 PM: Hands-on Session
1. Health Data Overview
2. Raw Materials Characterization
(David Wang, Sartorius Data Analytics)

16th Dec. Multivariate Data Analysis for Production of Biopharmaceuticals: Basics, Practice and Case Studies (2)

9.00-9.50 AM: Lecture 1- Partial Least Squares (PLS) and Orthogonal Partial Least Squares (OPLS)
(David Wang, Sartorius Data Analytics)
9.50-10.00 AM: Lecture 1- Q&A ***(David Wang, Sartorius Data Analytics)***
10.00-10.50 AM: Lecture 2: Batch Evolution model & batch level model
(David Wang, Sartorius Data Analytics)
10.50-11.00 AM: Lecture 2- Q&A ***(David Wang, Sartorius Data Analytics)***
11.00-11.15 AM: Break
11.15-1.15 PM: Hands-on Session
1. Modelling Cell Culture Process
2. Calibration Model in Spectroscopy
(David Wang, Sartorius Data Analytics)

OUR SPEAKERS

RAHUL BHAMBURE, PhD, is a Senior Scientist in the Chemical Engineering and Process Development Department at National Chemical Laboratory, Pune. His area of research covers both experimental and theoretical grounds applied mainly to the field of process and product development for biopharmaceuticals. For the last ten years, he has been working in the area of bioprocess development for recombinant protein and nucleic acid therapeutics. His future research interest will be more focused on applied protein biophysics and biochemical engineering for developing novel processes at various stages of biopharmaceutical manufacturing like upstream, downstream and formulation.

VADIRAJA BHAT, Ph.D., Biopharma Business Development Manager at Agilent Technologies, India. Vadi Bhat received his Ph.D. in Chemical Biology from JNCASR/IISc and did his post-doctoral research in the Department of Bioengineering at the Massachusetts Institute of Technology. Prior to join Agilent, he was associate director for mass spec core facility at the Baylor Scott & White Hospital/ Texas A&M University, Temple, TX. Vadi Bhat joined Agilent Technologies in 2008 as LC-MS applications scientist out of the Wilmington, Delaware, Center of Excellence. Since then, he has been focusing on developing novel LC-MS based workflows for proteomics and biopharma applications and delivering these solutions to the customers. From 2015, he also worked as proteomics market specialist in "Agilent North America Field Team" where he was responsible for customer collaborations and business development. In this role, he published several peer-reviewed journal articles and presented in many scientific conferences. From 2017, he is working as Biopharma Business Development Manager in India where he was responsible for biopharma customer collaborations and business development for Agilent Technologies.

NARENDRA CHIRMULE is the co-founder and CEO of SymphonyTech Biologics, a data analytics company focused on engineering solutions to biology. As former Head of R&D at Biocon (Bangalore), and leadership positions in Amgen (Thousand Oaks, CA) and Merck Vaccines (West Point, PA), has contributed to clinical development of vaccines and biopharmaceuticals. He did a PhD on development of a leprosy vaccine, from Cancer Research Institute, Mumbai; post-doctoral studies on pathogenesis of AIDS from Cornell University Medical College-North Shore Hospital, New York; teaching and research as assistant professor in gene therapy at University of Pennsylvania, Philadelphia. Dr. Chirmule is on the NIH advisory committee for HIV vaccines. He is a TEDx speaker and recently published a book "Good Genes Gone Bad" by Penguin Press, both of which describe lessons learned from colossal failures in drug development.

DAVY GUILLARME holds a Ph.D. degree in analytical chemistry from the University of Lyon, France. He is now senior lecturer and research associate at the University of Geneva in Switzerland. He authored more than 300 journal articles related to pharmaceutical analysis. His expertise includes HPLC, UHPLC, HILIC, LC–MS, SFC, SFC-MS, multidimensional LC, analysis of proteins, mAbs and ADCs. He is an associate editor of Journal of chromatography B and editorial advisory board member of several journals (Trends in analytical chemistry, Journal of Chromatography A, Journal of Separation Science, LC–GC North America…). He was the recipient of the LC-GC emerging leader award in chromatography in 2013 and the jubilee medal from the chromatographic society in 2018. He was also elected as one of the world's most influential analytical scientists by "Analytical Scientist" magazine in in 2013, 2014, 2015, 2017, 2019, 2020 and 2021. Last, he is also widely involved in teaching and education

activities, such as training courses, seminars, and conferences on HPLC, SFC, biopharmaceuticals analysis.

ALOIS JUNGBAUER received his PhD in Food Technology and Biotechnology from BOKU. He is professor of Protein Technology, Downstream Processing and Bioprocess Engineering. He also acts as deputy area head of Bioprocessing Engineering and Deputy Director of Research in the Austrian Centre of Industrial Biotechnology. He is currently working in the field of bioprocess engineering of proteins, plasmids and viruses. He has published 359 papers on recombinant protein production, bioseparation and advanced materials for bioprocess engineering, 17 patents and 12 book contributions and recently a monograph entitled "Protein Chromatography, Process Development and Scale Up". He is executive editor of Biotechnology Journal. He acts also as the vice president of research of the European Society of Biochemical Engineering Science.

RAVINDRA KHARE is the co-founder and Director of SymphonyTech. SymphonyTech works in the areas of Pharma and Engineering offering Software & Consulting in Data Analytics, Manufacturing, Design and Quality Engineering to their global customers spanning across 20 countries. Ravi has worked closely with SymphonyTech customers bringing them quantum benefits in Design and Manufacturing processes. He is a Graduate in Industrial Engineering, and has served the corporate as well as educational sectors in bringing technology training to students and working professionals. Ravi is an adventure cyclist. He has done over 2000 kms of cycling expeditions in the mountainous Region of Ladakh.

ASHUTOSH KUMAR is working as a Professor in the Department of Biosciences and Bioengineering, IIT Bombay, Mumbai. His work involves studying the structure and mechanism of action of protein complexes such SCF complex, specialized Nucleosome, and amyloid fibrils using state of the art solid- state and solution-state NMR spectroscopy along with other Biophysical tools. Ashutosh has made significant contribution in developing NMR methods and applying those on complex biological macromolecules to deduce structure and dynamics of these molecules. In recent time, he started working in the field of Biopharmaceuticals where he develops novel NMR methods to investigate HOS of Biosimilars and Biologics in their formulation states. Prof. Kumar received his M.Sc. in Chemistry from IIT Delhi followed by his Ph. D. at the Tata Institute of Fundamental Research, Mumbai supervised by Prof. R. V. Hosur in 2007. He did his postdoctoral research work under the supervision of Prof. Marc Baldus, Prof. Adam Lange and Prof. C. Griesinger at MPI for Biophysical Chemistry Gottingen, Germany before coming back to IIT Bombay.

SAURABH NAGPAL is working as Application Engineer in Centre Of Excellence, Agilent technologies, Manesar. His area of interest is High Resolution Mass-spectrometry applications in Biopharma and Omics. During his career-span of 18 years he has been involved in Proteomics and Metabolomics research at Indian Institute of Science (IISc) Bangalore and School Of life-sciences (JNU, Delhi). Prior to joining Agilent, he was working as Scientist-Proteomics in Pall Life-sciences, Bangalore. He has authored 8 articles in reputed journals of and has presented several posters at international conferences (HUPO congress, Pittcon, AOHUPO, ASMS). He is an affiliate member of Human Proteome Organization (HUPO) and has been an invited speaker to several symposia and workshops at reputed national Institutes like NIPERs, IITs, IISc, Indian Pharmacopeia commission and United States Pharmacoepia.

ASHISH PARGAONKAR is an Applications Engineer for Mass Spectrometry at Agilent Technologies, India since 2008. A Microbiologist by education with a Ph.D. degree in Botany, he holds more than 18 years of experience. Prior to joining Agilent, he was working as Scientist-at a reputed Analytical Testing Laboratory in Delhi leading a team for microbiological testing, method development and validation of food, drugs and materials. In his present role, he is responsible for Managing Agilent Centre of Excellences at Bangalore and Mumbai and an applications specialist for Agilent workflows on Hi Resolution Mass Spectrometry for Proteomics, Metabolomics and Biopharma markets.

VAIBHAV PATIL is a Manager, Data Science at Sartorius Data Analytics. He is M. Tech. in Bio-Chemical Engineering and B Engg. in Chemical Engineering. He has 13+ years of experience in both process development, manufacturing and data analytics in pharma/chemical industry. Before joining Sartorius Data Analytics in 2018, he was a Manager Statistics/Data Analytics at Pfizer. Prior experiences include Associate Investigator at DuPont and Jr Scientist at Dr. Reddy's Lab. His major focus areas are applying advanced data analytics tools for pharma applications, data driven decision making, predictive analytics, Continuous improvement and QbD/PAT.

ANURAG S. RATHORE is an Institute Chair Professor at the Department of Chemical Engineering, Indian Institute of Technology, Delhi, India. He is also the Coordinator for the DBT COE for Biopharmaceutical Technology. 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, medical image analysis, process analytical technology and quality by design. He has authored more than 600 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*. He also serves on the Editorial Advisory Boards for *Biotechnology Progress, Electrophoresis, BioPharm International, Journal of Chromatography B, Journal of Chromatography Open, Pharmaceutical Technology Europe,* and *Separation and Purification Reviews*. Dr. Rathore has edited books titled *Preparative Chromatography for Separation of Proteins and Peptides (2017), Quality by Design for Biopharmaceuticals: Perspectives and Case Studies (2009), Elements of Biopharmaceutical Production (2007), Process Validation (2005), Electrokinetic Phenomena (2004),* and *Scale-up and Optimization in Preparative Chromatography (2003)*. He has a Ph.D. in Chemical Engineering from Yale University. Prof. Rathore is presently serving as Dean, Corporate Relations, at IIT Delhi.

SUMIT K. SINGH is an Assistant Professor in the School of Biochemical Engineering at the Indian Institute of Technology (Banaras Hindu University) Varanasi. Before joining IIT BHU, he worked as a postdoctoral researcher at the University of Delaware and obtained his PhD degree in Chemical Engineering from IIT Delhi. His areas of interest principally encompass broad domain of therapeutic protein characterization and protein engineering. The current research endeavors of his group at IIT BHU are focused on developing novel biotechnologies aimed at clinical translation based on understanding of the underlying disease pathobiology involving glycan interactions. The research embodies a two-fold approach: (a) Identification of glycan biomarkers that are specific to a particular disease state; (b) utilization of the chosen biomarkers to develop therapeutics using data-driven protein engineering approaches. Sumit has authored 20 publications and several presentations in the area of analytical characterization and development of safe and efficacious protein-based therapeutics. He has also been a recipient of several awards at various conferences, including the Young Scientist in Bioprocessing Award at

the 6th Bioprocessing India Conference. He also serves as a reviewer of several journals, including Journal of Chromatography B, Biotechnology Progress, Bioanalysis, and Engineering in Life Sciences

MARK SMALES is Professor of Industrial Biotechnology at the University of Kent. He works on further advancing our understanding of biotechnological products and processes at the fundamental biological or chemical level to enable their manipulation and control for improved biotherapeutic recombinant protein yields and quality. His group is known in particular for work on (1) engineering of cell systems and their tuning for enhanced recombinant protein production and quality in fed-batch and continuous processes, (2) investigating how upstream processes impact on host cell proteins and their clearance during downstream processing, and (3) understanding stability and formulation of biotherapeutic proteins.

DAVID WANG is a senior data scientist at Sartorius Data Analytics based in Singapore. He mainly works on improving efficiency, optimality, and profitability in product development, process development, and manufacturing processes (Pharma, Biopharma, Chemical, Food & Feed, Pulp & Paper, Life Sciences, etc.) by applying advanced data analytics technology. His work is focused on data-driven modelling, process monitoring, advanced process control, design of experiments, PAT and QbD. He has delivered many data analytics courses and industry projects across Asia-Pacific region. He received his Ph.D. in Chemical Engineering, M. Eng. in Control Theory and Engineering, and B. Sci. in Mathematics and Statistics.