

WuXi Biologics

Global Solution Provider

CMC Knowledge Catalog



WuXi Bio Academy

From DNA to IND to BLA: Advance Your Knowledge Across
the Entire Biologics, ADCs & Vaccines Development Spectrum

The **WuXi Bio Academy** is a global knowledge-based program from WuXi Biologics to share our insights, stories and expertise in order to provide valuable educational, consultative, and thought leadership initiatives to the biopharmaceutical ecosystems. Through this program we would like to exchange ideas, provide an opportunity for professional career growth, and offer toolboxes to tackle the many drug development operational, technical and business issues we all face. By doing so, we can better help you advance your products into the clinic and beyond.



CMC Catalog

	Course Title	Speakers
1	Recent Advancements in Cell Line Development	Shuai Wang, Director Sam Zhang, ED Ying Huang, SD Amy (Yimin) He, SD
2	Points to Consider in Post IND Cell Line Change	Zichen Qian, AD Sam Zhang, ED Ying Huang, SD Xin Zhang, SD
3	Securing Success: The Critical Role of Cell Bank Testing, Characterization, and LIVCA Studies in Strengthening BLA Filing Approvals (New)	Yuanshu Dong, Director Zhengxi Zhang, Director Sherry Chang, Director Chengbin Lin, ED
4	Product Quality Fine Tuning in Cell Culture Development	He Huang, Director Lian Fan, AD Fei Chen, Director Yunling Bai, ED Joy Zhang, ED
5	Development and Implementation of Intensified and Continuous Bioprocessing	Mingyue Fang, Director Yunling Bai, ED Li Zhang, SD
6	An Innovative Ultra-Intensified Fed-Batch Strategy for Multi-fold Productivity Improvement and Cost-effective Commercial Manufacturing (New)	Le Yu, SD Ying Hou, Director Qiaorui Xing, Assistant Director Jun Luo, ED Mengmeng Xu, Director
7	Systematic and Standardized Process Characterization Strategy for Successful Process Validation and Accelerated Time-to-market (New)	Lian Fan, AD Xian Zhang, AD Le Yu, SD Yucai Li, ED
8	High Concentration Formulation Development: Challenges, Strategy, and Industry Trends	Fangyuan Zhou, AD Tingting Wang, Director Steven Ren, SD Wei Chen, ED
9	Development Challenges of Prefilled Syringe and Autoinjector for Biologics Combination Product	Guisheng Zhuang, Director Wei Chen, ED Steven Ren, SD
10	Polysorbate Degradation and Forensic Investigation: Better Prevention Than Mitigation (New)	Lu Cao, Assistant Director Chenlu He, Principal Scientist Hongbing Wu, Director Kewei Yang, Director Peng Ke, Director
11	Interlinking CMC and Clinical Studies: The Vital Role of Clinical-In-Use and Microbial Challenge Studies (New)	Luting Liu, Director Peng Ke, Director Kewei Yang, Director
12	Strategic Considerations in Biologics Manufacturing and Outsourcing - A Flexible, Integrated, and Agile Global Ecosystem	Xin Wang, SD Hui Cai, SVP Yi Xiong, ED George Tan, SD
13	An Accelerated Timeline from Gene Synthesis to IND: Expediting the Delivery of Innovative Biologics to the Clinic	Fenglin Wang, Director Melanie Lin, ED Sherry Gu, SVP
14	Getting the CMC Dossier Right – Perfect Balance of Content and Data Comes from a Good Storyboard Strategy and Structure	Ken Chen, ED
15	Navigating the Global Regulatory Landscape - Strategies for Filing in Different Countries	Ken Chen, ED Yucai Li, ED
16	Challenges and Strategies of Next Generation Bispecific Antibodies and Fusion Proteins	Sam Zhang, ED Yifeng Li, ED Ping Huang, ED Yimin (Amy) He, SD
17	From Preclinical Candidate Selection to IND for Antibody Drug Conjugates (ADCs) and Other Innovative Bioconjugates	Yuhua Hu, ED Rui Wu, SD
18	The Role of Microbial Expression Systems in the Next Wave of Biologics and Vaccine Modalities	Yan Chen, SD Li Zhang, SD Zhaopeng Li, Director
19	Post COVID-19 Revelations: The Need for Multi-platform Networks and Supply Chain Sustainability for Worldwide Vaccine Equality	Jian (Jason) He, SD
20	Revolutionizing Protein Production: Unveiling the Cutting-Edge HEK293 Platform for Overcoming Manufacturing Challenges (New)	Qiao Gao, AD Qing Zhao, AD Sam Zhang, ED Ying Huang, SD Yingchun Lu, SD
21	Clinical Supply Service: Deliver the Drug Product to the Last Mile Quickly, Safely, and Cost Effectively (New)	Chaowen (Jason) Xiao, Director Zhiguang Zhu, AD Bruce Jin, SD Kin Ho, SD George Tan, SD

More courses available upon customized request

All of the content and information, provided in the form of short courses or seminars, are prepared and presented by our technical experts and CMC leaders, each having vast and diverse experience across many disciplines including cell line, upstream, downstream, analytical, and formulation development, manufacturing, regulatory affairs and quality.

All speakers have hands-on experience with the development of frontline innovative biologics, ADCs and vaccines. This team brings to your organization the extensive knowledge base from managing and overcoming the myriad of operational obstacles that occur with any project and the experience from finding solutions that ensure project timelines and product quality are maintained.



Featured Speakers*

Ken Chen, MBA Executive Director	20+ years industry experience in regulatory affairs, process, analytical, and formulation development and quality at WuXi Biologics, Amgen and Guthy-Renker. B.S. from SUNY Buffalo School of Pharmacy and MBA from University of Southern California.
Jian (Jason) He, Ph.D., Senior Director	16 years industry experience and current Head of WuXi Vaccines CMC team. Expertise in process, analytical and formulation development of vaccines and biologics at WuXi Biologics & Merck. Ph.D. from University of Pennsylvania.
Ping Huang, Ph.D., Executive Director	24+ years of industry experience in CMC management and process development for biologics at WuXi Biologics, PDL Biopharma/Facet Biotech and Abbvie. Ph.D. from University of Maryland Baltimore County.
Sherry Gu, Ph.D., Senior Vice President	27 years of biopharmaceutical industry experience and current Head of US & EU CMC Management at WuXi Biologics. Extensive expertise in cell line, upstream and downstream development and portfolio leadership for biologics at WuXi Biologics, BMS & Eli Lilly. Ph.D. from Massachusetts Institute of Technology.
Steven Ren, Ph.D., Senior Director	22 years of industry experience in drug product development for biologics at WuXi Biologics, Teva, GSK, Allergan & Amylin. Ph.D. from University of Southern California.
Wei Chen, Ph.D., MBA Executive Director	20 years of industry experience in drug product for biologics at WuXi Biologics, Protagonist, Gilead, Eli Lilly & Fresenius. Ph.D. from University of Georgia, and MBA from Golden Gate University.
Yan Chen, Ph.D., Senior Director	15+ years of industry experience in CMC development and process development for biologics and vaccines at WuXi Biologics, BMS, Merck, and VaxInnale. Ph.D. from University of Rochester.
Yi Xiong, Ph.D., Executive Director	20 years of industry experience in CMC development and process development for biologics at WuXi Biologics, Takeda and GSK. Ph.D. from Peking University in China.
Ying Huang, Ph.D., Senior Director	20 years of industry experience in CMC management and cell line development for biologics at WuXi Biologics, Merck, GSK and KBI. Ph.D. from University of Tokyo in Japan.
Yuhua Hu, Ph.D., Executive Director	15 years of industry experience in pharmaceutical development, drug delivery, and drug product for biologics and bioconjugates at WuXi XDC, WuXi Biologics, Nektar, Kodiak Science and Genentech. Ph.D. from Massachusetts Institute of Technology.
Yunling Bai, Ph.D., Executive Director	17 years of industry experiences in upstream development and CMC management at WuXi Biologics, Gilead, Merck, and BD Biosciences. Ph.D. from The Ohio State University.
Sam Zhang, Ph.D., Executive Director	16+ years of biopharmaceutical industry experience at WuXi Biologics, Pfizer, AbbVie, Abbott and Amgen. Current Head of Cell Line Development at WuXi Bio, with expertise in DS development & manufacturing. Ph.D. from University of California at San Diego.
Yifeng Li, Ph.D., Executive Director	15+ year biologics development experience at WuXi Biologics, Texas Health Science Center Core Facility, and Cytovance Biologics. Current Head of Downstream Process Development at WuXi Bio with 40+ publications. Ph.D. from University of Nebraska Medical Center.

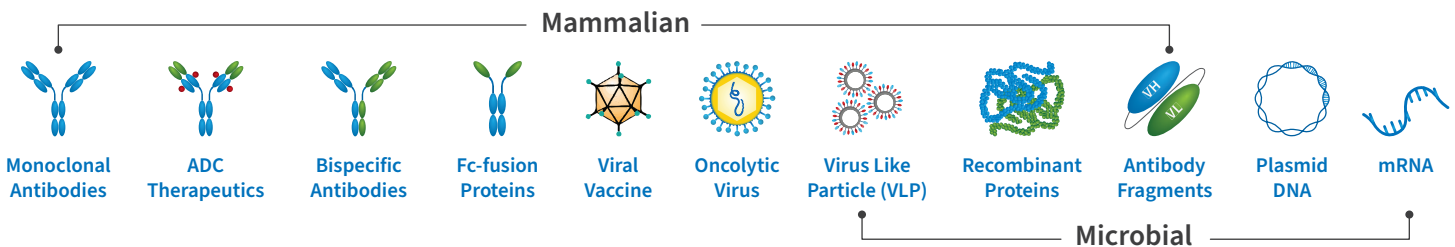
*Only select speakers are shown on this page. To see the full list of our expert speakers, visit our website: wuxibiologics.com/wuxibioacademy

Located Globally for Your Convenience

Besides the courses led by technical experts in each functional area, the WuXi Biologics CMC Management team is situated around the globe to support your education. The team provides strategic and tactical development, characterization, validation and GMP manufacturing insight and expertise across a wide array of biologics, ADCs and vaccines along with regulatory guidance on a project-by-project basis throughout the drug development life cycle.



Expertise Available for Many Product Types



Contact us to schedule your WuXi Bio Academy courses today! Let's come together, and we'll bring our expertise to help you advance your biologics into the clinic and beyond!

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Learning and improving is fundamental to your growth and success. Earn rewards as you advance your learning: for every 3 courses you complete you will receive a gift. The complete set of gifts will be awarded if you complete 12 courses.



About WuXi Biologics

WuXi Biologics is a leading contract research, development and manufacturing organization (CRDMO) that provides end-to-end capabilities to healthcare organizations worldwide. With operations in China, the United States, Ireland, Germany, and Singapore, we enable our partners to effectively and efficiently bring biologics and vaccines to patients worldwide through our comprehensive and high-quality drug development model.

The world's leading global single-source platform from concept to commercialization.

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