CHINESE BIOPHARMACEUTICAL ASSOCIATION, USA

2017-2018 Workshop series-1

Trends in Biopharmaceutical Industry: Opportunities and Challenges in the Development of Biosimilar Products

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Chinese Biopharmaceutical Association- USA (CBA-USA) is organizing this series of workshops, co-sponsored by Chinese Culture and Community Service Center (CCACC) with the goal of providing opportunities for professionals in the bioscience research field to gain a deeper understanding of drug development and marketing approval. Our speakers are experts with hands-on experience in biopharmaceutical industry or regulatory authority who will share their expertise and viewpoints with all participants. Come join us on August 26, 2017 to learn more.

Time: 9:30 am-1:30 pm, August 26, 2017 (Saturday)

Location: Chinese Culture and Community Service Center (CCACC), 9318 Gaither Road, Suite 215, Gaithersburg, MD 20877. Phone: 301-820-7200

Cost: $5.00 for public, but FREE for active members of CBA, and members of CCACC, NIH-CSSA, ASQ509

Registration: Click Eventbrite

Agenda

9:30-9:40 am	Introduction and Announcements
9:40-10:00 am	Self Introduction for All Attendees
10:30-11:00 am	Dance, Dance, Dance: Intricacy in Biosimilar Patent Challenge By Peng Sun, Ph.D, JD, Associate and Intellectual property lawyer with Foley & Lardner LLP
11:00-11:30 am	Development of Biosimilars: a small yet reliable step towards affordable healthcare

	By Juhong Liu, PH.D. Review Chief, Division III, Office of Biotechnology Product, CDER, FDA
11:30-11:40 am	**Break**
11:40-12:10 am	**Demonstration Biosimilarity - Challenges and Opportunities**
	By Patrick Liu, M.D., Ph.D., Vice President of Global Biologics R&D and Head of Global Bioassays and Technology at Teva Pharmaceuticals
12:10-12:40 pm	**Panel discussion: Opportunities and Challenges**
12:40-1:30 pm	**Pizza Lunch and Network**

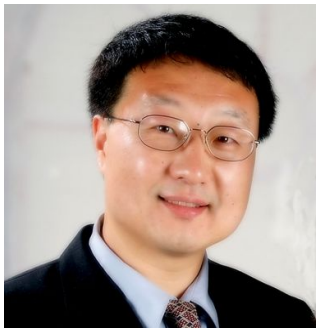
Speaker Biosketches

Peng Sun, PH.D., JD., Associate and Intellectual property lawyer with Foley & Lardner LLP

Dr. Sun is an intellectual property lawyer with Foley & Lardner LLP. He focuses his practice on patent counseling, portfolio strategy, and intellectual property due diligence for investment companies, public and private companies in life industry, and academic institutions. Dr. Sun has served clients in various technical fields including small molecules, peptides, antibodies, genomic, gene therapy, precision medicine, viruses, drug delivery, diagnostics, and medical devices. He is a member of the firm's Chemical, Biotechnology & Pharmaceutical Practice.

Prior to joining Foley, Dr. Sun was an associate attorney with a law firm in the D.C. metropolitan area, where he counseled domestic and international clients on patent, trademark, and comprehensive FDA regulatory matters. He also was a postdoctoral fellow at Johns Hopkins University School of Medicine.

During law school, Dr. Sun was a summer associate with Foley & Lardner LLP, as well as a judicial intern to the Honorable Susan Braden and the Honorable Dania Zane, both of the U.S. Court of Federal Claims. His experiences also include working as a patent agent at a reputable IP law firm and a law clerk for Maryland Office of the Public Defender.



Juhong Liu, PH.D. Review Chief, Division III, Office of Biotechnology Product, CDER, FDA

Dr. Juhong Liu received his Ph.D. in Biochemistry and Molecular Biology in Peking Union Medical College. He obtained research training as a postdoctoral and staff scientist in Laboratory of Pathology of the National Cancer Institute where he worked on purification and characterization of transcription factors. He joined the Division of Therapeutic Proteins, Office of Biotechnology Products (OBP) in 2008 and is now the Review Chief of Division of Biotechnology Review and Research II of OBP. He involved in reviews of regulatory submissions of a variety of protein products, including monoclonal antibodies, enzyme replacement therapy products, cytokines, and hormones. Over the past few years, he has also heavily involved in the regulatory review of biosimilar IND and BLA submissions of several product classes.

Patrick Liu, M.D., Ph.D., Vice President of Global Biologics R&D and Head of Global Bioassays and Technology at Teva Pharmaceuticals

Patrick Liu, M.D., Ph.D., is Vice President and Head of Biologics, Assays and Technology at Teva Pharmaceuticals. He leads a global team with responsibilities from late stage research, through IND, clinical trials and marketing registration, with focus on product biological characterization, nonclinical and clinical PK/PD, biomarker evaluation and immunogenicity assessment for both innovative biologics and biosimilars development.

Prior to joining Teva, Dr. Liu held positions as a Director at Tanox and then Genentech with increased responsibilities in the leadership role for the development and commercialization of a variety of new biologics across the therapeutic areas of oncology, hematology, immunology, allergy, respiratory and infectious diseases. He has contributed to the success of developing many blockbuster medicines including Avastin, Herceptin, Perjeta, Lucentis, Xolair and Copaxone, and many other biologics such as Lonquex, Granix, Ovaleap and most recently Cinqair. Dr Liu had practiced medicine, specializing in Endocrinology and also holds a Ph.D. in Molecular Biology and Biochemistry from Peking Union Medical College and Chinese Academy of Medical Sciences.

Organizer

CBA workshop organizing committee c/o Kevin Li
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Co-sponsors

CCACC (Chinese Culture and Community Service Center)

American Society for Quality Section 509 (www.asq509.org) – Washington DC and Maryland Metro - Biomed/Biotech Special-Interest-Group (http://www.asq509.org/ht/d/sp/i/31557/pid/31557)

NIH-CSSA (Chinese Students and Scholars Association of the National Institutes of Health)