Recent Advances in Coprocessed APIs and Proposals for Enabling Commercialization of These Transformative Technologies

An IQ Consortium webinar sponsored by the Drug Substance Leadership Group, providing an overview of the Coprocessed API Working Group's recently published perspective paper

SPEAKERS

Luke Schenck is a Principal Scientist at Merck & Co., Inc. in the Rahway, NJ Process Research & Development organization. In his 19 years at Merck, he has held positions of increasing responsibility in drug product and drug substance development and commercialization, culminating in his current role forming and leading the Particle Engineering Lab. In this role, he has developed innovative and pipeline enabling precipitation and crystallization processes spanning respiratory delivery, amorphous systems and subcutaneous administration. Advanced particle engineering capabilities have focused on developing materials achieving a global optimum across drug substance and drug product processes.

Deniz Erdemir is a Principal Scientist at Bristol-Myers Squibb (BMS). Prior to joining BMS, she received her Ph.D. in Chemical Engineering from the Illinois Institute of Technology. Dr. Erdemir's research focus lies at the drug substance-drug product interface with emphasis on crystal polymorphism and design of materials via particle engineering to enable robust drug products. She is the author of numerous publications on co-processed materials and crystallization process development, the inventor on two US patents and the co-editor of the 3rd edition of Handbook of Industrial Crystallization.

Lindsey Saunders Gorka is an Associate Director in Global Regulatory Chemistry, Manufacturing and Controls (CMC) at Pfizer, located in Peapack, NJ. She supports the development of CMC regulatory strategies and manages regulatory submissions for global clinical studies, new commercial registrations, and postapproval maintenance of innovative medicines. Prior to joining Pfizer, she was a CMC reviewer in the Office of New Drug Products at the FDA. Lindsey holds a B.S. in Chemistry from Brandeis University and Ph.D. in Chemistry from Yale University. She also completed a postdoctoral fellowship at the National Cancer Institute. Lindsey earned her Regulatory Affairs Certification in 2015 and has previous regulatory experience working at Technical Resources International. Lindsey is currently an active member of the IQ Co-processed APIs Working Group.

MODERATORS

Ivan Marziano is a Research Fellow at Pfizer R&D. A Pfizer veteran of 20+ years, Ivan completed a degree in Industrial Chemistry at the University of Bologna, Italy, in 1993, then obtained a DPhil in Chemistry from the University of Sussex in 1998 prior to joining Pfizer. During his career, Ivan has been involved in the development of many crystallization processes from early development to filing, including a deep understanding of Materials Sciences issues, modelling and implementation of new technologies. Ivan was Chairman of the British Association for Crystal Growth from 2007 to 2009, is a regular speaker at the main conferences in the field of Industrial Crystallization and has had his work published on peer-reviewed papers and patents. In addition to serving as a Scientific Advisor to the Editor of the Journal of Pharmaceutical Sciences, Ivan is also a permanent guest of the European Working Party on Crystallization.

Jeremy M. Merritt is a Principal Research Scientist at Eli Lilly and Co. in the small molecule design and development organization (SMDD). He currently leads the Particle Design Lab (PDL) responsible for crystallization process development with a focus on designing the commercial process and enabling physical property attributes for successful integration with drug product processing with emphasis on continuous processing. Prior to the PDL he was a contributor in growing the modeling and simulation capability group for SMDD with emphasis on scale-up and impurity control. He also advanced the mechanistic understanding behind salt disproportionation in the solid-state through modeling efforts. Jeremy received his PhD in physical chemistry from the University of North Carolina at Chapel Hill and spent one month as an invited researcher at the Fritz-Haber Institute of the Max-Plank Society in the department of molecular physics (Berlin) before completing a postdoctoral appointment at Emory University. He currently co-leads the IQ Co-processed API Working Group.