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New Concepts for Drug Product Innovation & Novel Excipients - FDA Novel Excipient Pilot Program

The need for Novel excipients is growing due to various formulation issues related to drug solubility, patient-centric considerations, unique needs in biologics and an increase in advanced manufacturing methods such as continuous manufacturing and 3D Printing. There has historically been significant uncertainty regarding the potential regulatory implications of using novel excipients and this has severely limited innovation in drug development. Due to this uncertainty and concerns about customer uptake, excipient manufacturers have also been reluctant to develop novel excipients. However, there is some big news on the horizon which could help resolve these uncertainties. On September 7, 2021, The U.S. FDA's Center for Drug Evaluation and Research (CDER) launched the voluntary Novel Excipient Review Pilot Program (Pilot Program), which is intended to allow excipient manufacturers to obtain FDA review of certain novel excipients prior to their use in drug formulations. If this pilot program is successful, this program could be made permanent. This would provide a new pathway which would encourage the early development and use of novel excipients to facilitate advancing the next generation of medicines to patients and help stimulate excipient innovation in the global pharmaceutical industry. This presentation will summarize the current need for novel excipients and will outline the current FDA Pilot Program and its potential impact on drug development and innovation.

Biography

David R. Schoneker is currently the President/Owner of Black Diamond Regulatory Consulting, LLC. With over 44 years of experience working in these areas, Dave has developed strong networks with trade associations, regulatory agencies and pharmacopeias around the world. He is also an Adjunct Professor at Temple University's School of Pharmacy in their RA/QA Master's Program teaching courses in Global Excipient Regulations and the Regulation of Dietary Supplements. Prior to August 2019, David R. Schoneker was the Global Regulatory Director – Strategic Relationships at Colorcon, Inc. He was at Colorcon from 1977 until 2019. Mr. Schoneker was the Chairman of IPEC-Americas during the period 2007-2009 and is currently a member of the Executive Committee and serves as the Chair of the Excipient QbD/Composition Committee.

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