David Schoneker

David R. Schoneker is currently an independent consultant who specializes in developing regulatory strategies related to excipients, food additives, color additives used in drug and dietary supplement development. He has over 42 years of experience working in these areas and has developed strong networks with regulatory agencies and pharmacopeias around the world.

Prior to August 2019, David R. Schoneker was the Global Regulatory Director – Strategic Relationships at Colorcon. His responsibilities included global coordination of Colorcon's worldwide regulatory activities and market expansion projects to gain regulatory acceptance of Colorcon's products and components for various target markets. Mr. Schoneker also worked closely with Colorcon's customers to provide regulatory training and advice.

He received his B.S. degree from Ursinus College and M.S. in Chemistry from Villanova University. His previous position at Colorcon was Director of Quality Assurance and Quality Control. He was at Colorcon from 1977 until 2019. Mr. Schoneker has been active in many professional organizations such as AAPS, PQRI, RAPS, ASQ, ACS, AOAC and the Delaware Valley Chromatography Forum. He also is involved with a number of trade organizations such as the International Pharmaceutical Excipients Council (IPEC), the International Association of Color Manufacturers (IACM), the Consumer Health Products Association (CHPA), the International Food Additives Council (IFAC), the Council for Responsible Nutrition (CRN) and the Institute of Food Technologists (IFT).

Mr. Schoneker was the President of IACM in 2019 and has been on the IACM Board for many years. In these roles he coordinated IACM's international regulatory activities related to Synthetic and Natural colorants for use in foods and drugs and participated as one of IACM's NGO representatives at the Codex Committee on Food Additives (CCFA) for several years.

Mr. Schoneker was the Chairman of IPEC-Americas during the period 2007-2009 and is currently a member of the Executive Committee. He is now serving as the Vice Chair for Science and Regulatory Policy where he is actively involved with the development of Regulatory, Safety, Excipient GMP and Supplier Qualification related guidelines to improve Excipient Acceptability, Safety and Global Supply Chain Security. Mr. Schoneker also Co-Chairs IPEC's QbD/Product Development Committee, Composition Committee and IID Working Group. He also is a member of the Board of Directors of the IPEC Foundation. He is the Global Expansion Coordinator for the IPEC Federation and has been critically involved in the development of many of the IPEC groups and Partnerships around the world.

He has acted as an interface with many international regulatory agencies and pharmacopeias for the organization. He previously was the USP Liaison for IPEC-Americas and represented them as a member of the United States Pharmacopeial Convention for many years. Mr. Schoneker previously coordinated International Harmonization efforts for IPEC-Americas and participated in the development of IPEC's Good Manufacturing Practices Guide and Auditing Guide for Bulk Pharmaceutical Excipients. He has also led IPEC's efforts in developing guidelines for excipient qualification, significant change notification and the appropriate use of certificates of analysis.

Additionally, Mr. Schoneker chairs a number of harmonization working groups on various excipients and has been chairing the Coalition for Rational Implementation of the Elemental Impurity Requirements since 2010.

Mr. Schoneker has participated in the area of Color Science for many years and is author of the chapter “Coloring Agents for Use in Pharmaceuticals” in the 4th edition of the *Enclyclopedia of Pharmaceutical Technology* which was published in 2013. He has also authored many other excipient quality and safety related papers in various journals and trade magazines.