PQRI Workshop: ***TiO2 Use in Pharmaceuticals: Global Regulatory and Technical Challenges***

June 13-14, 2023

Bios

MODERATOR/WORKSHOP ORGANIZING COMMITTEE CHAIR

David R. Schoneker
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David R. Schoneker is currently the President/Owner of Black Diamond Regulatory Consulting, LLC, a consulting firm specializing in providing regulatory and quality consulting for the pharmaceutical, dietary supplement, food and related industries. The firm provides expert advice for difficult problems and training on excipient and food additive regulatory, quality and supply chain concerns.

With over 45 years of experience working in these areas, he 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 where he teaches courses in Global Excipient Regulations and the Regulation of Dietary Supplements and Functional Foods.
Prior to August 2019, David R. Schoneker was the Global Regulatory Director – Strategic Relationships at Colorcon, Inc. His responsibilities included global coordination of Colorcon's worldwide regulatory activities. 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, 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 represents IPEC-Americas on the PQRI Steering Committee and belongs to several PQRI Technical Committees.

Mr. Schoneker currently Chairs IPEC's QbD/Composition Committee and was previously the Global Expansion Coordinator for the IPEC Federation where he was critically involved in the development of many of the IPEC regional groups and partnerships around the world.

Mr. Schoneker was the President of the International Association of Color Manufacturers (IACM) in 2019 and was 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, dietary supplements and drugs and participated as one of IACM's NGO representatives at the Codex Committee on Food Additives (CCFA) for several years.

SPEAKERS

Andreas Abend, Ph.D. **Senior Principal Scientist** Merck & Co., Inc. andreas_abend@merck.com 	Andreas Abend received his PhD degree in Organic Chemistry from the University of Karlsruhe in Germany. Prior to joining Merck and Co., Inc. as a Senior Project Chemist, Andreas spent 3 years as a Post-Doctoral Fellow at the University of Wisconsin's Enzyme Institute. He is currently a Senior Principal Scientist in the Biopharmaceutical Sciences group in MRL's Development Sciences and Clinical Supply Department. Throughout his career at Merck, Andreas provided analytical support to small molecule API and drug product development activities spanning all clinical phases. Over the last two decades, he and his team contributed to the more than a dozen new Market applications. Andreas is a member of Merck's Biopharmaceutical Advisory Team, co-chair of PQRI's BTC, and a member of IQ's Analytical Leadership Group. He presented at many national and international meetings, published several manuscripts on Clinically Relevant Dissolution specifications, photostability and impurity identification. In 2017 and 2019 he was a co-organizer of workshops at the Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) and he is currently co-organizing a PQRI workshop dedicated to pediatric formulation development (Nov. 2023).
Bram Baert, Ph.D. Associate Director Regulatory Affairs Lonza bram.baert@lonza.com 	With a PhD in Pharmaceutical Sciences obtained from the Ghent University Drug Quality & Registration laboratory, Bram developed a special interest in regulatory compliance. After working 5 years in a product-oriented quality team with responsibilities concerning registration, validation and implementation at Pfizer Manufacturing Belgium, Bram joined Lonza / Capsugel about 7 years ago covering regulatory affairs for empty capsules in the EMEA region.

Lance K. Blevins, Ph.D. Assistant Professor, Institute for Integrative Toxicology Michigan State University blevin24@msu.edu 	Lance received his BA in biology from the University of North Carolina at Chapel Hill where he conducted undergraduate research in a BSL3 laboratory setting. He then entered graduate school where he pursued his PhD in microbiology and immunology from Wake Forest University studying the regulation of virus-specific CD8+ T cell responses by invading bacterial pathogens. After earning his PhD, Lance then joined Dr. Norb Kaminski's laboratory at Michigan State University as a post-doctoral research fellow, where he has made significant contributions to the field of aryl hydrocarbon receptor immunotoxicity. Lance was promoted in 2020 to the position of assistant professor with the institute for integrative toxicology at Michigan State University where he currently conducts research into the biological role of aryl hydrocarbon receptor in B cell subsets. Dr. Blevins has over 10 years of experience in conducting hypothesis driven investigative research directed at elucidation of the cellular and molecular mechanisms by which pathogens and chemicals alter immune responses. These immunologic and immunotoxicologic studies have employed approaches spanning measurements of immune function in vivo, ex vivo and in vitro and Dr. Blevins has published research using murine, rat, non-human primate, as well as human model systems to study immune regulation and pathogenesis.
Thomas Broschard, Ph.D., ERT Senior Toxicologist, Chemical and Preclinical Safety Department EMD Serono/Merck Healthcare KGaA thomas.broschard@merckgroup.com 	Thomas Broschard is a senior toxicologist at the Chemical and Preclinical Safety Department of EMD Serono/Merck Healthcare KGaA in Darmstadt, Germany. He studied food chemistry and environmental toxicology at the University of Kaiserslautern from 1985 to 1990. He received his PhD in 1995 from the German Cancer Research Center (DKFZ), where he investigated mechanisms of chemical mutagenesis and carcinogenesis. From 1995 to 1997, he continued his research on this topic as a postdoctoral fellow at the Ecole Supérieure de Biotechnologie in Strasbourg, France. In 1998, he started his career as a regulatory toxicologist in the chemical and pharmaceutical industry. Since 2000, he held several positions at Merck's Toxicology Department. In his current position he is heading the Chemical Toxicology Group that is responsible for global registration of industrial chemicals, the establishment of substance-specific threshold values (OEL, PDE) and the risk assessment of impurities and excipients in drug products. He is very active in the E 172 (Iron Oxide) Consortium where he is co-chair of the Technical Steering Committee.

Samuel M. Cohen, MD, Ph.D. Professor University of Nebraska Medical Center scohen@unmc.edu 	MD and PhD (experimental oncology), University of Wisconsin, 1972 Board certified in anatomic and clinical pathology, 1976 Visiting professor, Nagoya City University Medical School, 1976-7 Staff pathologist, St. Vincent Hospital, and associate professor, Univ. of Massachusetts Medical School, Worcester, MA, 1977-1981 Professor, Dept. of Pathology and Microbiology and the Cancer Center, since 1981 Havlik-Wall Professor of Oncology, since 1985 Numerous honors and awards, Lehman award and Merit award from Society of Toxicology, and elected fellow of IATP, AAAS, and member of Academy of Toxicological Sciences. Numerous national and international committees, editorial boards (including Toxicologic Pathology), and reviewer for numerous journals and grants (including NIH, EPA, DOD) More than 470 publications in peer-reviewed journals and more than 50 chapters.
David W. Cragin, Ph.D., DABT Senior Director Teva Pharmaceutical david.cragin@tevapharm.com 	Dr. Dave Cragin, DABT, is Senior Director of Product Science in Environment, Health, Safety and Sustainability at Teva Pharmaceutical. He contributes to the overall leadership of EHS&S functions and also leads a team that creates safety data sheets and occupational exposure limits to support efforts to protect employee safety and acceptable daily exposures for quality operations. He's also a subject matter expert on beta lactams, titanium dioxide, and iron oxide. Previously he served as a Director in Quality Assurance and multiple other roles for Merck & Co. Outside of Teva, he teaches risk assessment and critical thinking for the Peking University, and Beijing Normal University. In addition, he has taught risk communication across the globe. He speaks Chinese and is knowledgeable in many languages. Dr. Cragin is a Trustee of the Toxicology Education Foundation, is Past-President of the Mid-Atlantic Society of Toxicology, and a Councilor for the Philadelphia Association for Critical Thinking. He received his Ph.D. in Pharmacology and Toxicology from University of California, Davis, his B.S. in Zoology from the University of Rhode Island, and is a Diplomate of the American Board of Toxicology.

Charlie Cunningham
Technical Director, NALAN
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Charlie Cunningham is Colorcon's Technical Director for the North America and Northern Latin America regions and is responsible for technical support of film-coating processes and solid oral dose formulation using immediate and modified release technologies supplied by Colorcon.

In his 30 year career at Colorcon, Charlie has focused on coating process applications and the scale-up and optimization of aqueous film-coating processes. Charlie has published numerous articles in the areas of immediate release and delayed release film coating technologies as well as solid oral dose formulation and excipient technologies. He holds four patents related to novel film-coating and excipient formulations.

Bruno C. Hancock, Ph.D.
Head of Materials Science
Pfizer Inc.
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Bruno C. Hancock currently leads the global pharmaceutical materials science group at Pfizer Inc. He holds a bachelors degree in Pharmacy from the University of Bath, UK and a Ph.D. in Pharmaceutical Technology from the University of Bradford, UK. He held a post-doctoral research appointment at the University of Wisconsin and worked at ICI Pharmaceuticals (now Astra Zeneca) in the UK and Merck Frosst & Co. in Canada before joining Pfizer. At Pfizer he has worked in the areas of formulation development (focused on spray dried dispersions), powder technology, pharmaceutical materials science, drug product process development & technology transfer, and computational drug product design. Bruno has supervised the research of students and post-doctoral researchers in Canada, the United States, and Europe. He has published over one-hundred-and-thirty full research papers and several patents. He has served as an advisor to the United States Pharmacopoeia on the use and testing of pharmaceutical materials since 1995, and was the recipient of the Royal Pharmaceutical Society of Great Britain Science Medal in 2000 for his contributions to pharmaceutical research. He was elected to Fellow status in the American Association of Pharmaceutical Scientists in 2004. He has been an Editor for the Journal of Pharmaceutical Sciences since 2014 and he currently serves as a co-editor for the Handbook of Pharmaceutical Excipients.

Kevin Hughes, BSc (Hons) Quality Assurance and Regulatory Affairs Manager - EMEA Colorcon Limited khughes@colorcon.com 	Kevin has been with Colorcon for over 18 years where he has been the Technical Expert in film coating, immediate release and extended release excipients. Kevin is now Regulatory Affairs and Quality Assurance Manager for Colorcon and is responsible for the EMEA region, providing regulatory support to customers in both the pharmaceutical and food industries, monitoring any regulatory changes, industry initiatives and is closely involved with the IPEC Quality and Regulatory Affairs Committee. Kevin is also responsible for Quality at the Dartford site, and hosting of all customer and certification audits as well as conducting supplier audits as an IRCA qualified Lead Auditor. As subject matter expert Kevin is responsible for the paediatric initiatives within Colorcon and to update the organization about paediatric regulations, guidelines and the industry perspective. Kevin is on the board of IPEC, actively participates in the IPEC Quality and Regulatory Affairs committee and also represents IPEC on the board of EUPFI (European Pediatrics Formulation Initiative). Kevin is also Vice-President of IPEC Federation. Prior to joining Colorcon Kevin spent 5 years at Boots Healthcare Development, where he was Team Leader developing solid oral dosage forms for Boots Pharmacies. Kevin graduated with a BSc (Hons) degree in Food Science from Nottingham University in 1994. He has been involved in the pharmaceutical industry for 22 years. Over this time he has built up a strong level of expertise in the development and manufacture of solid oral dosage forms.
David Kirkland, Ph.D. Genetic Toxicology Consultant Kirkland Consulting dkirkland@genetoxconsulting.co.uk 	Professor Kirkland has a BSc (microbiology) from the University of London and a PhD (cellular cancer studies) from Brunel University. Following 2 post-doctoral fellowships he became Research Director at Toxicol Laboratories. He then joined Microtest Research Limited in 1984, which became part of Covance where, over 25 years, he was Head of Genetic Toxicology, Vice-President of Toxicology and of Scientific and Regulatory Consulting. In 2009 he became an independent consultant. He has extensive experience with regulatory issues relating to genotoxicity data, has published >150 peer-reviewed papers and is a regular podium speaker/chairperson. He was awarded Fellowship of the UKEMS in 2002, and made Honorary Professor of the University of Wales, Swansea in 2006. In 2010 he received the first Industrial Genotoxicity Group (UKEMS) Distinguished Toxicologist Award, and also the US Environmental Mutagen Society Alexander Hollaender Award for global leadership in the regulation of genetic toxicology testing. In 2014 he was awarded The Kitashi Mochizuki Award by the Japanese Environmental Mutagen Society for promotion of

	international harmonization of genotoxicity tests through the International Workshops on Genotoxicity Testing (IWGT) of which he was chair of the steering committee for 20 years, and in 2015 he received the Jim Parry Award from UKEMS. For many years he was Special Issues Editor for Mutation Research and editorial board member of the Journal of Applied Toxicology. He was a member of the UK Government Advisory Committee on Mutagenicity for 10 years, was UK expert to OECD for genotoxicity guidelines, and Past President of the European EMGS.
David Lockley, Ph.D., ERT Toxicology and Regulatory Defence Director, Global Product EHS Venator david_lockley@venatorcorp.com 	David works at Venator, formerly the Pigments and Additives Division of the Huntsman Corporation, and provides global support to the business on toxicological and product stewardship issues for its new and existing products. He also provides technical (scientific) leadership to industry-wide trade associations, consortia and task forces involved in human health research, risk assessment, and regulatory agency interaction. David is the Chair of the Titanium Dioxide Manufacturers Association (TDMA) Scientific Committee and Regulatory Task Force. After receiving his undergraduate degree in Biomedical Sciences from the University of Sunderland, David obtained a MSc in Toxicology from Birmingham, PhD in Biochemical Toxicology from Newcastle and Post Doctoral Studies in Molecular Toxicology from Dundee. He has been a European Registered Toxicologist (ERT) since 2008 and is a member of the British Toxicology Society (BTS). David has over 20 years industrial experience working as a toxicologist in the Pharmaceutical, FMCG, Chemical, Retail and Consultancy sectors in the UK.

Jason Melnick, MS Senior Director Eli Lilly and Company melnick_jason_p@lilly.com 	Jason Melnick is a Senior Director at Eli Lilly and Company where he has worked for 26 years. He is a member of the global Technical Services and Manufacturing Sciences group supporting the development, technical transfer, and manufacturing of solid oral dosage forms. Jason co-chairs the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ) Titanium Dioxide Working Group.
Mike Tobyn, Ph.D. Senior Scientific Director, Materials Science and Engineering (Moreton) Bristol Myers Squibb mike.tobyn@bms.com	Mike has worked for BMS for 18 years and is part of Materials Science and Engineering function within Drug Product Development (Product Development and Supply. His team is based in Moreton, England and New Brunswick, New Jersey. Their function is to look at all small molecule assets, from Discovery through to Manufacturing, and assess the characteristics, and using data to predict and understand their performance in solid oral dosage forms. The work involves analytical science and big data analysis, and Mike has co-edited book on the use of Multivariate Data Analysis in the Pharmaceutical Industry. Mike has worked extensively in the area of excipients, and is a member of the USP Committee on excipient test methods, and is an advisor to the *Handbook of Pharmaceutical Excipients.* He is currently looking at mitigation strategies relating to the potential ban in European pharmaceuticals of titanium dioxide, which is in all BMS small molecule formulations, and 91,000 other pharmaceuticals across Europe. Mike is coordinating a cross industry technical response. A Registered Pharmacist, Mike trained in Pharmacy at the University of Strathclyde, and took his PhD there in 1994. Mike taught Pharmaceutical Technology at the University of Bath and at the University spin-out company Vectura, where he was with the company from inception through to IPO. In 2019 Mike was elected as the Eminent Fellow of the Academy of Pharmaceutical Sciences for his contribution to the field of Pharmaceutical Technology across the world. Mike is married with 4 children, two are currently at High School and two at University.

Jay West Senior Director, Chemical Products and Technology American Chemical Council jay_west@americanchemistry.com 	Jay West is Senior Director, Chemical Products and Technology, at the American Chemistry Council (ACC) in Washington, DC, where he serves as the Executive Director of several ACC groups, including the Titanium Dioxide Stewardship Council. The Council's exists to promote the safe use of TiO2 through research, product stewardship, advocacy, and outreach. Jay regularly advocates at the federal level, in all 50 states, and globally. He is the head of the industry delegation to the chemicals committee at the 38-country Organization for Economic Cooperation and Development, and he represents industry's interests in global environmental treaties, such as the Stockholm Convention on Persistent Organic Pollutants, and others. Jay has graduate degrees from Yale and the University of Michigan.

BREAKOUT MODERATORS	
Uma S. Bruen, Ph.D., MPH Director, Lead Occ & Env Toxicology Organon LLC uma.bruen@organon.com 	With more than 2 decades of pharmaceutical and academic experience, she brings extensive knowledge of the industry's risk assessment process in setting health-based exposure limits, therapeutic areas, and subsidiary operations to lead in occupational & environmental toxicology and quality programs in the creation and expansion of Organon. Uma is the lead and chair of Organon Drug Handling Committee. Uma has spent the last 11 years with Merck in several technical and leadership roles, most recently as Associate director with professional experience as a toxicologist, supporting and managing programs for occupational toxicology, hazard evaluation and communication, occupational toxicology testing and risk assessment, as well as environmental and product safety issues in the pharmaceutical industry. She was the Chair and secretary of the Merck Industrial Toxicology Advisory Committee which sets formal health-based exposure standards to support worker protection and product quality. She is also the lead in extractable & leachable safety assessments and is a contributing member and Chair of the ELSIE consortium. Prior to Merck, spent 12 years at Abbott in Pre-clinical safety, Occupational and Environmental Toxicology and Regulatory/Quality. Uma received her Master's in Public Health, Toxicology from the University of Michigan and Doctorate from Rutgers's School of Public Health, Environmental and Occupational Health.
George Collins Vice President Vanderbilt Chemicals LLC gcollins@vanderbiltchemicals.com 	George graduated from UCLA in 1977 with a Bachelor of Science Degree in Biochemistry. He worked from 1980 to 1984 as a Research Animal Attendant at Fort Collins Veterinary Teaching Hospital where he managed ~ 80 horses daily with a team of veterinarians. George would find his next employer, RT Vanderbilt Co Inc. in Norwalk, Ct in 1984 where he worked in R&D with minerals used as pharmaceutical excipients and sale of chemicals in international markets. Eventually George relocated to Murray, Ky in 1990 where he managed a production facility for the firm's mineral-based excipients and coordinated mining developments at the company's mines out west. George began seriously studying GMP and his company would become a member of IPEC-Americas in 2011. George would contribute with various assignments at IPEC including: • GMP Audit training • Vice Chair Compendia Review • Executive Committee • Vice Chair Membership • Core Revision Team for the 2022 GMP Guide George enjoys taking care of his horses in Kentucky with his family. He also enjoys skiing, riding his motorcycle, reading a good mystery, and traveling.