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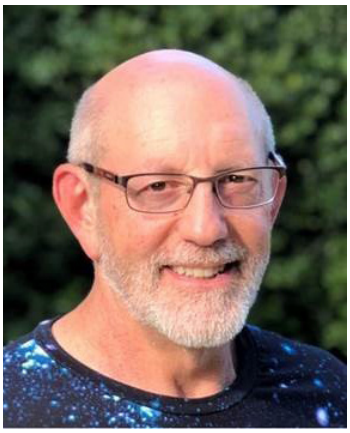
MEET THE EDITOR

Meet our Editorial Board Member: Mark Shapiro



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Mark Shapiro received his Bachelor of Science degree in Pharmacy from the Philadelphia College of Pharmacy and Science (now University of the Sciences in Philadelphia) in 1977. After three years of practicing community pharmacy, he switched careers and devoted himself to his childhood passion, chemistry. Beginning his career as a quality control analytical chemist, he worked for three generic and nutraceutical companies in PA, NJ, and VT , for the most part as a bench analyst-cum-lab supervisor.

In 1988, Mark joined McNeil Consumer Products Company in Fort Washington PA as a Research Associate, where he spent the next 7 years. In that time, he received the prestigious Vice President's Research Award for Outstanding Technical Achievement in 1991 for his work in the final determination of and cause/solution to an historic but sporadic product granulation discoloration issue. In additions, along with 18 podium or poster presentations, he also swiftly hypothesized and proved the underlying cause of a critical tablet discoloration issue, resulting in amelioration of the issue; proved the cause of an off-taste chewable tablet issue including synthesis and qualification of a reference standard material to aid in further analyses; and performed seminal patient clinical trial sample plasma/bioanalyses that contributed to and culminated in the approval of famotidine OTC tablets.

In 1995, Mark joined Warner-Lambert in Lititz, PA as Manager of the newly-formed Analytical Technical Services group, whose global role was in the area of analytical methods development/validation/transfer in support of a consent decree imposed by the FDA on the company, and responsible for a budget of $7-10 million. Over the next eleven years, during which time Pfizer acquired Warner-Lambert, he was pivotal in driving cultural change within the Quality Organization of 140+ members as well as being editor of the major quarterly publication, *The Qmunicator*. Mark became a company-recognized subject matter expert in the areas of analytical methods development/validation/transfer and of cleaning validation analytical methods, received accolades for implementation of a rewards and recognition system and for submission of new ideas, and was dubbed *The Idea Machine* in an official company-wide magazine, subsequently being recognized for submission of over 400 ideas for product improvements/line extensions and new therapeutic categories/treatments. On the scientific side, Mark and his team contributed 39 publications or presentations, among which most notably was the final determination of the root cause of an historic issue with production of a final tablet dosage form that had gone unexplained for decades, for which research Mark received his Master of Science

degree in Pharmaceutical Chemistry from Lehigh University in 2003. Mark spearheaded the effort to institute Process Analytical Technology (PAT) into the automated production of Listerine formulations, driving the multi-million dollar infrastructure and construction efforts as well as analytical methods developments with his sub-team of three analytical scientists, culminating within 15 months in validation of analytical methods and of the demonstrable ability to generate real-time on-line analytical data of five analytes in three different formulations of Listerine.

In 2006, Mark was promoted to Director of both the Global Reference Standards group and the Co-Development Analytical Resources team, with a budget in excess of $10 million, in Groton, CT. The Reference Standards team were responsible for storage and supply of reference standards to Pfizer sites and customers worldwide, many of which were qualified and periodically retested in-house; while the Co-Development Analytical Resources team's mission was to provide oversight to methods development as they transitioned from AR&D to Production, ensuring practicability and QC-friendliness, and for transfers of those and other methods.

The burgeoning size of Pfizer resulted in waves of layoffs, to which Mark fell prey, resulting in his next role as Manager of the AR&D team stationed at Noramco in Athens, GA in 2007-2008, with responsibility for colleagues at both that site and in Wilmington, DE.

In 2008, Mark accepted the challenges inherent in the newly-created role of Director of GMP Analytical Chemistry at PharmaCore, Inc., a CDMO producing early phase APIs, in High Point, NC. He was responsible for writing all SOPs, hiring all team members, purchasing all equipment, setting team policies, and for oversight of all scientific/analytical research. He was responsible for all direct interactions with PharmaCore's clients in the analytical chemistry arena, functioning as in-house analytical expert, and drafting and submitting quotations for analytical work. Mark continued at PharmaCore. and with Cambrex post-purchase in October 2016, until his retirement at the end of 2019. In this time, he or his team published seven journal articles and developed and qualified or validated innumerable analytical methods. Mark was the lead for a $6 million site expansion in 2017-18 that included complete build out of an 11,000 sq. ft. AR&D laboratory space.

Immediately upon retirement, Mark activated MCS Pharma Consulting LLC in December 2019, serving as President and Principal Consultant, and recognized as an expert in analytical method development, validation, and transfer, as well as in the area of analytical methods for cleaning validation, and with expertise and wide experience in other areas.

Outside of his professional pursuits, Mark is an avid amateur astronomer. He enjoys weightlifting, cycling, and spending time and traveling with his dear wife of over 36 years.

Selected Publications/Presentations

1. Lot Release Testing Analytics for Small-Molecule Drugs. Pharm Techn 46, 50-51(2018).
2. Setting Up a Modern Analytical Laboratory To Meet Current Pharmaceutical Challenges. Manuf Chem, September issue, 22-24 (2018).
3. Characterization of Unknowns in an NSAID Gel Formulation Via Oxymercuration. PharmaChem Magazine, July/August issue, 10-12 (2009).
4. Development of Analytical Methods to Accurately and Precisely Determine Residual Active Pharmaceutical Ingredients and Cleaning Agents on Pharmaceutical Surfaces. Annal Pharm Rev 5(2), 35-40 (2002).
5. Validation of a Reversed-Phase HPLC Method to Determine Residual Nonoxynol-9 on Pharmaceutical Process Equipment Using a 1.5µ Nonporous Silica (NPS) Col-

umn. LCGC 19(3), 312-317 (2001).
6. An Overview of Selected OVI/RS Methodologies (Replete with Anecdotes), 2001 Eastern Analytical Symposium. podium presentation (2001).
7. Validation of a Cation-Exchange Method to Test for Residual Amounts of a Cleaning and Sanitizing Solution on Pharmaceutical Process Equipment. BioPharm Int. 13(1), 51-64 (2000).
8. Investigation of the Behavior of Phenelzine Sulfate in the USP Ordinary Impurities Test, podium presentation at the April 2000 Southeastern Pennsylvania ACS Chapter Dinner Meeting (2000).
9. Miscellaneous (Various posters or podium topics): Extractables/Leachables testing; Pharmacokinetics of Ibuprofen in Febrile Children; Using Aromascan Digital Aroma Technology for On-Line Real-Time Listerine Antiseptic Release Testing; Importance of Data Interpretation During Methods Development for Ethosuximide Cleaning Validation; Determination of Potency of Separate Components of Bacitracin Zinc via Preparative HPLC.