PQRI DTC 2022 Webinar

Extractables and Leachables Testing for Transdermal Delivery Systems

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Bios

Moderators:

Desmond Hunt, Ph.D., Senior Principle Scientist
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Dr. Desmond G. Hunt has been with USP since 2005 and holds the position of Sr. Principle Scientist in the Compendial Science Group-General Chapters. He is the scientific liaison to the Packaging and Distribution and Dosage Forms Expert Committees, where he works to develop and revise USP Standards. He has authored many publications and peer-reviewed articles and is a frequent speaker and instructor on topics related to pharmaceutical packaging, particulate matter in parenteral and ophthalmic dosage forms and good storage and transportation practices. He participates on several industry Working Groups and Technical Committees related to his areas of expertise. Dr. Hunt obtained his M.S. and Ph.D. from the University of Texas at Austin and prior to joining USP, was a Research Fellow at the National Institutes of Health, Bethesda, MD, USA

Meenal Chavan, Ph.D., Senior Pharmaceutical Quality Assessor
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Meenal Chavan, Ph.D. is Senior Pharmaceutical Quality Assessor within OPQ's Office of Lifecycle Drug Products in CDER/FDA. She performs secondary review assessment of ANDAs, Pre-ANDAs and DMFs including ANDA submissions of complex dosage forms such as Transdermal drug delivery systems, Modified & Immediate release solid oral formulations, Implants & Intra-Vaginal ring. She is responsible for quality review of the ANDA's as an Application Technical Lead. She is a member of Transdermal working group and development of New Inspection Protocol Program (NIPP). Meenal joined FDA in 2016. She works on Developmental Technical Committee of PQRI to promote advancements in drug product development. Prior to joining FDA, she worked as a Sr. Manager R&D (Transdermal) at Sun Pharma, NJ. She has 20 plus years of complex product formulation products experience. She received her Ph.D. in Pharmaceutical Sciences from University of Mumbai, India.

Speakers:

Cedar Boakye, Ph.D., Drug Product Quality Assessor
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Cedar Boakye, Ph.D. is a drug product quality assessor within OPQ's Office of Lifecycle Drug Products in CDER/FDA. She performs quality assessment of prospective generic transdermal and topical drug delivery systems (TDS), implants, vaginal systems, intrauterine systems, and modified- & immediate-release solid oral products. Since joining the Agency in 2015, she has been particularly active in TDS regulatory assessment activities. She is a member of the CDER Transdermal Working Group and maintains an active interest in research associated with TDS quality. Her work to evaluate intrinsic safety issues associated with fentanyl reservoir transdermal systems led to removal of these products from the US market, and she was recognized with the FDA Scientific Achievement Award for Excellence in Review Science and the CDER Group/Team Honor Award due to the impact of this work. She also serves as a Government Liaison to the USP Expert Committee for Complex Excipients and the Polymer Subcommittee. She earned her PhD in pharmaceutical sciences from Florida A & M University, Tallahassee, Florida, and she is the author of over ten publications.

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Gyorgy Vas has over 25 years of experience in scientific research, pharmaceutical and medical device product development, and laboratory management. Over 15 years was spent in a cGMP environment, where that scientific expertise was applied to solve problems related to finished pharmaceutical products and medical devices. In his current position, he is advising regulatory filing strategy for multiple clients, and his group provides solutions for mitigate deficiency letters.

He is serving as an internal scientific consultant to the laboratory operations, evaluating new analytical techniques, software products for extractables and leachables testing. As part of his current role he is involved to evaluate and implement non-routine analytical instrumentations and methods for cGMP use. He published more than 20 analytical papers, related to various activities, including sample preparation, trace level method validation, molecular imaging, structure elucidation, and E&L testing. Those scientific publications papers have been cited more than 3000 times over the years.