MedPharm
Breaking through boundaries

MedPharm Seminar Series East

September 18, 2024 | Hilton East Brunswick Hotel & Conf. Center, East Brunswick, NJ

MedPharm is proud to sponsor a series of seminars featuring on some of the pharmaceutical industry's hottest topics. Featuring engaging and knowledgeable experts, this seminar will cover current trends and issues most relevant to pharmaceutical professionals involved in both early- and late-stage pharmaceutical development.

Join us for this one-day-only event where you can meet colleagues and learn how to face current industry challenges. Space is limited, so don't wait to register!

Hilton East Brunswick Hotel & Conference Center
3 Tower Center Boulevard
East Brunswick, NJ 08816
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Agenda:

11:00am - 11:30am	Registration	
11:30am - 12:00pm	Overcoming the bariers of topical - discovery to commercialization	*Jon Lenn*
12:00pm - 12:45pm	Lunch	
12:45pm - 1:45pm	CMC Regulatory Resources for Informing Drug Product Development	*Mark Gehrke*
1:45pm - 2:15pm	In Vitro Models for Transepithelial and Locally-Acting Drugs	*Jon Volmer*
2:15pm - 2:30pm	Networking & Refreshments	
2:30pm - 3:00pm	Complexity in Scale-Up: A Path to Commercialization	*Naveen Mallampati*
3:00pm - 4:00pm	Welcome to the Machine: What Life Science Companies Need to Know About FDA's Stance on AI	*Alan Minsk*
4:00pm - 5:00pm	Networking & Social Hour	

Overcoming the Barriers of Topicals: Discovery to Commercialization

The 'medicine' for any topical is the vehicle and the drug, where the vehicle becomes critical for local delivery. This 'medicine' must be uniquely formulated for the epithelium, whether it be mucosal or keratinized. Here we will discuss an overall formulation development strategy that can be used from early development through the different stages of development and into commercialization. This will include the use of phase appropriate performance and product characterization tests to derisk these formulations prior to the clinic. Thus, providing the patient and regulatory agencies with high quality medicines.

Jon Lenn, PhD
Chief Scientific Officer, MedPharm

Biography: Dr. Lenn is responsible for MedPharm's global scientific operations and is based out of Durham, North Carolina. Since joining in 2015 he has led MedPharm's development of cutting edge performance models for assessing penetration and activity of clients' products targeted towards key biochemical pathways. He has over 22 years of industry experience working with private, public, and private equity based pharmaceutical and contract research development organizations. Specialized knowledge in the development of topical and transdermal medications from early discovery through approval and into post-marketing support resulting in the approval of >50 marketed products. He received his PhD in Pharmaceutics from the University of Reading.

CMC Regulatory Resources for Informing Drug Product Development

Successful commercialization of a new therapeutic product requires data demonstrating that the involved manufacturing processes are reliable and capable of consistently supplying patients with products of consistent quality. There are multiple CMC regulatory resources available to help identify the data requirements which are necessary to achieve regulatory approval. This presentation will summarize a variety of available regulatory resources that many developers rely upon to design a successful CMC FDA submission strategy. Opportunities to benefit from the contract facilities expertise and for obtaining FDA feedback during development will be discussed. Themes from FDA feedback on a variety of IND, NDA, and BLA submissions will be introduced and provide an opportunity for engagement with the audience.

Mark Gehrke, PhD
Senior Consultant CMC, Dunn Regulatory Associates, LLC

Biography: Dr. Gehrke has more than 20 years of experience within CMC and bioanalytical from multiple early-stage Pharma companies, various roles within a CRO, and Regulatory CMC oversight of commercial products at a medium-sized pharma company. His CMC responsibilities have included discovery through commercialization activities including drug-device combination products. He received a doctorate in Analytical Chemistry from Missouri University of Science and Technology.

In Vitro Models for Transepithelial and Locally-Acting Drugs

In vitro testing models assess a formulation's relative ability to deliver API through the epithelium to its molecular target. The two main classifications of epithelial tissue (mucosal and keratinized) present their own unique challenges to drug formulation performance. Here, we present a subset of these models, highlighting the differences between the two main epithelial tissue types using respiratory epithelium as an example of a mucosal epithelium, and skin as an example of keratinized epithelium.

Jon Volmer, PhD
Senior Director of Research Biology and Innovation, MedPharm

Biography: Dr. Volmer joined MedPharm in 2016 to generate new technologies, systems, and biological models to expand MedPharm's capabilities to better serve the needs of current clients, and expand into new areas of expertise. He has over 15 years' experience developing a variety of biological models and technological lab support equipment in fields including immunology, microbiology, pulmonary disease, and mechanical modeling. Dr. Volmer received his PhD on the biochemical basis of inflammatory remodeling in the lung from the University of Texas Graduate School of Biomedical Sciences.

Complexity in Scale-Up: A Path to Commercialization

This session will cover various aspects of scale-up, including QbD/DOE, process nuances, equipment to bulk aspect ratios, and risk mitigation strategies. Naveen will discuss factors leading up to commercial launch such as supply chain, CCS, raw materials, compounding, fill, and finish, regulatory framework, cost and time. The session will include real-world case studies demonstrating effective commercial launch strategies.

Naveen Mallampati
Director of LateStage R&D, MedPharm

Biography: Mr. Mallampati has over 15 years of experience in the formulation development of drug product technology transfer and manufacturing of specialty complex generic, semisolid and liquid dosage forms. He is a well-rounded scientist with functional knowledge and training in product development (CMC and manufacturing) domain and a proven track record leading the development of products from the conceptual stage to commercialization. He is skilled as a project hampion and at data integration across functional teams while providing directional and technical leadership. Mr. Mallampati has a Bachelor of Science degree in Pharmacy and an Master of Business Administration in Pharmaceutical Management.

Welcome to the Machine: What Life Science Companies Need to Know About FDA's Stance on AI

As evidenced by FDA's recent discussion paper on artificial intelligence ("AI") and other guidance documents discussing the development of drug, biological, and medical device products, the burgeoning technology continues to be at the forefront of FDA's focus. Alan will delve into FDA's regulation of AI-driven technologies as it relates to product development and manufacturing, providing insight into FDA's statements on AI (such as FDA's discussion paper and guidance documents), a look at cybersecurity risks, and recommendations to maximize the AI opportunity while minimizing the regulatory risks. There will be an opportunity for Q&A at the end of this webinar.

Alan Minsk
Partner, Head of Food & Drug Team, Arnall Golden Gregory LLP

Biography: Mr. Minsk is a partner and co-chair of the Food & Drug practice and Life Sciences industry team at AGG. He focuses on advising pharmaceutical, biologic, medical device, cosmetic, and food companies on all legal and regulatory matters relating to the U.S. Food and Drug Administration. He has written book chapters, articles, and bulletins on a wide variety of issues, including 505(b)(2) NDAs, orphan drugs, product promotion, quality agreements, compliance, and medical device regulation. He is the editor of AGG's Food and Drug Newsletter and has spoken throughout the U.S. and in Canada, Israel, and Europe.