Vijendra Nalamothu, Ph.D.
Tergus Pharma

Dr. Vijendra Nalamothu is the Chairman & CEO of Tergus Pharma, a North Carolina-based CDMO which specializes in complete topical drug product development services, skin permeation, *in vitro* testing, and GMP manufacturing (up to 1500 kg per batch). Dr. Nalamothu earned his Ph.D. in Pharmaceutics from the University of the Science's Philadelphia College of Pharmacy. His efforts over the past 26 years in various dermatological companies have led to many commercial products in the market today. He has successfully taken Tergus Pharma from a small R&D facility to a 100,000 SFT commercial manufacturing facility with industry-leading capacities. His knowledge of the *unmet* needs in the Dermatology CDMO industry led to equipping Tergus Pharma with unique R&D capabilities such as Skin Biology and *In Vitro* Permeation (IVRT & IVPT) as well as Hormone and High Potent compound manufacturing at a commercial scale. Dr. Nalamothu draws from his exceptional background that combines scientific study with pragmatic, hands-on experience to solve R&D challenges and his ability to translate a concept into a commercial product. He has co/authored numerous publications and has patents for a few of his inventions. He serves as a member of various pharmaceutical associations as well as sits on the boards of various pharmaceutical companies. In his spare time, Dr. Nalamothu enjoys his quiet time with family, boating on Raleigh's Falls Lake.

Abstract:

"The Importance of Right Formulation":

Topical drug product delivery has a number of advantages: the ability to deliver drug substance more selectively to a specific site, avoiding fluctuations in drug levels, inter-and intra-patient variations, improved compliance, and enhanced suitability for self-medication. Skin provides an ideal site for the delivery of drug substances for both local and systemic effects. However, it also acts as a mechanical barrier to the penetration of many drug substances. All of the advantages of topical therapies rely on having the right formulation. A small change in the formulation can make a large difference in the efficacy of topical treatments. With topical therapies, the formulation is as important as the molecule itself because the interaction of the vehicle with the skin can alter the efficacy of the penetrant. The formulation ensures that the drug substance is delivered to the right target site and that it maintains dosage integrity, drug transport, and the duration of the activity.

Whether the molecule maintains purity, potency, and delivery to the right target site may be masked by the ingredients that surround it. Both the mechanical barrier properties of the top layer of skin, stratum corneum, and the physicochemical properties of the drug affect the transportation of the drug substance from the formulation vehicle to the site of action. In addition to the formulation components, a simple change in properties, such as pH, viscosity, the relative amounts of oil, water, surfactants, stabilizers, droplet size, ionic nature, or the method of preparation, can often influence skin absorption and efficacy.

This topic covers the development of a good formulation with an appropriate pre-formulation program and careful selection of excipients, including stabilizers and permeation enhancers, early stability studies, cell line/tissue toxicological studies, IVRT and skin penetration studies, and finally formulation development and optimization. The topic also covers the de-risking approaches built into the right formulation that takes the product through various clinical stages and into a commercial launch.