10th Anniversary
2011-2021

# RESEARCH REMOTE SEMINAR SERIES

The Center for Dermal Research welcomes

Dr. Robert Falcone, Prestige Consumer Healthcare

*"How to leverage real world data for claim substantiation?"*

**Monday, January 25th at 5:30pm EST**

Robert received his B.S. in Physical Chemistry and Chemical Engineering from the U.S. Naval Academy. He received his M.S. in Chemical Engineering from Manhattan College and his Ph.D. in Material Science and Engineering from NJIT. From 1980 to 1987, he worked with the ONR as a Materials Scientist/Line officer. He worked at Zeneca (now known as Astra-Zeneca) as a Regulatory Scientist in Active Pharmaceutical Ingredients for Human and Animal Prescription Applications to FDA and EU. Program Regulatory Manager for the Hartz Mountain Corporation / Church and Dwight working with Veterinary and Human Drugs (Prescription and OTC) - FDA & EPA. Director of Regulatory Devices (Class I and II) and Combination Products – Nice Pak – FDA and Health Canada. Director of Regulatory Affairs for Prescription and OTC Dermatological Products – FDA, EMA and Health Canada – Peter Thomas Roth LLC. Sr. Global Regulatory Manager – API development and submissions to FDA, Health Canada, Mexico, Brazil, EU and China – Vantage Specialty Ingredients. Sr. Global Regulatory Affairs Manager for Finish Prescription and OTC products representing companies selling in the US, Canada and EU – Integris Biosolutions and Presently working as a Sr. Regulatory Affairs Manager for Finish Prescription and OTC products sold in US and Canada – Prestige Consumer Healthcare.

Inducted into Tau Beta Pi (Engineering), Sigma Xi (Research), Alpha Sigma Mu (Materials Science) and the American Academy of Dermatology.

**ABSTRACT**: Unlike pharmaceuticals in the US, claims in personal care products are usually not reviewed nor require approvals before products are sold in the US market. However, it is not implied that regulators do not monitor the market for misrepresentations on such products. Moreover, since label and advertising approvals are not required to sell cosmetic products in the US, other US agencies will conduct additional oversights. Because of this lack of clarity, personal care and cosmetics manufacturers have, on several occasions, trespassed the boundaries on the claims used, resulting in being cited for promoting unsafe/unadulterated products in the US market.

The presentation will focus on research looking at leveraging techniques used in the drug industry to leverage real world data for claim substantiation

CONFERENCE LINK:

Meeting link:
https://rutgers.webex.com/rutgers/j.php?MTID=m7df5d4292331cb5317699f480aefb0da

For direct link send an email to cdr_frontdesk@dls.rutgers.edu; or visit
https://sites.rutgers.edu/centerfordermalresearch/cdr-events/seminar-series/

RUTGERS

*Center for Dermal Research, 145 Bevier Road, Piscataway, NJ 08854*
*Tel: 848.445.3589 Fax: 732.445.5006 For more information: cdr_frontdesk@dls.rutgers.edu*