



RESEARCH SEMINAR SERIES

The Center for Dermal Research Welcomes

Romit Jani, Director and Head of Formulation R&D at Solaris Pharma

“Generic topical drug development: formulation development, process development and scale-up”

Monday, April 24; 5:30 EST Remote



Romit Jani is the Director and Head of Formulation R&D at Solaris Pharma, a company primarily focused in the development of complex dosage forms. Currently, he leads the research and development activities of the company including formulation development, scale up and commercialization. Prior to Solaris, he worked as a Research Scientist at Amneal Pharmaceuticals and was responsible for formulating and scaling up of various complex dosage forms including topicals, extended-release powders and ophthalmics. He received his Master of Science in Pharmaceutical Manufacturing from

Stevens Institute of Technology in Hoboken NJ and has around 10 years of experience in the pharmaceutical industry taking products from concept to commercialization.

Abstract: This presentation provides insights on the key concepts of generic topical drug development which aims at matching the desired quality attributes of the generic drug product to the reference-listed drug (RLD) product. The key elements of generic drug development being discussed in this presentation are:

- 1) Formulation development strategy to develop the generic product with qualitative (Q1) and quantitative (Q2) formulation similarity as well as similarity in formulation microstructure (Q3) to the RLD.
- 2) Key aspects of formulation development, process development and scale up activities with quality by design (QbD) approach and its elements such as the quality target product profile (QTPP), critical material attributes (CMAs), critical process parameters (CPPs) and linking CMAs and CPPs to CQAs.
- 3) Scale-up challenges from lab to commercial scale formulation with examples.

CONFERENCE LINK:

Meeting link: <https://rutgers.zoom.us/j/97297467705?pwd=Y1FiTGh1TG9adUZtNklocEFBaU0yQT09>

Link is also available on our website: <https://sites.rutgers.edu/centerfordermalresearch/>

under the Events menu.

