CHICAGOLAND PHARMACEUTICAL DISCUSSION GROUP

Affiliated with the American Association of Pharmaceutical Scientists

Fall, 2022 Volume XXX, Number 1

PROGRAM: DESIGN AND DEVELOPMENT OF HIGH CONCENTRATION PARENTERAL

NANOSUSPENSION: OVERCOMING STABILITY AND MANUFACTURING

CHALLENGES

DATE: THURSDAY, OCTOBER 6, 2022

SPEAKER: DR. SHAH, RESEARCH FELLOW AND HEAD OF TOPICAL AND ADVANCED

DRUG DELIVERY GROUP, PHARMACEUTICAL SCIENCES SMALL

MOLECULES, PFIZER

Parenteral nanosuspensions with high concentration of nanoparticles creates unique challenges in levels of stabilizer that can be used, and particle size stability during manufacturing and stability. The presentation will provide example of how high concentration ready to use (RTU) nanosuspension was developed with very low levels of stabilizer that demonstrated multi-year room temperature stability. Different manufacturing processes for generating nanoparticles were evaluated, and process scaled up suitable for sterile nanosuspension. The ready to use 21-42% nanosuspension was modified to be able to terminally sterilize by autoclaving and irradiation, successfully delivering GMP supplies with a larger scale process.

Dr. Jaymin Shah is a Research Fellow in Pharmaceutical Sciences and heads a topical and advanced drug delivery group in Pfizer R & D-Groton. He also holds an adjunct faculty appointment at the University of Houston. Dr. Shah obtained his Ph.D. in Pharmaceutics from University of Houston. From 1988-1999 he served as Associate Professor (Tenured) of Pharmaceutical Sciences at Medical University of South Carolina, where he led a lab developing sustained release parenteral delivery systems and modeling of skin transport and mentored 7 Ph.D. and 2 MS graduates. Dr. Shah joined Pfizer in 1999 where he has led formulation groups and project teams supporting development of various candidates as parenteral/ophthalmic dosage forms, peptide and oligonucleotides development and research initiatives in parenteral and ophthalmic delivery including LAI, depots, sterile suspensions, implants, and nanoparticles. He has been recognized with achievement awards for leadership and innovation in Pfizer. Dr. Shah has published 63 papers, 10 patents/patent applications, 75 abstracts and made more than 114 presentations at various scientific forums such as Arden House Conference, AAPS symposia, CRS, FDA and academic centers. His current research interests include topical drug delivery, parenteral sustained release (depot), nanoparticles, ophthalmic delivery, and topical formulation development.

TIME: 5:30 PM - SOCIAL HOUR

6:00 PM - DINNER

7:00 PM - MEETING

PLACE: JAMESON'S CHARHOUSE

151 E TOWNLINE RD, VERNON HILLS

COST: \$55.00

REGISTER AT cpdgmeeting@gmail.com

THE DINNER MEAL CHOICES ARE THE FOLLOWING:

- 1. DE JONGHE CRUSTED COD SERVED WITH RICE PILAF & VEGETABLES
- 2. LEMON PEPPER CHICKEN SERVED WITH RICE PILAF & VEGETABLES
- 3. VEGETABLE KABOBS SERVED WITH RICE PILAF (VEGETARIAN)

WHEN REGISTERING, PLEASE INDICATE YOUR SELECTED DINNER MEAL:

Meal Choice: Fish, Chicken, or Vegetarian	First Name	Sur (Last) Name	Company

MAIL CONFIRMATION WILL BE SENT CPDG ACCEPTS CASH AND CHECKS (PERSONAL OR COMPANY) ONLY!!! FIRST FIVE STUDENTS ARE FREE PLEASE MAKE RESERVATIONS EARLY NO-SHOWS WILL BE BILLED ACCORDINGLY Firm Registration Deadline of 12:00 p.m., Tuesday, October 4, 2022

DIRECTIONS TO THE OCTOBER 6, CPDG MEETING AT JAMESON'S CHARHOUSE 151 E TOWNLINE RD, VERNON HILLS, IL

- EXIT I-94 AT TOWN LINE RD. (60)
- HEAD WEST ON TOWN LINE ROAD (60) PAST MILWAUKEE AVE (21)
- RESTURANT WILL BE ON THE LEFT-HAND SIDE OF THE ROAD

