

CHICAGOLAND PHARMACEUTICAL DISCUSSION GROUP

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PROGRAM: ROLE OF PRIMARY DRYING IN THE DEVELOPMENT OF LYOPHILIZATION CYCLES FOR AN ENZYME, A PROTEIN, AND ANTIBODY DRUG CONJUGATES

DATE: THURSDAY, APRIL 11, 2024

SPEAKER: DR. GREGORY SACHA, SIMTRA BPS

Lyophilization is a key unit operation for the formulation of stable biologic formulations. This presentation examines the role of primary drying using three recent case studies for lyophilized large molecules. The first case study will examine a phenomena known as vial fogging. A client transferred a formulation containing a 16 kD protein to full-scale manufacturing and operated at full-scale for many years. The process routinely discarded 30% of each batch due to severe vial fogging. One batch was manufactured using a completely new lot of glass, tubing vials and over 99% of the batch was discarded due to severe vial fogging. Another formulation was transferred directly into the manufacturing area and was composed of mostly sucrose and tris with 1 mg/mL of an enzyme and a 0.9 mL fill volume in a 3 mL vial. Two full-scale batches were immediately lost due to collapse of the product resulting in a loss of at least \$1 million. Insufficient primary drying time was provided for the batches when transferring from a different site. This required transferring the formulation and process to development to thermally characterize the formulation and improve the process.

Simtra BPS approaches lyophilization cycle development using quality by design (QbD). Multiple formulations and processes have been developed for antibody drug conjugates and transferred to our manufacturing site in Halle, Germany. A primary drying design space is created using a QbD approach to identify the most efficient primary drying cycle and establish the safe zone of operation. This approach has reduced cycles from four to five days to three days and provided the site with a method to solve for potential process excursions.

Dr. Sacha leads the research and development team at Simtra BPS in Bloomington, IN, and has been a member of the team for over 18 years. Dr. Sacha has over 23 years of experience in the pharmaceutical industry with expertise in injectable drug product development. He leads analytical method development, formulation development, and process development for large and small molecules. He and his team are especially well-versed in lyophilization process development where they follow a design space approach to primary drying cycle development. Dr. Sacha and his team support manufacturing operations through their expertise in lyophilization and also through isolation and identification of particles. Dr. Sacha directs a short course titled Sterile Products: Formulation, Manufacture and Quality Assurance and developed a lyophilization workshop. He and his team are active members of LyoHUB where they lead the development of best practice papers on lyophilization operations.

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

ZELLE PAYMENT AT cpdg2022@gmail.com

THE DINNER MEAL CHOICES ARE THE FOLLOWING:

1. DE JONGHE CRUSTED COD – FRESH BAKED PACIFIC COD WITH SIGNATURE SAUCE
2. CHICKEN PICANTE – SAUTÉED IN WHITE WINE AND MUSHROOMS & SERVED WITH RICE AND VEGETABLES
3. VEGETABLE KABOBS (GREEN PEPPER, ONION, MUSHROOM AND TOMATO) – SERVED WITH RICE (VEGETARIAN)

WHEN REGISTERING, PLEASE INDICATE YOUR SELECTED DINNER MEAL:

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

**E-MAIL WILL BE SENT
CPDG ACCEPTS CASH, CHECKS (PERSONAL OR COMPANY) OR THROUGH ZELLE
FIRST FIVE STUDENTS ARE FREE
PLEASE MAKE RESERVATIONS EARLY NO-SHOWS WILL BE BILLED ACCORDINGLY
MORE INFORMATION CAN BE FOUND ON THE CPDG WEBPAGE:**

<https://aaps-cpdg.org/>

Firm Registration Deadline of 12:00 p.m., Tuesday, April 9, 2024

**DIRECTIONS TO THE APRIL 11, 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

