

# CHICAGOLAND PHARMACEUTICAL DISCUSSION GROUP

Affiliated with the American Association of Pharmaceutical Scientists

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## **PROGRAM: BIOWAIVERS FOR CMC CHANGES: REGULATORY AND SCIENTIFIC CONSIDERATIONS**

**DATE: THURSDAY, MARCH 16, 2023**

**SPEAKER: DR. YIHONG QIU, QPD SOLUTIONS LLC**

Drug products and processes rarely remain unchanged during development or commercialization. CMC changes often include raw materials, formulation, process, manufacturing site, shelf-life or specification, etc. Before these changes, it is essential to understand and assess the potential effects of the changes on product quality, safety and efficacy. Depending on the nature and extent of the changes, bioequivalence (BE) or bioavailability (BA) studies are usually required for certain types of changes that are considered to have a substantial potential of adverse impact by the regulatory agencies. However, BE/BA studies may be waived (biowaiver) when relevant regulatory requirements are met, and/or scientific justification can be provided based on understanding of product, process, quality tests and their in vivo impact. This presentation will discuss regulatory requirements and scientific justifications for biowaiver with case studies involving formulation & process changes, dissolution failures and specification revision.

Dr. Qiu currently serves as technical director of QPD Solutions LLC, a technical service company providing a broad range of scientific and technical expertise, hands-on guidance and trainings on science-based design, development of pharmaceutical products & processes, intellectual properties (IP) and commercial manufacturing. Prior to establishing QPD Solutions in 2022, he was a Senior Research Fellow, Formulation Sciences at AbbVie. He has in-depth knowledge and extensive hands-on experience in different stages of drug product lifecycle, from preformulation, biopharmaceutics/pharmacokinetics, drug delivery technology to product/process design & development, scale-up, technology transfer, manufacturing troubleshooting, IP, product line-extension, and regulatory filing. During his 30-year tenure with Abbott/AbbVie, Dr. Qiu's work resulted in many successful products and processes, patented delivery technologies and products, IVIVC's and biowaivers. His research interests include modified-release delivery, enhancing dissolution and oral bioavailability, IVIVC and science-based regulatory approaches. Dr. Qiu is an elected fellow of AAPS with more than 60 publications in journals and books, over 35 patents granted or pending, and numerous invited presentations. He received BS in Pharmacy, MS. in Pharmaceutics from China Pharmaceutical University, and Ph.D. in Pharmaceutics from The University of Iowa.

**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](mailto:cpdgmeeting@gmail.com)  
ZELLE PAYMENT AT [cpdg2022@gmail.com](mailto:cpdg2022@gmail.com)**

**THE DINNER MEAL CHOICES ARE THE FOLLOWING:**

1. MACADAMIA CRUSTED TILAPIA – FRESH TILAPIA WITH LEMON BUTTER SAUCE
2. LEMON PEPPER CHICKEN – SAUTÉED IN WHITE WINE WITH GARLIC SAUCE & 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

**MAIL CONFIRMATION 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, March 14, 2023**

**DIRECTIONS TO THE MARCH 16, 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

