

CHICAGOLAND PHARMACEUTICAL DISCUSSION GROUP

Affiliated with the American Association of Pharmaceutical Scientists

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PROGRAM: ADVANCING GLOBAL PHARMACEUTICAL QUALITY THROUGH M4Q(R2)

DATE: THURSDAY, DECEMBER 12, 2024

SPEAKER: DR. LAWRENCE YU, DIRECTOR, OFFICE OF PRODUCT QUALITY ASSESSMENT II, US FDA, AND RAPPORTEUR, ICH M4Q(R2) EXPERT WORKING GROUP.

The International Council for Harmonization (ICH) is revising the M4Q(R1) guidelines, originally introduced in 2002, to establish M4Q(R2). This modernization seeks to redefine the framework for quality information in pharmaceutical registrations to meet evolving industry, regulatory, and patient needs while integrating advances in technology. Key objectives of M4Q(R2) include:

- Enhancing efficiency in registration and lifecycle management processes.
- Harmonizing with recent ICH quality guidelines (Q8–Q14).
- Addressing specific challenges associated with complex products, including vaccines, advanced therapies, and combination products.
- Leveraging advancements in digital tools, data management, and analytics.

The M4Q(R2) guideline represents a transformative step in ensuring global access to high-quality pharmaceuticals while fostering innovation and improving regulatory efficiency. It underscores a critical opportunity for regulators and industry stakeholders to collaborate, ultimately advancing patient care worldwide.

Dr. Yu is the Director of the Office of Product Quality Assessment II at the U.S. Food and Drug Administration (FDA) and the Rapporteur of the ICH M4Q(R2) Expert Working Group. He also serves as an adjunct professor at the University of Michigan and as an Associate Editor of the AAPS Journal.

Key Accomplishments:

- FDA Biopharmaceutics Classification System (BCS): Chaired the FDA BCS committee from 2000 to 2016, leading to BCS' global acceptance and ICH M9 guideline in 2019.
- Pharmaceutical Quality by Design (QbD): Played a significant role in introducing QbD principles into pharmaceutical development and regulatory practices.
- Knowledge-aided Assessment and Structured Applications (KASA): Originated the KASA initiative to enhance knowledge management and facilitate the digitalization of regulatory assessment.

Currently, Dr. Yu is spearheading an ICH Expert Working Group dedicated to transforming the M4Q(R1) guideline to improve the registration and lifecycle management. He has authored or co-authored over 150 scientific papers and delivered more than 400 invited presentations.

TIME: 5:30 PM – SOCIAL HOUR

6:00 PM – DINNER

7:00 PM – MEETING

PLACE: DOVER STRAITS

890 US-45, MUNDELEIN, IL 60060

COST: \$55.00

REGISTER AT cpdgmeeting@gmail.com

ZELLE PAYMENT AT cpdg2022@gmail.com

THE DINNER MEAL CHOICES ARE THE FOLLOWING:

1. NY STRIP STEAK – WITH BÉARNAISE SAUCE
2. LAKE SUPERIOR WHITFISH – WITH AMANDINE SAUCE
3. CHICKEN LIMON – SAUTÉED WITH LEMON JUICE, WHITE WINE, AND HERBS & SERVED OVER STEAMED SPINACH
4. PASTA PRIMAVERA – SERVED VETAGABLES (VEGETARIAN)

WHEN REGISTERING, PLEASE INDICATE YOUR SELECTED DINNER MEAL:

Meal Choice: Steak, 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, December 10, 2024

**DIRECTIONS TO THE DECEMBER 12, CPDG MEETING AT DOVER STRAITS
890 US-45, MUNDELEIN, IL**

- EXIT I-94 AT TOWN LINE RD. (60)
- HEAD WEST ON TOWN LINE ROAD (60) AND TURN LEFT ONTO US-45 SOUTH
- TURN LEFT TO STAY ON US-45 S
- RESTURANT WILL BE ON THE LEFT-HAND SIDE OF THE ROAD

