Small Business and Industry Assistance
Knowledge Management and Modernization of Regulatory Quality Assessment and Submissions at FDA

January 29, 2025

Version 6 – Updated December 23, 2024

For files and resources, please visit
The Event Page on SBIAevents.com

Add Event to Your Calendar

AGENDA

All times are Eastern (EST UTC-4)

View Start Time on World Clock

Wednesday, January 29, 2025

9:00 – 9:15

Administrative Overview

Brenda Stodart, PharmD, MS, BCGP, RAC
Captain, United States Public Health Service (USPHS)
Director, Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)

9:15 – 9:20

Welcome

Lawrence Yu
Director
Office of Product Quality Assessment II (OPQA II)
Office of Pharmaceutical Quality (OPQ) | CDER

9:20 – 9:45

Overview of KASA Program

This presentation will give an overview of the KASA program, including current status and future directions.

Andre Raw
Associate Director for Science and Communication
Office of Product Quality Assessment I (OPQA I)
OPQ | CDER

9:45 – 10:30

ICH M4A(R2): Advancing Common Technical Document for the Registration of Pharmaceuticals

M4Q(R2) aims to enhance registration efficiency, harness digital technologies, and expedite patient access to pharmaceuticals. It establishes Module 2 as the basis for regulatory assessment, with Module 3 providing support. This presentation will introduce the structure of Modules 2 and 3, highlighting their roles in the registration of pharmaceuticals for human use.

Lawrence Yu
Director
OPQA II | OPQ | CDER

10:30 – 10:45: BREAK

Wednesday, January 29, 2025

10:45 – 11:30

M4Q(R2) Lifecycle Management Considerations, New Concepts and Next Steps

This presentation will introduce product lifecycle management considerations from the perspective of M4Q(R2), as well as new concepts such as Overall Product Development Strategy, Overall Control Strategy, and Integrated development. The M4Q(R2) business plan will also be presented.

Larisa Wu
Associate Director for Science and Communication
OPQA II | OPQ | CDER

11:30 – 12:00

Q&A Panel

Andre Raw, Lawrence Yu, Larisa Wu and Elvira Argus
Biological Reviewer | Office of Gene Therapy (OGT)
Office of Therapeutic Products (OTP)
Center for Biologics Evaluation and Research (CBER)

Rakhi Shah
Associate Director for Science and Communication
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER

12:00 – 1:00: LUNCH BREAK

1:00 – 1:45

ICH M4Q(R2) Revisions: Drug Substance, Materials, and Analytical Procedures

This presentation will describe the revisions to the Drug Substance, Materials, and Analytical Procedures sections of the ICH M4Q(R2) guideline.

Elvira Argus
Biological Reviewer
OGT | OTP | CBER

1:45 – 2:30

ICH M4Q(R2) Revisions: Drug Product, Manufacturing, Facilities and Packaging

This presentation will cover the M4Q(R2) revisions with respect to product, manufacturing process including packaging of single and multiconstituent products, and facilities.

Rakhi Shah
Associate Director for Science and Communication
OPMA | OPQ | CDER

2:30 – 2:50

Q&A Panel

Elvira Argus, Rakhi Shah, Larisa Wu, Lawrence Yu

2:50 – 3:00: BREAK

All times shown are Eastern (EST UTC-4)

Wednesday, January 29, 2025

3:00 – 3:45

FDA Pharmaceutical Quality Electronic Data Standards - Objectives

This presentation will provide an overview of the FDA's pharmaceutical quality chemistry manufacturing and control (PQ/CMC) effort in establishing CMC data standards and data exchange standards to enable structured submissions.

Geoffrey Wu
Commander | USPHS
Acting Director
OPQA 1 | OPQ | CDER

3:45 – 4:05

Case Study: Data Elements for Solid Oral Dosage Forms

This presentation will detail data standards and present case studies on data elements of solid oral dosage forms developed in the PQ/CMC project. Such structured data submissions enhance the efficiency of drug product application reviews and support lifecycle knowledge management.

Zhouxi (Josie) Wang
Senior Biologist
OPMA | OPQ | CDER

4:05 – 4:25

Q&A Panel

Geoffrey Wu, Josie Wang

4:25 – 4:30

Closing Remarks

Geoffrey Wu
Commander | USPHS
Acting Director
OPQA 1 | OPQ | CDER

4:30: ADJOURN WORKSHOP

All times shown are Eastern (EST UTC-4)