Small Business and Industry Assistance

Knowledge Management and Modernization of Regulatory Quality Assessment and Submissions at FDA

January 28-29, 2025

Version 4 – Updated November 14, 2024

For files and resources, please visit
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AGENDA

All times are Eastern (EST UTC-4)

View Start Time on World Clock

DAY ONE: Tuesday, January 28, 2025

8:45 – 9:00

Welcome & Administrative Overview

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

9:00 – 9:30

Keynote: Modernization of Quality Assessment and Submissions at FDA

Susan Rosencrance
Acting Deputy Super Office Director of Science
Office of Pharmaceutical Quality (OPQ) | CDER

9:30 – 9:55

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

DAY ONE: Tuesday, January 28, 2025

9:55 – 10:20

FDA KASA Enhancements for ANDA Drug Product Assessments

A behind the scenes look into KASA and the enhancements made to the system to allow ANDA drug product assessors the flexibility to review more complex drug product systems.

Charles Robertson
Senior Chemist
Office of Product Quality Assessment II (OPQA II)
OPQ | CDER

10:20 – 10:35

Q&A Panel

Andre Raw, Charles Robertson

10:35 - 10:55: BREAK

10:55 – 11:20

KASA for Liquids ANDA: Process Facility Assessment

This presentation will cover expansion of the OPMA KASA process and facility evaluation to liquid dosage forms. It incorporates considerations around liquids unit operations, evaluation of process equipment related leachables assessment and builds in combination product quality system evaluation.

Vidya Pai
Supervisory Chemist
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER

11:20 – 11:35

KASA for Liquids ANDA: Microbiology Assessment

This presentation will illustrate the KASA elements around the microbiology assessment process for sterile dosage forms. The KASA approach will lead to a more efficient and consistent review process for sterile products and incorporates parameters from all common sterilization methods (filtration, moist heat, ethylene oxide, and x-ray sterilization processes.)

Catherine Gilbert
Senior Microbiologist
OPMA | OPQ | CDER

11:35 – 12:00

KASA for ANDAs Containing Liquid and Other Non-oral Drug Products: Biopharmaceutics Assessment

This presentation will cover enhancements to existing KASA for Biopharmaceutics assessment of solid oral dosage forms. This KASA expansion will enable evaluation of liquid and other non-oral dosage forms. It incorporates considerations for dosage form, route of administration specific risk assessment and evaluation of in vitro drug release testing methods and acceptance criterion/criteria.

Anitha Govada
Senior Pharm Quality Assessor
OPQA I | OPQ | CDER

DAY ONE: Tuesday, January 28, 2025

12:00 – 12:20

Q&A Panel

Vidya Pai, Catherine Gilbert, Anitha Govada, Rakhi Shah

12:20 – 1:30: LUNCH BREAK

1:30 – 1:55

Recent Enhancements in the Drug Substance KASA Review Platform

This presentation is about recent enhancements in the Drug Substance KASA platform that address design issues, add functionality, and expand the review assessment.

David Green
Senior Pharm Quality Assessor
OPQA III | OPQ | CDER

1:55 – 2:20

KASA and GSRS integration

Here we demonstrate how the GSRS data has been used within FDA to meet critical regulatory needs and how the GSRS project works to develop open-source automation tools for the wider community.

Tyler Peryea
Chemist
Office of the Commissioner | FDA

2:20 – 2:45

Application of KASA to New Drugs

This presentation will discuss the perspective, recent development and future vision of utilizing KASA platform for new drug quality assessment.

Hong Cai
Division Director
OPQA II | OPQ | CDER

2:45 – 3:05

Q&A Panel

David Green, Tyler Peryea, Hong Cai

3:05 – 3:25: BREAK

DAY ONE: Tuesday, January 28, 2025

3:25 – 3:50

KASA for Biologics

This presentation will provide a summary of the development, current progress and future directions of the KASA for biologics platform designed for assessment of monoclonal antibody and recombinant protein products.

Bazarragchaa Damdinsuren
Lead Interdisciplinary Scientist
OPQA III | OPQ | CDER

3:50 – 3:55

Q&A Panel

Bazarragchaa Damdinsuren

3:55 – 4:00

Closing Remarks

Andre Raw
Associate Director for Science and Communication
OPQA I | OPQ | CDER

4:00: ADJOURN DAY ONE

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DAY TWO: Wednesday, January 29, 2025

8:45 – 8:55

Administrative Overview

Brenda Stodart, PharmD, MS, BCGP, RAC
Captain, USHPS | *Director,* SBIA
DDI | OCOMM | CDER

8:55 – 9:00

Welcome

Lawrence Yu
Director
OPQA II | OPQ | CDER

9:00 – 9:45

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

9:45 – 10:30

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

10:30 – 10:50

Q&A Panel

Lawrence Yu, Larisa Wu, Elvira Argus, Rakhi Shah

10:50 – 11:10: BREAK

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DAY TWO: Wednesday, January 29, 2025

11:10 – 11:55

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 | Office of Gene Therapy (OGT)
Office of Therapeutic Products (OTP)
Center for Biologics Evaluation and Research (CBER)

11:55 – 12:40

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

12:40 – 1:00

Q&A Panel

Elvira Argus, Rakhi Shah, Larisa Wu, Lawrence Yu

1:00 – 2:00: LUNCH BREAK

DAY TWO: Wednesday, January 29, 2025

2:00 – 2:45

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 | US Public Health Service
Acting Director | OPQA I
OPQ | CDER

2:45 – 3:30

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

3:30 – 3:50

Q&A Panel

Geoffrey Wu, Josie Wang

3:50 – 4:00

Closing Remarks

Geoffrey Wu
Commander | US Public Health Service
Acting Director | OPQA I
OPQ | CDER

4:00: ADJOURN WORKSHOP

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