Version 2 – Updated September 28, 2022

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AGENDA

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Wednesday, November 30, 2022

8:00 – 8:15

Welcome

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

8:15 – 8:30

Keynote: Cloud-based Regulatory Submission and Assessment: FDA KASA and ICH M4Q(R2) Initiatives

Lawrence Yu
Director, Office of New Drug Products (ONDP)
Office of Pharmaceutical Quality (OPQ) | CDER
Rapporteur, ICH M4Q(R2) Expert Working Group

Your SBIA Hosts for Day One

Forest "Ray" Ford, PharmD, BCPS
CAPT, USPHS
DDI | OCOMM | CDER

Renu Lal, PharmD
LCDR, USPHS
DDI | OCOMM | CDER

Nora Lim, PharmD, BCPS
LT USPHS, *Pharmacist*
SBIA | DDI | OCOMM | CDER

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Wednesday, November 30, 2022

8:30 – 8:50

Closing out GDUFA II: Summary of DMF Performance

The FDA will present the GDUFA II data for Completeness Assessments (CA), Email Exchange, First Adequate letters (FA), and No Further Comments letters (NFC) to show how the Agency delivered on the GDUFA II commitments.

Benjamin Danso
Commander, United States Public Health Service
Lead DMF Project Manager
Office of Program and Regulatory Operations (OPRO)
OPQ | CDER

8:50 – 9:00

Introducing the DMF Enhancements in the GDUFA III Commitment Letter

The FDA will discuss the GDUFA III DMF enhancements and their potential impact on the generic drug program.

Jayani Perera, PhD
Senior Chemist, Division of Lifecycle API (DLAPI)
ONDP | OPQ | CDER

9:00 – 9:30

GDUFA III Enhancements - Assessment of Solicited DMF Amendments

The FDA will discuss assessment of GDUFA III Solicited DMF Amendments to enhance industry understanding of this new process.

Jennifer Nguyen, PharmD
Senior Regulatory Business Process Manager
OPRO | OPQ | CDER

9:30 – 9:50

Q&A Panel

Benjamin Danso, Jayani Perera, Jennifer Nguyen
and
David Skanchy
Commander, United States Public Health Service
Director, DLAPI | ONDP | OPQ | CDER

9:50 – 10:05: BREAK

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Wednesday, November 30, 2022

10:05 – 10:25

GDUFA III DMF Prior Assessments: Explanation and Overview

The FDA will discuss the benefits of GDUFA III DMF Prior Assessments and explain key elements of the associated Guidance.

Erin Skoda, PhD
Branch Chief, DLAPI
ONDP | OPQ | CDER

10:25 – 10:50

GDUFA III Enhancements - DMF Prior Assessments

The FDA will discuss the overall process for the GDUFA III DMF Prior Assessment enhancement including a tutorial on how the industry can submit a valid request following the guidelines provided in the Appendix to the draft guidance.

Jayani Perera, PhD
Senior Chemist, DLAPI
ONDP | OPQ | CDER

10:50 – 11:15

Prioritization Assessment of DMFs

The section will describe the different types of prioritization factor categories and how we determine if a DMF would qualify for a prioritization under those categories.

Iain Margand, RPh
Commander, United States Public Health Service
Patent and Exclusivity Team
Division of Legal & Regulatory Support (DLRS)
Office of Generic Drug Policy (OGDP)
Office of Generic Drugs (OGD) | CDER

11:15 – 11:25

GDUFA III Prior Assessment Process: Presumptive Q & A

The FDA will present some questions and answers and best practices for the GDUFA III Prior Assessment process focused on fostering better understanding so that industry can take advantage of this enhancement.

Jayani Perera, PhD
Senior Chemist, DLAPI
ONDP | OPQ | CDER

11:25 – 12:00

Q&A Panel

Erin Skoda, Jayani Perera, Iain Margand, David Skanchy, and

Ziyang Su
Policy Lead
Division of Regulations, Guidance and Standards (DRGS)
Office of Policy for Pharmaceutical Quality (OPPQ)
OPQ | CDER

12:00 – 12:45: LUNCH BREAK

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12:45 – 1:15

The Future of FDA's Quality Assessment and Knowledge Management -KASA

This topic will present Knowledge-Aided Assessment and Structured Application (KASA) and how this will modernize drug product quality assessments.

Andre Raw, PhD
Associate Director for Science and Communications
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER

1:15 – 1:40

Modernization of Regulatory Submission

FDA will present two ongoing initiatives to modernize regulatory submissions: Revision of ICH M4Q and Pharmaceutical Quality Electronic Data Standards.

Larisa Wu, PhD
Associate Director for Science and Communications
ONDP | OPQ | CDER

1:40 – 2:05

Quick Guide to Creating a Structure-Data File (SD File) for Submissions

This presentation is designed to help you quickly create an SD File for regulatory submission.

Marlene Kim
Chemist, Health Informatics Staff (HIS)
Office of Data, Analytics, & Research (ODAR)
Office of Digital Transformation (ODT)
Office of the Commissioner (OC)

2:05 – 2:30

Q&A Panel

Andre Raw, Larisa Wu, Marlene Kim, Erin Skoda

2:30 – 2:45 PM: BREAK

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2:45 – 3:05

Improving (Q)SAR Review with Structure-Data Files

This presentation describes the role of the SD File in CTCS' (Q)SAR review workflow, which includes structure verification, generation of model predictions, and databasing of results. Additionally, the benefits of receiving structures in an SD File format will be highlighted as a way to reduce structural errors and eliminate the need for redrawing to promote the efficient and accurate review of submitted data.

Naomi L. Kruhlak, PhD
Scientific Lead
Computational Toxicology Consultation Service (CTCS)
Division of Applied Regulatory Science (DARS)
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS) | CDER

3:05 – 3:30

What are UNIIs and How Do You Get Them?

UNII requests are typically managed by the GSRS team (FDA-SRS@fda.hhs.gov). This presentation will describe what substance information is captured and communicated by the GSRS team.

Frank L. Switzer, PhD
HIS | ODAR | ODT | OC

3:30 – 3:55

Machine Readable Synthetic Pathways in GSRS and KASA

This presentation will cover the history, design approach, current features and potential future uses of Global Substance Registration System (GSRS), an open-source synthetic scheme registration tool.

Tyler Peryea
HIS | ODAR | ODT | OC

3:55 – 4:25

Q&A Panel

Naomi Kruhlak, Frank Switzer, Tyler Peryea
and
Barbara O. Scott
Review Chemist
DLAPI | ONDP | OPQ | CDER

4:25 – 4:30

Closing Remarks

David Skanchy
Commander, United States Public Health Service
Director, DLAPI | ONDP | OPQ | CDER

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