Version 4 – Updated July 27, 2022

Regulatory Best Practices for Global Access to Medicines, Including Anti-TB Medicines

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AGENDA

All times are Eastern (EST UTC-4)

View Start Time on World Clock

DAY ONE: Tuesday, August 16, 2022

8:30 – 8:45

SBIA Welcome and Administrative Overview

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

8:45 – 9:00

FDA Keynote

Robert M. Califf, MD
Commissioner of Food and Drugs
Food and Drug Administration
(invited)

Your SBIA Hosts for Day One

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

Renu Lal, PharmD
Lieutenant Commander, USPHS
DDI | OCOMM | CDER

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

DAY ONE: Tuesday, August 16, 2022

9:00 – 9:10

USAID Keynote

Dr. Atul Gawande
Assistant Administrator for Global Health
United States Agency for International Development (USAID)

9:10 – 9:20

WHO Keynote

Tereza Kasaeva, MD, PhD
Director
Global TB Programme
World Health Organization (WHO)
(invited)

Rogerio Gaspar, PhD
Director of Regulation and Prequalification
WHO
(Invited)

9:20 – 9:25

USP Keynote

Ronald T. Piervincenzi, PhD.
Chief Executive Officer
United States Pharmacopeia (USP)

9:25 – 9:35

Promoting the Quality of Medicines Plus (PQM+) Program

This presentation provides an overview of the United States Agency for International Development (USAID) funded and United States Pharmacopeia (USP) led PQM+ program. PQM+ is a cooperative agreement between USAID and USP to sustainability strengthen medical product quality assurance systems in low and middle-income countries. The presentation outlines complex global challenges due to poor-quality medical products and how PQM+ is addressing these through a systems strengthening approach. The presentation will also provide a glimpse of PQM+ principles of maximizing impact through alignment and coordination at all levels; custom built capacity building strategies tailored to country needs; amplifying thought leadership and research; and delivering measurable results.

Jude Nwokike
Vice President & Director
Promoting the Quality of Medicines Plus (PQM+) Program
U.S. Pharmacopeial Convention

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DAY ONE: Tuesday, August 16, 2022

9:35 – 10:05

WHO Prequalification Process for Medicines: Collaborative Registration Procedure for WHO Prequalified Medicines

This presentation explains what drug prequalification process and WHO Collaborative Procedure for Accelerated registration of WHO Prequalified medicines are. How LMICs can benefit from these procedures and ensure timely access to quality-assured medicines. Emphasis will be made on TB medicines. Explains how FDA intersects with WHO for WHO prequalification program.

Deus Mubangizi
Unit Head, Prequalification Unit (PQT)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)
World Health Organization (WHO)

10:05 – 10:25

Collaborative Registration Procedure for WHO Prequalified Medicines and Its Impact on Accelerated Registration and Timely Access to Quality-assured Medicines in LMICs

This presentation explains the WHO Collaborative Procedure for Accelerated registration of WHO Prequalified medicines are. How LMICs can benefit from these procedures and ensure timely access to quality-assured medicines. Emphasis will be made on TB medicines. Explains how FDA intersects with WHO for WHO prequalification program.

Hiiti B. Sillo
Unit Head, Regulation and Safety
RPQ | MHP | WHO

10:25 – 10:35

Questions & Answer Panel

Deus Mubangizi, Hiiti B. Sillo

10:35 – 11:05

Opportunities for International Engagement: Regulatory Cooperation, Convergence and Harmonization

This presentation will highlight various key international and regional initiatives that promote regulatory cooperation, convergence and harmonization, such as ICH, IPRP, ICMRA. FDA's scientific engagements with WHO and support for regulatory systems strengthening in low-and-middle-income countries will also be discussed. Opportunities for regulatory engagement at both the leadership level, as well as in expert working groups, will be reviewed.

C. Michelle Limoli, PharmD
Senior International Health Science Advisor
CBER International Affairs
Office of the Director (OD)
Center for Biologics Evaluation and Research (CBER)
FDA

11:05 – 11:20: BREAK

11:20 – 11:50

The New Drug Approval Process

An overview of the review and approval process for a New Drug Application (NDA). Topics include the types of NDAs, contents and requirements of an NDA submission, the milestones of an NDA review, and communication opportunities before and during the review.

Margaret M. Kober, RPh., MPA
Chief, Project Management Staff
Office of Regulatory Operations (ORO)
Office of New Drugs (OND) | CDER

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DAY ONE: Tuesday, August 16, 2022

11:50 – 12:05

ANDA Approval Process

An overview of the review and approval process for an Abbreviated New Drug Application (ANDA). This presentation includes the general contents and requirements of an ANDA submission and the overall lifecycle of an ANDA review. It also includes prioritization of review for specific types of ANDAs and the different actions that FDA may take on ANDAs.

John Ibrahim, PharmD, BCPS
Associate Director for Regulatory Affairs
Office of Regulatory Operations (ORO)
Office of Generic Drugs (OGD) | CDER

12:05 – 12:20

Questions & Answer Panel

Michelle Limoli, Gopa Raychaudhuri, John Ibrahim, Margaret M. Kober

12:20 – 12:25

Day One Closing

SBIA Staff

12:25: DAY ONE ADJOURN

All times shown are Eastern (EST UTC-4)

DAY TWO: Wednesday, August 17, 2022

8:30 – 8:40

SBIA Welcome and Administrative Overview

Forest "Ray" Ford, PharmD, BCPS
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Renu Lal, PharmD
Lieutenant Commander, USPHS
DDI | OCOMM | CDER

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

8:40 – 9:10

Bringing New TB Drugs to Market: A Regulatory Perspective

This session will provide an overview of regulatory pathways and designations utilized by the Food and Drug Administration to facilitate and expedite drug development for serious or life-threatening conditions including accelerated approval, fast track designation, breakthrough therapy designation, qualified infectious disease product designation (QIDP), and the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD). Additionally, drug development programs for tuberculosis will be discussed with emphasis on clinical trial design, study populations and endpoints, including surrogate endpoints. The approvals of bedaquiline in 2012 and pretomanid in 2019 will be discussed.

Ramya Gopinath, MD
Medical Officer
Division of Anti-Infectives (DAI)
OND | CDER

9:10 – 9:55

FDA's Use of the Tentative Approval Pathway to Meet the Urgent Needs of PEPFAR (President's Emergency Plan for AIDS Relief)

We will describe the use of the Tentative Approval Pathway for drug products to quickly get critical anti-retroviral medicines found acceptable for use into the areas of greatest need. This description will include some of the regulatory challenges that were faced especially during the early phases of the program, as well as the need to adapt review practices to meet the demand for timely drug product quality assessments. Maintenance and administration of the many tentatively approved PEPFAR drug products was also an area of innovation compared to previous practices. Finally, a description of the current state/scope of the PEPFAR program will be presented as demonstrated in the FDA PEPFAR website including the current PEPFAR drug product list.

Tina T. Nhu PharmD, Mc. PM, BS Pharm
Commander (CDR), USPHS
Team Leader, Regulatory Project Manager
Division of Project Management (DPM)
Office of Generic Drugs (OGD) | CDER

Peter Capella, PhD
Director
Division of Immediate and Modified Release Products II (DIMRPII)
Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ)
CDER | FDA

Monica Zeballos

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DAY TWO: Wednesday, August 17, 2022

9:55 – 10:25

Project Facilitate: An Overview of Expanded Access and the Review Process

Expanded Access, also known as Compassionate Use, is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. Project Facilitate was launched in June 2019 to provide a comprehensive program to support health care professionals in submitting oncology Expanded Access requests. This presentation will provide an overview of the oncology Expanded Access pathway and how Project Facilitate is making the process more accessible to oncologists around the nation. Project Facilitate will also provide insight into their regulatory and clinical review process.

Mitchell Chan, PharmD, BCPS
Lieutenant Commander, USPHS
Clinical Analyst
Team Leader, Project Facilitate
Oncology Center of Excellence (OCE) | FDA

10:25 – 10:40

Questions & Answer Panel

Ramya Gopinath, Tina Nhu, Peter Capella, Monica Zeballos, Mitchell Chan

10:40 – 10:55: BREAK

10:55 – 11:25

Stability – Why Do We Care? / Justifying Your Product!

The session will discuss expectations for product stability. It will provide a discussion of the purpose of stability requirements. It will include general topics for consideration in developing an appropriate stability program. Guidance used by the FDA during stability evaluation, including shelf-life, will be described

Frank O. Holcombe, Jr. PhD
Senior Advisor, Immediate Office (IO)
OLDP | OPQ | CDER | FDA

11:25 – 12:10

Lifecycle Management of Approved Drug Product:FDA Perspective

The real life of a drug product starts after approval by a regulatory body. This talk will focus on the post-marketing changes that can happen after the approval of a new drug by the FDA. The discussion will involve the changes a drug product can undergo during its life and how the regulations and guidances are applied to help make those changes while maintaining the standards of Quality.

Ramesh Raghavachari, PhD
Chief, Branch I
Division of Post Marketing Activities I (DPMAI)
OLDP | OPQ | CDER

12:10 – 12:25

Questions & Answer Panel

Frank O. Holcombe, Ramesh Raghavachari

12:25 – 12:30

Day Two Closing

SBIA Staff

12:30: DAY TWO ADJOURN

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DAY THREE: Thursday, August 18, 2022

8:30 – 8:40

SBIA Welcome and Administrative Overview

Forest "Ray" Ford, PharmD, BCPS
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Renu Lal, PharmD
Lieutenant Commander, USPHS
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Nora Lim, PharmD, BCPS
Lieutenant, USPHS, *Pharmacist*
SBIA | DDI | OCOMM | CDER

8:40 – 9:10

Identification and Control of Harmful Impurities in Pharmaceutical Products: Nitrosamine as an Example

The talk will provide an introduction to the impurities in pharmaceutical products in a context of a 'cohort of concern' impurities with nitrosamines as an example. The attendees will get information about the USP's response to the nitrosamine concern including tools and solutions provided to the industry in terms of documentary standards (GC<1469>) and reference standards (existing and proposed). A summary of current nitrosamine challenges and USP's plans will provide an insight into USP's strategy to address the issue.

Mrunal A. Jaywant, PhD, PGDMM
Senior Director, R&D
USP Nitrosamines Lead
Unites States Pharmacopoeia (USP)
India

9:10 – 9:50

Control of Nitrosamine Impurities in Human Drugs

Nitrosamine compounds are potent genotoxic agents and are referred to as "cohort of concern" compounds in the ICH guidance for industry M7(R1). This presentation describes conditions that may introduce nitrosamine impurities in pharmaceutical active ingredients and drug products. This talk provides recommendations manufacturers can take to detect and prevent objectionable levels of nitrosamine impurities in pharmaceutical products.

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

9:50 – 10:05

Questions & Answer Panel

Mrunal A. Jaywant, Andre Raw

10:05 – 10:35

Introduction to Bioequivalence for Generic Drug Products

This session will provide an overview of bioequivalence (BE) for generic drug products, various types of BE studies that may be submitted in support of Abbreviated New Drug Applications (ANDAs), general considerations to conduct the BE studies with pharmacokinetic endpoints and a list of bio-waiver drug products. In addition, this session will provide related regulations and resources for development of generic drug products (e.g., product-specific guidance (PSG), the Agency's approved drug products with therapeutic equivalence evaluations (Orange Book) and Guidance Documents for Industry).

Ja Hye Myung, PhD, MS, BPharm
Pharmacologist
Division of Bioequivalence III (DBIII)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD) | CDER | FDA

DAY THREE: Thursday, August 18, 2022

10:35 – 10:50

Bioequivalence Studies for Generic Drug Development

The presentation is intended to provide a broad overview of the scientific and regulatory principles governing bioequivalence with an emphasis on Abbreviated New Drug Applications (ANDAs). Specifically, the seminar will describe key bioequivalence concepts and regulation as well as highlight some bioequivalence-related general and product specific guidances. Moreover, the speaker will discuss bioequivalence information that is generally assessed in support of ANDAs. Finally, the presentation will share some common deficiencies associated with bioequivalence studies.

Rong Wang, PharmD, PhD
Acting Division Associate Director
Division of Bioequivalence I (DBI)
OB | OGD | CDER | FDA

10:50 – 11:05

Questions & Answer Panel

Ja Hye Myung, Rong Wang

11:05 – 11:35

Essential Elements of Biopharmaceutics Classification System (BCS III)-Based Waiver Request

This presentation will discuss essential elements of BCS Class 3-based biowaiver requests to be assessed for generic drug development and approval. The talk will share some internal research results on solubility and dissolution studies of potential BCS 3 drug products. In addition, the presentation will discuss the assessment criteria of BCS 3-based waiver request, especially on the formulation similarity evaluation.

Yi Zhang, PhD
Commander, USPHS
Senior Advisor
Division of Therapeutic Performance II (DTPII)
Office of Research and Standards (ORS)
OGD | CDER | FDA

11:35 – 11:50

BCS Methodology: Solubility, Permeability & Dissolution

FDA's guidance on biopharmaceutics classification system (BCS)-based biowaivers provides an outline as to how to conduct experiments to classify a drug substance (solubility, permeability) and drug product (dissolution). Equilibrium solubility is determined over the pH range of 1.2 to 6.8 with the drug classified by its lowest measured solubility in comparison to its highest therapeutic dose. A drug's permeability is determined in human pharmacokinetic studies or with a validated and standardized in vitro Caco-2 cell assay. Dissolution experiments are conducted in buffers at pH 1.2, 4.5, and 6.8 under specific conditions.

Donna A. Volpe, PhD
Research Chemist
Division of Applied Regulatory Science
Office of Clinical Pharmacology (OCP)
CDER | FDA

11:50 – 12:05

Biowaivers

Haritha Mandula
Lead Pharmacologist
Division of Biopharmaceutics
OND | CDER | FDA

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DAY THREE: Thursday, August 18, 2022

12:05 – 12:20

Questions & Answer Panel

Yi Zhang, Donna A. Volpe, Haritha Mandula

12:20 – 12:30

Conference Closing

Jude Nwokike
Vice President & Director
Promoting the Quality of Medicines Plus (PQM+) Program
U.S. Pharmacopeial Convention

12:30: CONFERENCE ADJOURN

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