Center for Drug Evaluation and Research (CDER)

Pharmaceutical Science and Clinical Pharmacology Advisory Committee (PSCP) Meeting November 2-3, 2022

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Rhea Bhatt, MS

Division of Advisory Committee and Consultant Management Office of Executive Programs, CDER, FDA

PHARMACEUTICAL SCIENCE AND CLINICAL PHARMACOLOGY ADVISORY COMMITTEE MEMBERS (Voting)

Jeffery M. Carrico, PharmD, BCPS

Director, Research Pharmacy Department of Pharmacy Dana-Farber Cancer Institute Boston, Massachusetts

Leonid Kagan, PhD

Associate Professor Department of Pharmaceutics, Ernest Mario School of

Pharmacy Rutgers, The State University of New Jersey

Piscataway, New Jersey

Kelvin H. Lee, PhD

Gore Professor of Chemical Engineering Department of Chemical and Biomolecular Engineering University of Delaware Newark, Delaware

Frances Richmond, PhD

Director, D K Kim International Center for Regulatory Science Department of Regulatory and Quality Sciences School of Pharmacy, University of Southern California Los Angeles, California

William C. Zamboni, PharmD, PhD

Professor

Director, UNC Advanced Translational Pharmacology and Analytical Chemistry Lab UNC Eshelman School of Pharmacy UNC Lineberger Comprehensive Cancer Center Carolina Institute of Nanomedicine University of North Carolina at Chapel Hill Chapel Hill, North Carolina

Sandra Finestone, PsyD

(Consumer Representative)
Executive Director
Association of Cancer Patient Educators
Irvine, California

Walter K. Kraft, MD

Professor of Pharmacology, Medicine & Surgery
Department of Pharmacology, Physiology, & Cancer
Biology
Thomas Jefferson University
Philadelphia, Pennsylvania

Kenneth R. Morris, PhD, FAAPS

(Chairperson, Pharmaceutical Science) Professor Emeritus University of Hawaii at Hilo Hilo, Hawaii

Eric V. Slud, PhD

(November 3rd only)
Area Chief for Mathematical Statistics
Center for Statistical Research and Methodology
Census Bureau
Washington, District of Columbia

Center for Drug Evaluation and Research (CDER)

Pharmaceutical Science and Clinical Pharmacology Advisory Committee (PSCP) Meeting November 2-3, 2022

MEETING ROSTER (cont.)

PHARMACEUTICAL SCIENCE AND CLINICAL PHARMACOLOGY ADVISORY COMMITTEE MEMBERS (Non-Voting)

Mark C. Rogge, PhD

(Industry Representative) Chief Development Officer Sail Bio, Inc. Cambridge, Massachusetts

Pravin Rothe, MPharm

(Industry Representative)
Validation Lead, Manufacturing Sciences and Technology
Novartis
Wilson, North Carolina

T.G. Venkateshwaran, PhD

(Industry Representative)
Vice President and Global Head, Global Regulatory
Affairs- CMC and Devices
Takeda
Cambridge, Massachusetts

TEMPORARY MEMBERS (Voting)

Gregory E. Amidon, PhD

(November 3rd only)
Research Professor Emeritus, Pharmaceutical Sciences
College of Pharmacy
University of Michigan
Ann Arbor, Michigan

William Hancock, PhD

(November 3rd only)
Bradstreet Chair Emeritus
Barnett Institute
Department of Chemistry and Chemical Biology
Northeastern University
Boston, Massachusetts

Mittal Sutaria, PharmD

(November 2nd only)
Senior Vice President, Contract and Program
Services
Sourcing Ops – Pharmacy
Vizient
Irving, Texas

Maureen Donovan, PhD

(November 3rd only)
Professor
Department of Pharmaceutical Sciences and
Experimental Therapeutics
College of Pharmacy
University of Iowa
Iowa City, Iowa

Tonglei Li, PhD

(November 3rd only)
Professor of Pharmaceutical Sciences
Department of Industrial and Physical Pharmacy
Purdue University
West Lafayette, Indiana

Center for Drug Evaluation and Research (CDER)

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

November 2nd FDA Participants

Patrizia Cavazzoni, MD

CDER, FDA

Director

Lucinda (Cindy) Buhse, PhD

Deputy Director, Operations

OPQ, CDER, FDA

Jennifer Maguire, PhD

Director

Office of Quality Surveillance (OQS)

OPQ, CDER, FDA

Alex Viehmann

Director

Division of Quality Intelligence II

OQS, OPQ, CDER, FDA

November 3rd FDA Participants

Lawrence Yu, PhD

Director

Office of New Drug Product (ONDP)

OPQ, CDER, FDA

Stelios Tsinontides, PhD

Director

Office of Pharmaceutical Manufacturing

Assessment (OPMA)

OPQ, CDER, FDA

Andre Raw, PhD

Associate Director of Science and Communication Office of Lifecycle Drug Products (OLDP)

OPQ, CDER, FDA

Michael Kopcha, PhD, RPh

Director

Office of Pharmaceutical Quality (OPQ)

CDER, FDA

Adam Fisher, PhD

Science Staff—Immediate Office

OPQ, CDER, FDA

Ashley Boam, MSBE

Director

Office of Policy for Pharmaceutical Quality

(OPPQ)

OPQ, CDER, FDA

Sau "Larry" Lee, PhD

Deputy Director of Science

OPQ, CDER, FDA

Larisa Wu, PhD

Associate Director of Science and Communication

ONDP, OPQ, CDER, FDA

Rakhi Shah, PhD

Associate Director of Science and Communication

OPMA, OPQ, CDER, FDA

Center for Drug Evaluation and Research (CDER)

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November 2-3, 2022

MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting) (cont.)

November 3rd FDA Participants (cont.)

Joel Welch, PhD

Associate Director for Science and Biosimilar Strategy
Office of Biotechnology Products (OBP)
OPQ, CDER, FDA