The use of model-informed drug development (MIDD) for new and generic drugs has significantly increased over the past several years. The committee will discuss strategies, approaches, and challenges in MIDD with specific focus on two areas. During the morning session, the committee will discuss approaches and evidentiary information needed for applying physiologically-based pharmacokinetic modeling and simulation throughout a drug’s lifecycle. During the afternoon session, the committee will discuss mechanistic model-informed safety evaluation with a focus on drug potential for causing arrhythmias. The Comprehensive in Vitro Proarrhythmia Assay will be discussed as an examplar.

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<tr>
<th>Time</th>
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<tr>
<td>7:30 a.m.</td>
<td>Call to Order and Introduction of Committee</td>
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<td>7:35 a.m.</td>
<td>Conflict of Interest Statement</td>
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<tr>
<td>7:45 a.m.</td>
<td>Model-Informed Drug Development (MIDD): Opportunities and Challenges</td>
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<td>8:00 a.m.</td>
<td>FDA Presentations</td>
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<td>8:20 a.m.</td>
<td>Absorption PBPK Modeling and Applications to Support Formulation and Generic Drug Development</td>
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<tr>
<td>8:40 a.m.</td>
<td>Guest Speaker Presentations</td>
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**Session I: Role for Physiologically-Based Pharmacokinetic (PBPK) Modeling and Simulation in Drug Development and Regulation**

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<td>8:00 a.m.</td>
<td>Towards Consistent Regulatory Assessment of Physiologically-based Pharmacokinetic (PBPK) Modeling to Support Dosing Recommendations</td>
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**Guest Speaker Presentations**

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<td>8:40 a.m.</td>
<td>PBPK Submissions and Review Experience in European Medicines Agency (EMA) and EMA Draft PBPK Guideline</td>
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**AGENDA**

**Scott Waldman, MD, PhD**  Chairperson, PSCP

**Jennifer Shepherd, RPh**  Designated Federal Officer, PSCP

**Shiew-Mei Huang, PhD**  Deputy Director, Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS), CDER, FDA

**Ping Zhao, PhD**  PBPK Lead, Division of Pharmacometrics OCP, OTS, CDER, FDA

**Liang Zhao, PhD**  Division Director, Division of Quantitative Methods & Modeling Office of Research and Standards Office of Generic Drugs (OGD), CDER, FDA

**Anna Nordmark, PhD**  Pharmacokinetic Assessor Medical Products Agency, Sweden Member of the Modelling and Simulation Working Group, European Medicines Agency (EMA) Rapporteur of the EMA PBPK Guideline
AGENDA (CONT.)

GUEST SPEAKER PRESENTATIONS (CONT.)

9:00 a.m.  Experience, Opportunity, and Challenges in Submitting PBPK Analyses to Regulators, and Comments to EMA and FDA Draft PBPK Guidance Documents  Neil Parrott, PhD  Distinguished Scientist  Roche Pharma Research and Early Development  Roche Innovation Center Basel, Switzerland  Leader, The Innovation & Quality (IQ) Consortium Working Group on PBPK Guidances

9:20 a.m.  Clarifying Questions

9:35 a.m.  BREAK

9:45 a.m.  Open Public Hearing Session I

10:15 a.m.  Questions to the Committee/Committee Discussion I

11:15 a.m.  LUNCH BREAK

Session II: MECHANISTIC MODEL-INFORMED SAFETY EVALUATION: COMPREHENSIVE IN VITRO PROARRHYTHMIA ASSAY (CiPA) AS AN EXAMPLE

12:05 p.m.  Call to Order and Introduction of Committee  Scott Waldman, MD, PhD  Chairperson, PSCP

Conflict of Interest Statement  Jennifer Shepherd, RPh  Designated Federal Officer, PSCP

12:10 p.m.  FDA PRESENTATION

Overview of the ICH E14 Guideline and its Implementation within FDA  Christine Garnett, PharmD  Clinical Analyst and QT Lead  Division of Cardiovascular and Renal Products  Office of Drug Evaluation I, Office of New Drugs, CDER, FDA

12:30 p.m.  GUEST SPEAKER PRESENTATIONS

Goals of CiPA: the Comprehensive In Vitro Proarrhythmia Assay  Gary Gintant, PhD  Senior Research Fellow  Department of Integrative Pharmacology  Abbvie
12:50 p.m. Background and Rationale for Mechanistic Cardiac Electrophysiology Models
Gary Mirams, PhD
Sir Henry Dale Fellow
Centre for Mathematical Medicine and Biology
University of Nottingham, United Kingdom

1:05 p.m. FDA PRESENTATIONS

CiPA In Silico Modeling Development Strategy and Results
Zhihua Li, PhD
Staff Fellow
Division of Applied Regulatory Science
OCP, OTS, CDER, FDA

1:20 p.m. Phase 1 Electrocardiogram (ECG) Analysis under CiPA, Integration of All CiPA Components, and Potential Implementation Strategy
David Strauss, MD, PhD
Division Director
Division of Applied Regulatory Science
OCP, OTS, CDER, FDA

1:40 p.m. Clarifying Questions

1:55 p.m. BREAK

2:05 p.m. Open Public Hearing Session II

2:35 p.m. Questions to the Committee/Committee Discussion II

3:35 p.m. CONCLUDING REMARKS
Kathleen Uhl, MD
Director
OGD, CDER, FDA

3:45 p.m. ADJOURNMENT