FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

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

AGENDA

The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The meeting will focus on two topics related to the Office of Pharmaceutical Quality's mission of promoting the availability of quality medicines for the American public. On November 2, 2022, the committee will discuss the Center for Drug Evaluation and Research (CDER) Quality Management Maturity (QMM) program. QMM is the state attained when drug manufacturers have consistent, reliable, and robust business processes to achieve quality objectives and promote continual improvement. CDER has proposed the development of a rating system that will help incentivize drug manufacturers to adopt more mature quality management practices at their facilities. The committee will consider the impact that a QMM program would have on the pharmaceutical industry, drug shortages, and supply chain resiliency. FDA will seek input to determine if experts from academia and industry support the development of a CDER QMM program to incentivize investments in mature quality management practices.

On November 3, 2022, as part of CDER's continued effort to provide key updates on modernization of quality assessment, the committee will discuss the next stages of Knowledge-Aided Assessment and Structured Application (KASA). The concept of KASA was envisioned in 2016 and discussed at the Pharmaceutical Science and Clinical Pharmacology Advisory Committee (PSCP-AC) meeting on September 20, 2018 as an IT system that modernizes FDA's assessment. Through the development, testing, and implementation of various KASA prototypes, the KASA system has been refined over the course of multiple years. FDA will seek input on the vision and plan to expand KASA over the next five years to include drug substances, all generic dosage forms, new drug and biologics applications, and post-approval changes. Moreover, FDA will seek input regarding the need for advancing digitalization in KASA, including data standardization and mobilization of data from cloud-based servers.

Day 1: November 2, 2022 - Quality Management Maturity (QMM)

9:00 a.m.	Call to Order	**Kenneth R. Morris, MS, PhD** Chairperson (Pharmaceutical Science), PSCP
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	**Rhea Bhatt, MS** Designated Federal Officer, PSCP
9:15 a.m.	**FDA PRESENTATIONS**	
	The Importance of Quality Throughout the Drug Supply Chain	**Patrizia Cavazzoni, MD** Director CDER, FDA
	The Future of Pharmaceutical Quality	**Michael Kopcha, PhD, RPh** Director Office of Pharmaceutical Quality (OPQ) CDER, FDA

AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

	QMM Lessons Learned	**Jennifer Maguire, PhD** Director Office of Quality Surveillance (OQS) OPQ, CDER, FDA
	Stakeholder Perspectives	**Adam Fisher, PhD** Director Science Staff—Immediate Office OPQ, CDER, FDA
	FDA's Vision for Quality Management Maturity	**Alex Viehmann** Director Division of Quality Intelligence II OQS, OPQ, CDER, FDA
	Potential QMM Benefits to Stakeholders and FDA	**Lucinda (Cindy) Buhse, PhD** Deputy Director, Operations OPQ, CDER, FDA
11:00 a.m.	**BREAK**	
11:10 a.m.	Clarifying Questions to the Presenters	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Questions to the Committee/Committee Discussion	
3:30 p.m.	**ADJOURNMENT**	

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AGENDA (cont.)

Day 2: November 3, 2022 - Knowledge-Aided Assessment and Structured Application (KASA)

9:00 a.m.	Call to Order	**Kenneth R. Morris, MS, PhD** Chairperson (Pharmaceutical Science), PSCP
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	**Rhea Bhatt, MS** Designated Federal Officer, PSCP
9:15 a.m.	**FDA PRESENTATIONS**	
	Quality Assessment Modernization: Vision and Future Roadmap	**Sau Larry Lee, PhD** Deputy Director of Science Office of Pharmaceutical Quality (OPQ) CDER, FDA
	KASA Accomplishments to Date	**Andre Raw, PhD** Associate Director of Science and Communication Office of Lifecycle Drug Products OPQ, CDER, FDA
	KASA and Manufacturing/Facility Evaluation	**Stelios Tsinontides, PhD** Director Office of Pharmaceutical Manufacturing Assessment (OPMA) OPQ, CDER, FDA
		Rakhi Shah, PhD Associate Director of Science and Communication OPMA, OPQ, CDER, FDA
	Application of KASA to New Drugs	**Larisa Wu, PhD** Associate Director of Science and Communication Office of New Drug Products (ONDP) OPQ, CDER, FDA
	Application of KASA to Biologics	**Joel Welch, PhD** Associate Director for Science and Biosimilar Strategy Office of Biotechnology Products OPQ, CDER, FDA
	Cloud-Based Assessment and Structured Application	**Lawrence Yu, PhD** Director ONDP, OPQ, CDER, FDA

AGENDA (cont.)

11:15 a.m.	**BREAK**
11:25 a.m.	Clarifying Questions to the Presenters
12:10 p.m.	**LUNCH**
1:10 p.m.	**OPEN PUBLIC HEARING**
2:10 p.m.	Questions to the Committee/Committee Discussion
3:30 p.m.	**ADJOURNMENT**