Food and Drug Administration
Center for Drug Evaluation and Research

Final Summary Minutes of Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting
November 2-3, 2022

Location: Please note that due to the impact of this COVID-19 pandemic, all meeting participants joined this advisory committee meeting via an online teleconferencing platform.

Topic: On November 2, 2022, the committee discussed 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 considered the impact that a QMM program would have on the pharmaceutical industry, drug shortages, and supply chain resiliency. FDA sought 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 discussed 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 sought 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 sought input regarding the need for advancing digitalization in KASA, including data standardization and mobilization of data from cloud-based servers.

These summary minutes for the November 2-3, 2022 Meeting of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee of the Food and Drug Administration were approved on December 22, 2022 .

I certify that I attended the November 2-3, 2022 meeting of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee (PSCP) of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/
Rhea Bhatt, MS
Designated Federal Officer, *PSCP*

/s/
Kennth R.Morris, PhD, FAAPS
Chairperson, *PSCP*

Final Summary Minutes of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting
November 2-3, 2022

The Pharmaceutical Science and Clinical Pharmacology Advisory Committee (PSCP) of the Food and Drug Administration, Center for Drug Evaluation and Research, met on November 2-3, 2022. The meeting presentations were heard, viewed, captioned, and recorded through an online teleconferencing platform. Prior to the meeting, the members and temporary voting members were provided briefing materials from the FDA. The meeting was called to order by Kenneth R. Morris, PhD, FAAPS (Chairperson). The conflict-of-interest statement was read into the record by Rhea Bhatt, MS (Designated Federal Officer). There were approximately 229 people online on November 2nd and approximately 201 people online on November 3rd. On November 2nd, there were a total of four Open Public Hearing (OPH) speaker presentations. On November 3rd, there were two OPH speaker presentations.

A verbatim transcript will be available, in most instances, at approximately ten to twelve weeks following the meeting date.

Agenda:

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On November 3, 2022, as part of CDER's continued effort to provide key updates on modernization of quality assessment, the committee discussed 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 sought 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 sought input regarding the need for advancing digitalization in KASA, including data standardization and mobilization of data from cloud-based servers.

Attendance:

Pharmaceutical Science and Clinical Pharmacology Advisory Committee Members Present (Voting): Jeffery M. Carrico, PharmD, BCPS; Sandra Finestone, PsyD (Consumer Representative), Leonid Kagan, PhD; Walter K. Kraft, MD; Kelvin H. Lee, PhD; Kenneth R. Morris, PhD, FAAPS (Chairperson, Pharmaceutical Science); Frances Richmond, PhD; Eric V. Slud, PhD (November 3rd only); William C. Zamboni, PharmD, PhD

Pharmaceutical Science and Clinical Pharmacology Advisory Committee Members Not Present (Voting): Paul M. Beringer, PharmD; Arthur H. Kibbe, PhD

Pharmaceutical Science and Clinical Pharmacology Advisory Committee Member (Non-Voting): Mark C. Rogge, PhD (Industry Representative); Pravin Rothe, MPharm (Industry Representative), T.G. Venkateshwaran, PhD (Industry Representative)

Temporary Members (Voting): Gregory E. Amidon, PhD (November 3rd only); Maureen Donovan, PhD (November 3rd only); William Hancock, PhD (November 3rd only); Tonglei Li, PhD (November 3rd only); Mittal Sutaria, PharmD (November 2nd only)

FDA Participants (Non-Voting):

November 2nd: Patrizia Cavazzoni, MD; Michael Kopcha, PhD, RPh; Lucinda (Cindy) Buhse, PhD; Adam Fisher, PhD; Jennifer Maguire, PhD; Ashley Boam, MSBE; Alex Viehmann

November 3rd: Lawrence Yu, PhD; Sau "Larry" Lee, PhD; Stelios Tsinontides, PhD; Larisa Wu, PhD; Andre Raw, PhD; Rakhi Shah, PhD; Joel Welch, PhD

Designated Federal Officer (Non-Voting): Rhea Bhatt, MS

Open Public Hearing Speakers Present:
November 2nd: Giuseppe Randazzo (Association for Accessible Medicine); Denyse Baker (Parenteral Drug Association); Tami J. Frederick (International Society for Pharmaceutical Engineering); Raghuram Pannala (ScieGen Pharmaceuticals, Inc.)

November 3rd: Mike Abernathy (Amgen); Raghuram Pannala (ScieGen Pharmaceuticals, Inc.)

The agenda was as follows:

November 2, 2022: Quality Management Maturity (QMM)

Call to Order	**Kenneth R. Morris, MS, PhD** Chairperson (Pharmaceutical Science), PSCP
Introduction of Committee and Conflict of Interest Statement	**Rhea Bhatt, MS** Designated Federal Officer, PSCP
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
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
BREAK	
Clarifying Questions to the Presenters	
LUNCH	
OPEN PUBLIC HEARING	

Questions to the Committee/Committee Discussion	
ADJOURNMENT	

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

Call to Order	**Kenneth R. Morris, MS, PhD** Chairperson (Pharmaceutical Science), PSCP
Introduction of Committee and Conflict of Interest Statement	**Rhea Bhatt, MS** Designated Federal Officer, PSCP
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

BREAK

Clarifying Questions to the Presenters

LUNCH

OPEN PUBLIC HEARING

Questions to the Committee/Committee Discussion

ADJOURNMENT

Questions to the Committee:

November 2, 2022: Quality Management Maturity (QMM)

1. **VOTE**: Should CDER establish a QMM program to incentivize investments in mature quality management practices?

   Vote Result: Yes: 9 No: 0 Abstain: 0

   Committee Discussion: *The committee unanimously agreed that CDER should establish a QMM program to incentivize investments in mature quality management practices. Establish was clarified to include the development, implementation, and operation of the QMM program with continued stakeholder engagement. The committee commented that the concept of drug shortages is a pressing issue that requires multiple approaches. Specifically, the committee discussed development of the QMM program and the need to include the development of rubrics and assessments, for instance, how they are managed and how they interface with other stakeholders in a complex system. Committee members agreed that developing a guidance may be a useful next step to continue the process of interacting with stakeholders. Several committee members agreed that implementation of the program itself will be challenging. Please see the transcript for details of the Committee's discussion.*

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

1. **VOTE:** Do you support the long-term strategy for developing and implementing KASA at FDA and expanding the system from generic drugs to new drugs and biologics assessments?

   Vote Result: Yes: 13 No: 0 Abstain: 0

   Committee Discussion: *The committee unanimously supports the long-term strategy for developing and implementing KASA at FDA and expanding the system from generic drugs to new drugs and biologics assessments. In addition, the committee agreed that the potential for KASA to increase consistency and efficiency of reviews is significant. Some considerations the committee stated regarding KASA include: 1) ensuring the veracity of the techniques that are used for risk assessment 2) ensuring the experiential part of reviewer's job is not lost and is translated to structured findings 3) ensuring continued flexibility to handle different product complexity levels such as defining quality attributes of biologics and 4) sharing the techniques that are used to ensure transparency. Several committee members highlighted the importance of inclusion of stakeholders that are not pharmaceutical companies. Please see the transcript for details of the Committee's discussion.*

   DISCUSSION: In the age of digitalization, what additional actions should the FDA take to realize cloud-based assessment?

   Committee Discussion: *Relating to cloud-based assessment, the committee agreed that FDA should consider the double- edged recommendation that cloud data be made available outside the Agency to access data for modeling and other applications and activities. On the other hand, the committee acknowledged that it is difficult to de-identify data reliably. Also, committee members discussed the idea that multidirectional communication is important between FDA and stakeholders. In addition, the committee generally agreed that cloud-based tools that are used in and outside the Agency are critical areas for further discussion and development. Please see the transcript for details of the Committee's discussion.*

The meeting was adjourned at approximately 2:03 p.m. ET on November 2, 2022, and at approximately 2:43 p.m. ET on November 3, 2022.