

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

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

QUESTIONS

November 2, 2022: Quality Management Maturity (QMM)

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

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