U.S. Food & Drug Administration

Regulatory Science Public Meeting

Pre-Meeting Material for Attendees

These questions are intended to allow workshop attendees to reflect on key topics in regulatory science and come prepared to share perspectives, experiences, and ideas as part of facilitated discussion.

1. **Where is medical device technology headed?** Think about the capabilities of devices on the horizon, what is being developed, what is becoming possible, and what patient needs are driving innovation. What does the next decade of medical device innovation look like, and what kinds of technologies do you anticipate will be relevant to define it?
2. **How is the *setting* of medical device use changing and what does that mean for patients?** Increasingly, devices are being used outside of traditional clinical environments: in the home, in community settings, and in care models where a clinician may not be present in real time. When a device is used without immediate professional oversight, questions may arise about how it performs, how errors are identified t, and whether it is working as intended across a variety of users and conditions. How is the care setting for device use evolving, and what considerations does that raise for patients, caregivers, and the healthcare system?
3. **What regulatory science gaps exist in our ability to evaluate the performance of a medical device?** Current methods for assessing device safety, effectiveness, and performance were largely built around controlled settings and supervised use. The tools used to generate evidence are evolving to keep pace, from bench testing and non-animal approaches to computational modeling and simulation. Where do current evaluation methods have limitations for the devices being developed today, and where do emerging tools and capabilities hold promise for filling those gaps? If there is a gap between the testing environment and real-world use, what does that mean for our long-term confidence in a device's safety and performance?
4. **How do we generate the clinical evidence needed to keep pace with rapidly advancing medical device technologies?** As devices become more novel and complex, traditional clinical study designs and endpoints may not be well suited to capture what matters most to patients about how a device performs. What are the most pressing challenges in generating meaningful clinical evidence for next-generation devices, and what advancements in clinical trial design, endpoints, or data collection are most relevant to obtaining meaningful data for patients?