

**FDA and Industry OMFU Implementation Meeting
December 4, 2023**

Agenda:

- **FDA Updates**
- **Industry Updates and Discussion Topics**

Participants:

FDA		Industry	
Carol Bennett	CDER (ORP)	Lisa Parks	CHPA
Michael Bernstein	CDER (ORP)	David Spangler	CHPA
Anuj Shah	CDER (ORP)	Lauren Quinn	CHPA (Haleon)
Theresa Michele	CDER (OND)	James Kim	CHPA (ACI)
Karen Murry	CDER (OND)	Cornell Stamon	CHPA (PBOA)
Michael Boblitz	CDER (OND)	Gil Roth	CHPA (PBOA)
Andrea Frydl	CDER (OCOMM)		
Matthew Brancazio	CDER (OM)		
Grace Carmouze-Cunningham	CDER (OEP)		

FDA Updates:

FDA indicated the following:

- The Annual Forecast for Planned Monograph Activities was published on September 29, 2023.
- Certain over-the-counter monograph order request (OMOR) performance goals have begun, and monograph meeting management performance goals have increased as of October 1, 2023.
- CDER NexGen Portal began accepting certain OMOR submissions on October 1, 2023.

FDA reviewed the timeline for publication of final guidance documents.

FDA provided an update on user fee rates for OMORs.

FDA provided updates on hiring and communications.

Industry Updates and Discussion Topics:

FDA and Industry discussed the following:

- Industry feedback regarding meetings, administrative order initiation and data submissions.
- Industry provided an update of progress and challenges regarding use of the CDER NextGen Portal.