



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry CMC Subgroup

March 3, 2026 | 10:30am -11:00am

FDA White Oak Campus, Silver Spring

### MEETING PURPOSE

To address clarifying questions about FDA and Industry Chemistry, Manufacturing, and Controls (CMC) commitment language.

### PARTICIPANTS

#### FDA

Sau (Larry) Lee	CDER
Don Henry	CDER
Mahesh Ramanadham	CDER
Denise Gavin	CDER
Emily Ewing	CDER
Rebecca Frey-Cooper	CDER
Danielle Villata	CDER

#### Industry

Carl Garner	PhRMA (Eli Lilly)
Ryan Kaat	PhRMA
Derek Scholes	BIO
Drew Sansone	BIO (Alkermes)
Kelly Goldberg	PhRMA

### MEETING SUMMARY

Industry reviewed feedback and edits to the CMC commitment letter language drafted by the Agency. Industry presented the rationale for their feedback and provided clarification to FDA questions.

#### Draft Commitment Letter Language

Industry explained their intent to streamline the opening paragraphs of the CMC section. Industry noted that they added a training reference for CMC reviewers to focus implementation of facility engagement improvements under the CMC Facility Lifecycle Program. Industry also clarified that, while certain pilot programs from PDUFA VII may be discontinued, the desire is to ensure any learning from PDUFA VII will inform future activities. Industry also highlighted language that would be better reflected in guidance and FDA agreed. Industry highlighted their enhancement of language for meeting minutes of pre-submission and post-inspection meetings to provide firmer expectations around regulatory feedback and follow-up actions.

FDA explained that language was currently being developed after consultation with Office of Chief Counsel to properly frame goal date extension authority and criteria to include in the existing section of the letter regarding goal date extensions. A three-month maximum extension was agreed upon, with emphasis that FDA will strive to meet original goal dates when possible. There was a shared understanding established between both FDA and Industry that extensions should only occur when necessary to allow for time to move applications forward toward approval in the first cycle. The Agency emphasized the importance of "strive to" language being maintained for publication of guidance in fiscal year 2028, due to policy clearance uncertainties, with agreement this approach applies to, and was reasonable for, guidance supporting CMC Facility Lifecycle Program. Lastly, details around workshop coordination were discussed to ensure third-party assessment data supports public workshop objectives and timing.

### **Next Steps**

The goal for the next meeting on March 5<sup>th</sup>, 2026 is to address additional questions and provide clarity on the drafted commitment letter language.