



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry CMC Subgroup

February 24, 2026 | 10:30am -11:00am

Virtual Format

### MEETING PURPOSE

To address clarifying questions about FDA and Industry Chemistry, Manufacturing, and Controls (CMC) review process enhancement proposals.

### PARTICIPANTS

#### FDA

Sau (Larry) Lee	CDER
Don Henry	CDER
Mahesh Ramanadham	CDER
Lisa Harlan	CDER
Denise Gavin	CDER
Emily Ewing	CDER
Rebecca Frey-Cooper	CDER
Francis Godwin	CDER
Ivy Sweeny	CDER
Danielle Villata	CDER
Derek Smith	CDER

#### Industry

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

### MEETING SUMMARY

FDA reviewed a draft of CMC commitment letter language with Industry. The Agency reviewed their rationale and provided clarification to Industry questions.

#### Draft Commitment Letter Language

FDA discussed details of the language they drafted, calling out specific details for Industry to highlight to their stakeholders. FDA noted a chronological structure allowing the CMC commitment letter language to follow the facility lifecycle from readiness criteria through pre-submission, inspection notification, post inspection, and post action meetings. The draft language also noted the expanded scope of the program to include both original applications and supplements with facility-related changes, requiring clarification that not all CMC supplements

would be covered. The Agency also highlighted language in the draft commitment letter acknowledging commitments from PDUFA VII and carrying through many of the concepts and learnings in PDUFA VIII including those related to enhanced facility engagement and transparency, improved facility readiness, and proactive approaches to address facility issues.

Industry questioned details for goal date extensions and Letter of Authorization (LOA) communication during the meeting grant or denial process. Industry also raised questions around implementation and managing the program before published guidance.

### **Next Steps**

The goal for the next meeting on February 26<sup>th</sup>, 2026 is to address any additional questions and provide clarity on the drafted commitment letter language.