FDA and Industry GDUFA II Implementation Quarterly Meetings – 3Q2019 Meeting
July 16, 2019, 1:30 PM – 3:30 PM
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1211

Agenda

- DMF Issues (Industry Led)
- Updates on FDA's Goal Performance (FDA Led)
- ICH Q12 Training (FDA Led)
- Industry Feedback on "Bottle of Lies" (Industry Led)

Participants

FDA:		Industry:	
Don Ashley	CDER	Deb Autor	Mylan (AAM)
Tiana Barnes	CDER	Rafael Antunes	EFCG (Hovione)
Ashley Boam	CDER	John DiLoreto	BPTF
Sally Choe	CDER	David Gaugh	AAM
Alonza Cruse	ORA	Lisa Parks	AAM
Lyndsay Hennessey	CDER	Gil Roth	PBOA
Michael Kopcha	CDER	Cornell Stamoran	Catalent (PBOA)
Ted Sherwood	CDER	Filipe Tomas	Hovione (BPTF)
Dave Skanchy	CDER	Scott Tomsky	AAM (Teva)
Maryll Toufanian	CDER	Molly Ventrelli	AAM (Fresenius Kabi)

DMF Issues

FDA and Industry discussed DMF deficiencies and steps both sides are taking to minimize their occurrences. Industry will provide FDA with recommendations, for our consideration, on potential next steps.

Updates on FDA's Goal Performance

FDA and Industry discussed FDA's current goal performance and possibly working through the goal date towards an imminent approval.

ICH Q12 Training

FDA shared that the ICH Q12 guideline is expected to receive final Expert Working Group sign-off at the November 2019 ICH meeting in Singapore. FDA requested Industry provide input on guidelines/training that they would find particularly useful as the ICH Q12 Expert Working Group will be developing global training materials at the November meeting.

Industry Feedback on "Bottle of Lies"

Industry has not received significant inquiries after the publishing of the book Bottle of Lies."