FDA and Industry GDUFA II Implementation Quarterly Meetings – 1Q2020 Meeting
January 21, 2020 1:30 PM – 3:30 PM
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1227

Agenda

- Industry Challenges with Combination Products (Industry Led)
- Advanced Manufacturing – Challenges and Advantages of Implementing (FDA Led)

Participants

FDA:		Industry:	
Don Ashley	CDER	Rafael Antunes	EFCG (Hovione)
Tiana Barnes	CDER	John DiLoreto	BPTF
Lisa Bercu (SME)	CDER	David Gaugh	AAM
Ashley Boam	CDER	Kiran Krishnan	AAM (Apotex)
Sally Choe	CDER	Matt Moran	EFCG (BioPharmaChem)
Mary Beth Clarke	CDER	Lisa Parks	AAM
Alonza Cruse	ORA	Gil Roth	PBOA
Michael Kopcha	CDER	Wayne Talton	AAM (Mylan)
Kristina Lauritsen (SME)	CDER	Scott Tomsky	AAM (Teva)
Anne Marie Montemurro	ORA	Molly Ventrelli	AAM (Fresenius-Kabi)
Iilun Murphy	CDER	Cornell Stamoran	PBOA (Catalent)
Maryll Toufanian	CDER		
Kimberly Peters	CDER		

Industry Challenges with Combination Products

Industry presented the challenges of developing complex drug-device combination products. Industry recognized the progress made under GDUFA II and made some recommendations for FDA's consideration.

Advanced Manufacturing – Challenges and Advantages of Implementing

FDA discussed continuous and advanced manufacturing and industry shared its insight into unique challenges related to the technical and financial aspects of implementing the concepts.