U.S. FOOD & DRUG ADMINISTRATION

Voluntary Medical Device Manufacturing and Product Quality Program

Public Workshop

FDA White Oak Campus

October 10, 2017

Morning Agenda

Time	Topic	Speaker
7:30 - 8:00 AM	Registration	
8:00 - 8:10AM	Welcome and Meeting Goals	Jeffrey Shuren FDA, CDRH
8:10 - 8:55 AM	Case for Quality Background and MDIC Collaboration	Stephanie Christopher MDIC
8:55 – 9:40 AM	CMMI Institute, Tools, and Playbook	George Zack Two Harbors Consulting, LLC Kimberly Kaplan CMMI Institute
9:40 - 10:00 AM	Quality Program Pilot Framework	Robin Newman FDA, CDRH
10:05 – 10:30 AM	Participation Criteria and Rules of Engagement	Capt. Sean Boyd FDA, CDRH
10:30 – 10:45 AM	Break	
10:50 - 11:25 AM	FDA Modifications to Decrease Regulatory Burden	Francisco Vicenty FDA, CDRH
11:25 - 12:00 PM	Value Proposition from Stakeholders	Nathan Tenzer Edwards Lifesciences Luann Pendy Medtronic

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Lunch

12:00 to 1:00 pm

Boxed lunches from Sodexo (pre-order and pre-pay at registration in the morning)

Afternoon Agenda

Time	Topic	Speaker
1:00 - 1:30 PM	Value Proposition from Stakeholders	Frank Meledandri Zoll LifeVest Cynthia Grossman Faster Cures
1:30 - 2:15 PM	**Panel Discussion 1:** *Health Outcomes to Patients, Value to Industry, Benefits to Healthcare*	Hudson Garrett Joe Friedrich Cynthia Grossman Al Crouse Adrian Furey Robin Newman
2:15 - 3:00 PM	**Panel Discussion 2:** *Identifying Risks and Mitigation Strategies*	George Zack Pat Baird Francisco Vicenty Al Crouse Cindy Winfrey Emily Miner
3:00 – 3:10 PM	Break	
3:10 – 5:00 PM	Open public session for Presentations by Participants	

Comments to the Docket

https://www.regulations.gov/docket?D=FDA-2017-N-4180

Or go to

http://www.regulations.gov

And enter into the Docket ID

FDA-2017-N-4180

FR notice for reopening of comment period is in progress

Other feedback option: email

CaseForQuality@fda.hhs.gov

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Morning Break

15 minutes

Back at 10:30 am


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