FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

AGENDA

DEVICES GOOD MANUFACTURING PRACTICES (GMP) PANEL

21 CFR 820 Quality System Regulation Amendment Proposed Rule

March 2, 2022

Panel Chairperson
Yadin David, Ed.D., P.E.

Designated Federal Officer
Jarrod Collier, M.S.

9:00 AM	Call to order Panel Introductions Conflict of Interest Statements
9:15 AM	Opening Remarks – Ariel Seeley
9:25 AM	Overview of Proposed Rule/History of Harmonization: FDA – Melissa Torres
9:42 AM	Similarities & Differences (Documentation; CAPA; Risk Management): FDA – Keisha Thomas
10:00 AM	Industry Presentation: AdvaMed – Jamie Wolszon
10:10 AM	Industry Presentation: MITA – Diane Wurzburger
10:18 AM	Standards Presentation: ISO/TC 210 Chair – Peter Linders
10:45 AM	Break
11:00 AM	Open Public Hearing*
11:15 AM	Panel Deliberations
12:15 PM	Lunch
1:15 PM	FDA Questions to Panel
2:45 PM	FDA Summary
3:00 PM	Adjournment

*** Open Public Hearing –** Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.