

Cultivating Compliance

September 1, 2020

11:00AM-4:30PM EDT

AGENDA

Welcome/Opening Remarks

Blake Bevill | Program Division Director OMDRHO Div. 2

Anne Reid | Deputy Program Director, ORA

Current Trends of 483 Observations, WL's, & Firm Responses to Both

Karen Archdeacon | Compliance Officer, Division 1

CAPA – Presentation

Laiza Garcia | CSO, Division 2

Design Controls-Presentation

Matthew Vernon | CSO, Division 3

Design Changes

Dharmesh Patel | Acting Assistant Director, PMA, HDE, Q-Submission & Device Tracking Lifecycle Team, CDRH

Recalls

Meredith Andress | Recall Coordinator Division 2