



Working Together – Keeping Informed

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Schedule

10:30 am - 10:40 am

Office of Medical Devices and Radiological Health Operations (OMDRHO) Update

Speaker: Joseph Matrisciano Jr., Program Division Director-Division 1

10:40 am - 11:15 am

ORA/CDRH Resources Available to Industry

Speakers: Justine Corson, Medical Device Specialist; LCDR David Sullivan, Investigator; & Ruth Bediakoh, Consumer Safety Officer

11:15 am - 12:00 pm

AccessGUDID, Are You There Yet & Why You Should Be?: understanding UDI & the latest deadlines

Speaker: CDR Stephen Smith, Medical Device Specialist

12:00 pm - 12:30 pm

Break

12:30 pm - 1:15 pm

FDA Review of Class I and II Recalls

Speaker: Meredith Andress, Recall Coordinator

Schedule

1:15 pm – 2:15 pm

Effective Communication with FDA Before, During and After an Inspection

Speakers: Debara Reese, Medical Device Specialist; & Karen Archdeacon, Compliance Officer

2:15 pm – 2:30 pm

Break

2:30 pm – 3:30 pm

Risk Management and the Total Product Lifecycle

Speaker: Katelyn Staub-Zamperini, Medical Device Specialist

3:30 pm – 4:15 pm

Uncovering and Maximizing the Value of FDA Inspections

Speaker: LT Colin Tack, Investigator

4:15 pm – 4:45 pm

Let's talk Remote Regulatory Assessment (RRA) for OMDRHO

Speaker: Shari Shambaugh, Program Division Director-Division 3

4:45 pm – 5:00 pm

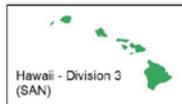
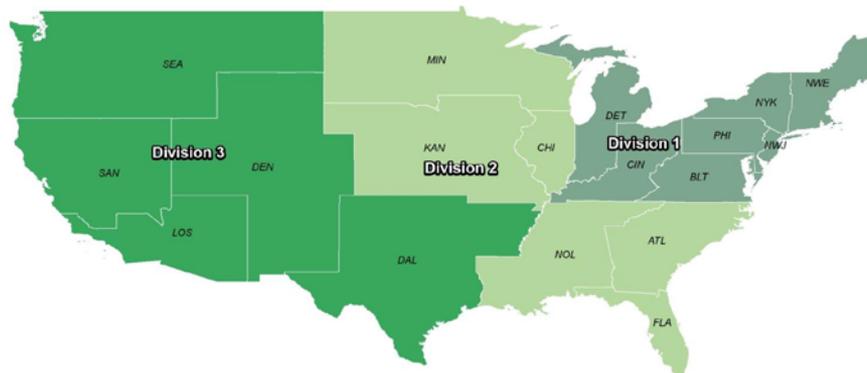
Closing Remarks

If you have any questions...

- Use the questions/comment box in AdobeConnect
- Email us at ORAMedDeviceConference@fda.hhs.gov

Office of Medical Devices and Radiological
Health Operations (OMDRHO)

FDA U.S. FOOD & DRUG
ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS



**Medical Devices Program
Divisions**

- Division 1 (BLT, CIN, DET, NWE, NWJ, NYK, PHI)
- Division 2 (ATL, CHI, FLA, KAN, MIN, NOL, SJN)
- Division 3 (DAL, DEN, LOS, SAN, SEA)
- FDA Current Districts Boundaries



Source: ORA

Prepared by Office of Regulatory Affairs (ORA) Division of Planning, Evaluation & Management (DPEM), Program Evaluation Branch

Office of Medical Devices and Radiological Health Operations (OMDRHO) Update

*Joseph
Matrisciano Jr.,
Program Division
Director-Division
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Let's Get to Know You...