



Agenda: Fall 2020 FDA/Industry IVD Roundtable

Thursday, November 19, 2020

- 10:00-10:05** **Welcome**
- 10:05-11:30** **OPEQ/OIR Update**
Tim Stenzel, Director, OHT7/OIR
Owen Faris, Principal Deputy Office Director, OPEQ
- 11:30-12:15** **RADx Program**
Sara Brenner, Associate Director for Medical Affairs, OHT7/OIR
- 12:15-12:30** **Break**
- 12:30-1:15** **FDA Response to COVID**
Tim Stenzel, Director, OHT7/OIR
Toby Lowe, Associate Director for Programs and Performance, OHT7/OIR
CBER Representative TBD
- 1:15-1:45** **CLIA-Waiver Final Guidances**
Tamara Pinkney, Policy Analyst, OHT7/OIR, DPOM,
Laboratory Improvements Outreach and Analysis Team
- 1:45-2:15** **CDRH Implementation of 506J Legislation and 'Buy America' Executive Order**
Linda Ricci, Director, Division of All Hazard Response, Science and Strategic Partnerships,
Office of Strategic Partnerships and Technology Innovation (OST)
- 2:15-3:00** **Question and answer session**
OIR Panel
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WebEx Event Details

Event address for attendees:

<https://fda1.webex.com/fda1/onstage/g.php?MTID=e16264820eaf633f3bf0782341fd1f6fe>

Audio conference information

To receive a call back, provide your phone number when you join the event, or call the number below and enter the access code.

+1-210-795-0506 US Toll

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