



Agenda: Spring 2023 FDA/Industry IVD Roundtable

Monday May 22, 2023

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| 11:00-11:05 | Welcome
Tiffany Levin, AMDM Past President/Industry Liaison
Jamie Wolszon, VP AdvaMed
Grainne Tobin, Policy Analyst, OHT7/DPOM |
| 11:05-11:30 | OPEQ/OHT7 Update
Tim Stenzel, Director OHT7 |
| 11:30- 11:50 | The End of the Public Health Emergency - Question and Answer Session
OHT7 Panel |
| 11:50-12:10 | Pre-Determined Change Control Protocols
Industry presentation |
| 12:10-12:30 | OHT7 Hot Topic – Submitting a Request for CLIA Categorization: Challenges of an Uncategorized Test System
Tamara Pinkney, Policy Analyst, OHT7/DPOM |
| 12:30-2:00 | Question and Answer Session
OHT7 Panel |
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Zoom Meeting Details

Registration address for attendees:

<https://fda.zoomgov.com/j/1609157778?pwd=YXVqU0VnMHdKbmhLKy9qSE14ZTBPd09>