



MARSQA Computer Validation Committee (CVC) Roundtable - Advanced CSV Topics Roundtable Agenda

Thursday, 6 November 2025 | 9:00 AM - 5:00 PM EST

Earl's New American Restaurant

Located in Peddler's Village

2400 Street Rd. | New Hope, PA 18938

Thursday, Nov 6

- | | |
|----------------------|---|
| 8:30 - 9:00 AM: | Check-in and Continental Breakfast |
| 9:00 – 9:15 AM: | Welcome – Heidi Krueger (Former MARSQA President and CVC Co-Chair)
and Denise Botto (CVC Co-Chair) |
| 9:15 - 10:15 AM: | Foundations of AI in GxP |
| 10:15 - 10:25 AM: | Break (System related Warning Letters) |
| 10:30-11:30 AM: | Validation Challenges for AI Systems |
| 11:30 AM - 12:30 PM: | QA Challenges for AI/ML in GxP Systems: Explainability, Oversight, and
Auditability |
| 12:30 – 1:20 PM: | Lunch (System related Warning Letters) |
| 1:30 – 2:30 PM: | How to Transfer the Skill Set of Computer System Validation to Quality
Assurance |
| 2:30 – 3:30 PM: | Data Integrity & Governance |
| 3:30 – 3:40 PM: | Break (System related Warning Letters) |
| 3:45 – 4:45 PM: | Computer Software Assurance (CSA): QA's Role in Risk-Based Validation |
| 4:45 – 5:00 PM: | Closing (System related Warning Letters) |