

Program Agenda

Start/End Date	Track 1	Track 2
07:30 AM - 09:30 AM	Registration/Networking/Continental Breakfast + PDA Announcements	
09:00 AM - 10:00 AM	Keynote speaker – Tim Culbreth, President US Operations, Polypeptide <i>Process Validation concepts related to Individualized Therapies</i>	
10:00 AM - 10:30 AM	Networking Break	
<i>Technical Sessions</i> 10:00 AM - 12:30 PM	(1a) Equipment Qualification – Randy Hartly, Propharma	(1b) Method/Lab Validation – Joe Page, Eurofins
<i>Technical Sessions Contd.</i>	(2a) Risk Management Tools for Validation – Lisa Lawson, PMS	(2b) The Goldilocks of Statistics for Process Validation – Tara Scherder, Synolostats
12:30 PM - 01:30 PM	Lunch & Vendor Announcements	
<i>Technical Sessions</i> 01:30 PM - 3:30 PM	(3a) Process Validation – Javier Cardenas, Azzur Group	(3b) Cleaning Process Validation Life Cycle for Pharmaceutical Industry – Sunil Patel, Ecolab
<i>Technical Sessions Contd.</i>	(4a) Data Integrity – William Honeck, VTI Life Sciences	(4b) Why Do Disinfectant Qualification Studies Fail? – Ziva Abraham, Microrite
3:30 PM - 04:00 PM	Networking Break	
<i>Case Studies</i> 04:00 PM - 05:00 PM	(5a) Computer Systems Validation – Laurent Saugrin, Dexcom	(5b) Cleaning Validation for Medical Device Industry – Diane Vu, Medtronic
05:00 PM - 06:00 PM	Networking Reception (w/beer & wine) & Poster Announcement	

*Program subject to change