



PTEA 2025 Annual Conference

October 30, 2025 | Overland Park Convention Center

Time	Session Title	Speaker
8:00 – 8:30 AM	Registration	
8:30 – 8:45 AM	Welcome to PTEA	William C. Putnam, PhD, RAC – President, PTEA
8:45 – 9:15 AM	FDA Update	Gretchen VanDeusen, Branch Chief, FDA/OII/OHADI/Division 4
9:15 – 10:00 AM	Keynote Address - Breaking the Butterfly Upon the Wheel: Hurdles and Enablers of Patient Centered, Fit for Purpose Specifications	Jeffrey C. Baker, PhD.; Sr. Fellow, National Institute for Innovation in Manufacturing of Biopharmaceuticals; Deputy Director, Office of Biotechnology Products, FDA (retired)
10:00 – 10:15 AM	Break	
10:15 – 10:45 AM	Drug Supply Chain Security Act (DSCSA) – Industry Status Update	Ryan Kelly; Senior Director, Supply Chain Security & Brand Protection, Rx360
10:45 – 11:05 AM	Laboratory practices	Chad Rice, Drug Specialist, FDA, OHADI Division 4
11:05 – 11:30 AM	Implementing a Supplier Management Program	Donna Steve, Director Regulatory Affairs and Quality Oversight, Eurofins Viracor BioPharma and Pharma Bioanalytics Services
11:30 – 12:00 PM	Morning Panel Q&A	All Morning Speakers
12:00 – 1:15 PM	Networking Lunch	
1:15 – 1:45 PM	CVM Update (Virtual) & Q&A	Cindy L. Burnsteel, DVM; FDA Center for Veterinary Medicine
1:45 – 2:15 PM	Using FDA.gov for Inspections	Gerald Bromley III, Program Support Specialist, OHADI Division 4
2:15 – 2:45 PM	Observation Trends Review	Chad Rice, Drug Specialist, FDA, OHADI Division 4; Gerald Bromley III, Program Support Specialist, OHADI Division 4
2:45 – 3:00 PM	Break	
3:00 – 3:30 PM	Expecting the Unexpected Inspection	Jeb S. Hunter, Sr. Regulatory Consultant, EAS Consulting Group
3:30 – 4:00 PM	Inspection Preparation	Discussion with FDA panel
4:00 – 4:30 PM	Afternoon Panel Q&A	All Afternoon Speakers
4:30 – 4:45 PM	Wrap-Up & Adjourn	

For full speaker bios and updates, visit www.ptea.org

2025 Gold Sponsors

