Association for GXP Excellence

Winter Meeting

Date & Time: 28-Feb-2020 9:00 am – 3:30 pm Veeva, 601 W Office Center Dr, Fort Washington, PA 19034



Register Now at: http://www.agxpe.wildapricot.org/

	Presented by:	Time
Coffee and Networking		8:30 am – 9:00 am
 Welcome and Logistics ◆ Site and new member welcome 	John Lewis, LSSMBB — Merck & Co., Inc/AGXPE President Kent Malmros — Corporate Training Expert, Learning Technologist, Author & Speaker Veeva	9:00 am – 9:20 am
CAPA Management & Continuous Improvement Shifting the traditional focus of CAPAs from creating short term fixes to implementing long term initiatives	Sharon Brower, CQA - Head of Clinical Training, Process & Continuous Improvement Global Development Operations -BMS	9:20 am – 10:20 am
Networking Break		10:20 am – 10:45 am
 Modernizing Quality Management Modernizing your quality management systems provides greater agility and oversight of unified GxP critical content, data and process. 	Snehal Srikrishna - Senior Director, Vault Quality @ Veeva	10:45 am – 11:45 am
Lunch		11:45 am – 12:45 pm
 TMF Panel Discussion TMF use, compliance, maintenance, analytics and reporting 	Jamie Marie Toth, CPM, MS - Director, Head of TMF Operations Clinical Development Operations, Daiichi Sankyo, Inc. Pinkey Tupparwar - Director, Global Process Lead TMF, Global Development Operations, BMS Jason Methia – VP of SiteConnect and eTMF, Veeva Heather Frankhouser - Associate Director TMF Business Operations, J&J	12:45 pm – 2:15 pm
Networking Break		2:15 pm – 2:30 pm
Overview of the Documenting Investigations Content: Interactive session sharing advice on improving not only the effectiveness of these documents but also the efficiency of writing them Strategies to improve the readability and clarity of investigation documents Clear documenting of root causes and streamlined corrective and preventative actions	Danielle Heuere - Director, WD Communications	2:30 pm – 3:00 pm
Association Membership Business Review New Chapter news (San Francisco/Boston) 2020 Conference Update Future meeting topics Future meeting sponsors	<i>Vince Ranieri</i> – Manager, Laboratory Analyst Training & CP. Jansen, J&J	3:00 pm - 3:30 pm
Meeting Close	• John Lewis, AGXPE Leadership	3:30 pm – 3:45 pm