





# Conference Agenda

2018 Conference and Expo, Cambridge, MA  
October 28 - 31, 2018

Track 1	GXP
Track 2	Regulatory/Quality
Track 3	Learning Tools and Resources

<b>SUNDAY, October 28, 2018</b>	
6:00 p.m. - 10:00 p.m.	<p><b>Registration &amp; Welcome Reception</b> Location: Luscomb Ballroom, 3<sup>rd</sup> Floor</p> <p>Live Music Entertainment by: </p> <p><i>Arrive early to register and network with other attendees, vendors, and AGXPE Leadership while enjoying drinks, light food and live music entertainment</i></p>

<b>MONDAY, October 29, 2018</b>								
7:00 a.m. - 8:30 a.m.	Continental Breakfast Location: Amuse Restaurant							
8:00 a.m. - 4:00 p.m.	Registration Location: Social Foyer outside Luscomb Ballroom							
9:00 a.m. - 10:30 a.m.	<p><i>The Happiness Advantage: Bringing the Research to Life at Work</i></p> <p>Keynote Speaker: <b>Devin C. Hughes</b> Chief Inspiration Officer International Thought Leader Network</p> <p>(Luscomb Ballroom, 3<sup>rd</sup> Floor)</p>							
10:30 a.m. - 10:45 a.m.	Networking and Vendor Break							
10:45 a.m. - 12:00 p.m.	<table border="1"> <tr> <td rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">Exhibits Open</td> <td> <p><i>Keeping Companies Safe: Best Practices in Communications Surveillance from Other Regulated Industries</i> <b>Anish Parikh</b> <b>Kathleen Hamann</b> (Jerome Hunsaker A)</p> </td> <td> <p><i>Strategies to Build Resilience and Avoid Change Fatigue</i> <b>Juliet Hart</b> (Jerome Hunsaker B)</p> </td> <td> <p><i>Roche Biometrics Training Strategy - Scaling to Meet the Needs of the Business</i> <b>Christopher O'Leary</b> (Jerome Hunsaker C)</p> </td> </tr> <tr> <td colspan="3">Lunch Break Location: Amuse Restaurant</td> </tr> </table>	Exhibits Open	<p><i>Keeping Companies Safe: Best Practices in Communications Surveillance from Other Regulated Industries</i> <b>Anish Parikh</b> <b>Kathleen Hamann</b> (Jerome Hunsaker A)</p>	<p><i>Strategies to Build Resilience and Avoid Change Fatigue</i> <b>Juliet Hart</b> (Jerome Hunsaker B)</p>	<p><i>Roche Biometrics Training Strategy - Scaling to Meet the Needs of the Business</i> <b>Christopher O'Leary</b> (Jerome Hunsaker C)</p>	Lunch Break Location: Amuse Restaurant		
Exhibits Open	<p><i>Keeping Companies Safe: Best Practices in Communications Surveillance from Other Regulated Industries</i> <b>Anish Parikh</b> <b>Kathleen Hamann</b> (Jerome Hunsaker A)</p>		<p><i>Strategies to Build Resilience and Avoid Change Fatigue</i> <b>Juliet Hart</b> (Jerome Hunsaker B)</p>	<p><i>Roche Biometrics Training Strategy - Scaling to Meet the Needs of the Business</i> <b>Christopher O'Leary</b> (Jerome Hunsaker C)</p>				
	Lunch Break Location: Amuse Restaurant							
12:00 p.m. - 1:30 p.m.								
1:30 p.m. - 2:45 p.m.	<table border="1"> <tr> <td rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">Exhibits Open</td> <td> <p><i>ICH E6(R2) Compliance: Employing GMP Techniques in GCP for More Robust, Compliant Clinical Trials</i> <b>Judy Carmody</b> (Jerome Hunsaker A)</p> </td> <td> <p><i>Regulatory Convergence: Bringing Academia, Industry and Regulators Together</i> <b>Jared Auclair</b> (Jerome Hunsaker B)</p> </td> <td> <p><i>Data-driven Learning Design</i> <b>Lori Niles-Hofmann</b> (Jerome Hunsaker C)</p> </td> </tr> <tr> <td colspan="3">Networking and Vendor Break</td> </tr> </table>	Exhibits Open	<p><i>ICH E6(R2) Compliance: Employing GMP Techniques in GCP for More Robust, Compliant Clinical Trials</i> <b>Judy Carmody</b> (Jerome Hunsaker A)</p>	<p><i>Regulatory Convergence: Bringing Academia, Industry and Regulators Together</i> <b>Jared Auclair</b> (Jerome Hunsaker B)</p>	<p><i>Data-driven Learning Design</i> <b>Lori Niles-Hofmann</b> (Jerome Hunsaker C)</p>	Networking and Vendor Break		
Exhibits Open	<p><i>ICH E6(R2) Compliance: Employing GMP Techniques in GCP for More Robust, Compliant Clinical Trials</i> <b>Judy Carmody</b> (Jerome Hunsaker A)</p>		<p><i>Regulatory Convergence: Bringing Academia, Industry and Regulators Together</i> <b>Jared Auclair</b> (Jerome Hunsaker B)</p>	<p><i>Data-driven Learning Design</i> <b>Lori Niles-Hofmann</b> (Jerome Hunsaker C)</p>				
	Networking and Vendor Break							
2:45 p.m. - 3:15 p.m.	Networking and Vendor Break							

3:15 pm - 4:30 pm	<p><b>SOP Simplification Through a Principles-based Approach</b>  <b>Regina Neubauer</b>  <b>Alice Savoca</b>  (Jerome Hunsaker A)</p>	<p><b>Revamping The Vendor Qualification Process For Clinical Stage Outsourcing</b>  <b>Laurie Halloran</b>  (Jerome Hunsaker B)</p>	<p><b>Building a Positive Team - Helping Your People Be Happy and Engaged</b>  <b>Devin C. Hughes</b>  <b>Tammy Cullen</b>  (Jerome Hunsaker C)</p>
4:30 pm - 5:30 pm	Networking and Vendor Break		
5:30 pm - 6:30 pm	Vendor Reception Location: Social Foyer outside Luscomb Ballroom		
7:00 pm - 10:00 pm	<p>Murder Mystery Dinner  Theme: <i>Best Laid Plans - An Old Hollywood Whodunit</i></p>  <p>Location: Amuse Restaurant</p>		

**Confirmed Vendors**

	
	
	
	<p>Performance. At a higher level.</p> 
	



# Conference Agenda



<b>TUESDAY, October 30, 2018</b>			
7:00 a m - 8:30 a m	Continental Breakfast Location: Amuse Restaurant		
7:30 a m - 4:00 p m	Registration Location: Social Foyer outside Luscomb Ballroom		
8:30 a m - 9:45 a m	<b>Risk-based Thinking and Risk Management: Where are we in 2018?</b> General Session Speaker: <b>James Vesper</b> (Luscomb Ballroom, 3 <sup>rd</sup> Floor)		
9:45 a m - 10:00 a m	Networking and Vendor Break		
10:00 a m - 11:15 a m	<b>GXP Best Practices: How to Be Even more Compliant</b> <b>Michelle Durcholz</b> (Jerome Hunsaker A)	<b>Narrative Medicine: Innovative techniques for including the voice of the patient in drug development</b> <b>Jesus Rivera</b> (Jerome Hunsaker B)	<b>Incorporating Lean Principles into an Approach to Rapid Content Development</b> <b>Joshua Gilliam</b> (Jerome Hunsaker C)
11:15 a m - 11:30 a m	Networking and Vendor Break		
11:30 a m - 12:30 p m	Exhibits Open	<b>2018 - Inspection Trends, Updates, and Activities</b> FDA Guest Speaker: <b>Karen Archdeacon</b> <b>FDA Compliance Officer</b> <b>FDA Office of Medical Device and Radiological Health Operations (OMDRHO)</b> <b>Collaborating partner of the Center for Devices and Radiological Health (CDRH)</b> (Luscomb Ballroom, 3 <sup>rd</sup> Floor)	
12:30 p m - 1:45 p m		Lunch Break Location: Amuse Restaurant	
1:45 p m - 3:15 p m		<b>Data Integrity Panel Discussion</b> Featuring DI Industry Panelists: <b>Karen Archdeacon, Judy Carmody, James Vesper, Anish Parikh, Eric Thostesen, Mary Jo Egbert, and others</b> (Luscomb Ballroom, 3 <sup>rd</sup> Floor)	
3:15 p m - 3:45 p m		Networking and Vendor Break	
3:45 p m - 5:00 p m	<b>Clinical Trials: Reduce risk and improve outcomes in the most costly aspect of new drug development</b> <b>Rich Lanchantin</b> (Jerome Hunsaker A)	<b>Revamping Learning and Development with AI</b> <b>Giselle Mota</b> (Jerome Hunsaker B)	<b>Keep it Simple! 5 Simple Rules of Explanation</b> <b>Andrea Acosta</b> (Jerome Hunsaker C)

5:00 p.m. - 5:15 p.m.		<b>Networking and Vendor Break</b>
5:15 p.m. - 6:30 p.m.		<b>Career Corner</b> <b>Location: (Luscomb Ballroom, 3<sup>rd</sup> Floor)</b>  <b><i>College students Welcome!</i></b> <b><i>Local and regional recruiters will be available to discuss opportunities.</i></b>
		<b>Dinner is on Your Own!</b>





# Conference Agenda



<b>WEDNESDAY, October 31, 2018</b>			
7:00 am - 8:30 am	Continental Breakfast Location: Amuse Restaurant		
8:30 am - 10:00 am	Exhibits Open	<i>Handling Challenging Situations During FDA Inspections with Grace Under Pressure.</i> <b>Kim Mejia</b> (Luscomb Ballroom, 3 <sup>rd</sup> Floor)	
10:00 am - 10:15 am		Networking and Vendor Break	
10:15 am - 11:30 am		<b>System Validation -- Different Approaches to Interface Validation</b> <b>Robert Migliore</b> (Jerome Hunsaker A)	<b>What's the Problem with Procedures?</b> <b>James Vesper</b> (Jerome Hunsaker B)
11:30 am - 11:45 am	Networking Break		
11:45 am - 12:30 pm	Closing Ceremonies Gift Basket Raffle Final AGXPE Leadership Remarks <i>See you next time!</i>  (Luscomb Ballroom, 3 <sup>rd</sup> Floor)		



Topics and Solutions Covered	
Artificial Intelligence	
AV use in Training	
Big Data	
Career Development	
Certification	
Clinical Trial Master Files	
Coaching	
Comedy in Training	
Compliance Trends	
Content Development	
Data Integrity	
E-learning	
Good Clinical Practices	
Good Distribution Practices	
Good Laboratory Practices	
Good Manufacturing Practices	
Health Authority Observation Responses	
Health Authority Topics	
Human Error Reduction	
ICH Guidelines	
Inspection Readiness	
Instructional Design Tools	
Learning Management Systems	
Mindfulness Techniques	
Mentoring	
Personal Development and Branding	
Product Serialization	
Qualification	
Quality by Design	
Quality Management	
Risk Management	
Role-based Curricula	
SOP Writing	
Training Effectiveness Techniques	
Video Creation	

# Map of Conference Center Floor Plan

*(More detailed information will be made available later.)*



# Map of Conference Center Location

*(More detailed information will be made available later.)*

