



# Conference Agenda

2015 Conference and Expo, Annapolis, MD

Track 1	Specialty Training
Track 2	Quality & Regulatory Compliance
Track 3	Multi-Platform Training

## SUNDAY, September 27, 2015

6:00 pm - 8:00 pm	Registration (Main Concourse)
7:00 pm - 10:00 pm	Welcome Reception Guitarist/Musician - <b>Tyler Carson</b> (Mainsail East & Main)

## MONDAY, September 28, 2015

7:30 am - 8:30 am	Registration (Main Concourse)			
7:30 am - 8:30 am	Continental Breakfast (Mainsail East & Main)			
8:30 am - 10:00 am	<p style="text-align: center;"><b>Opening Ceremonies</b></p> <p style="text-align: center;"><b>Keynote Address: Personnel Qualification Truly is Rocket Science</b> <b>Don Thomas - NASA Mission Specialist Astronaut aboard Space Shuttles</b> <b>Columbia and Discovery</b> (Mainsail East &amp; Main)</p>			
10:15 am - 11:30 am	<b>483 Forum</b> <b>T. Cullen</b> <b>Eli Lilly</b> (Mainsail East)	<b>Combination Product Regulations</b> (21 CFR Part 4) <b>H. Naik</b> <b>BMS</b> (Mainsail Main)	<b>Online Learning Design and Development Techniques</b> <b>Dr. C. McKeague</b> <b>UL-EduNeering</b> (Mainsail West)	
11:30 am - 12:30 pm	Lunch Break (Mainsail East & Main)			
12:45 pm - 2:00 pm	Exhibits Open	<b>Lab Analyst Training &amp; Certification Program</b> <b>V. Ranieri</b> <b>Janssen</b> (Mainsail East)	<b>Evolution Of Quality</b> <b>F. Lavallee</b> <b>Aliter Concept</b> (Mainsail Main)	<b>SOP Creation Using the Subject Matter Experts</b> <b>P. Salvatore</b> <b>Author</b> (Mainsail West)
2:15 pm - 3:30 pm		<b>Aseptic Process Training</b> <b>B. Krenc</b> <b>DPT Labs</b> (Mainsail East)	<b>ICH Q9 Quality Risk Management</b> <b>P. Gandhi</b> <b>BMS</b> (Mainsail Main)	<b>Using Audience Response Devices to Make Risk Management Training Engaging and Effective</b> <b>Dr. J. Padfield</b> <b>Proffer Brainchild, Inc.</b> (Mainsail West)
3:30 pm - 4:45 pm		<b>Speed Training - GXP Exercise</b> <b>T. McGinn</b> <b>SkillPad</b> (Mainsail East)	<b>Training Effectiveness and 21CFR Part 211.25</b> <b>K. Petelinkar</b> <b>BMS</b> (Mainsail Main)	<b>The Training Needs Analysis</b> <b>D. Gallup</b> <b>GmpTraining.com</b> (Mainsail West)
5:00 pm - 6:00 pm		Vendor and Networking Reception with Prize Baskets (Main Concourse)		
6:30 pm - 8:30 pm		Theme Dinner - <b>Murder Mystery Co.</b> (Mainsail East & Main)		

TUESDAY, September 29, 2015

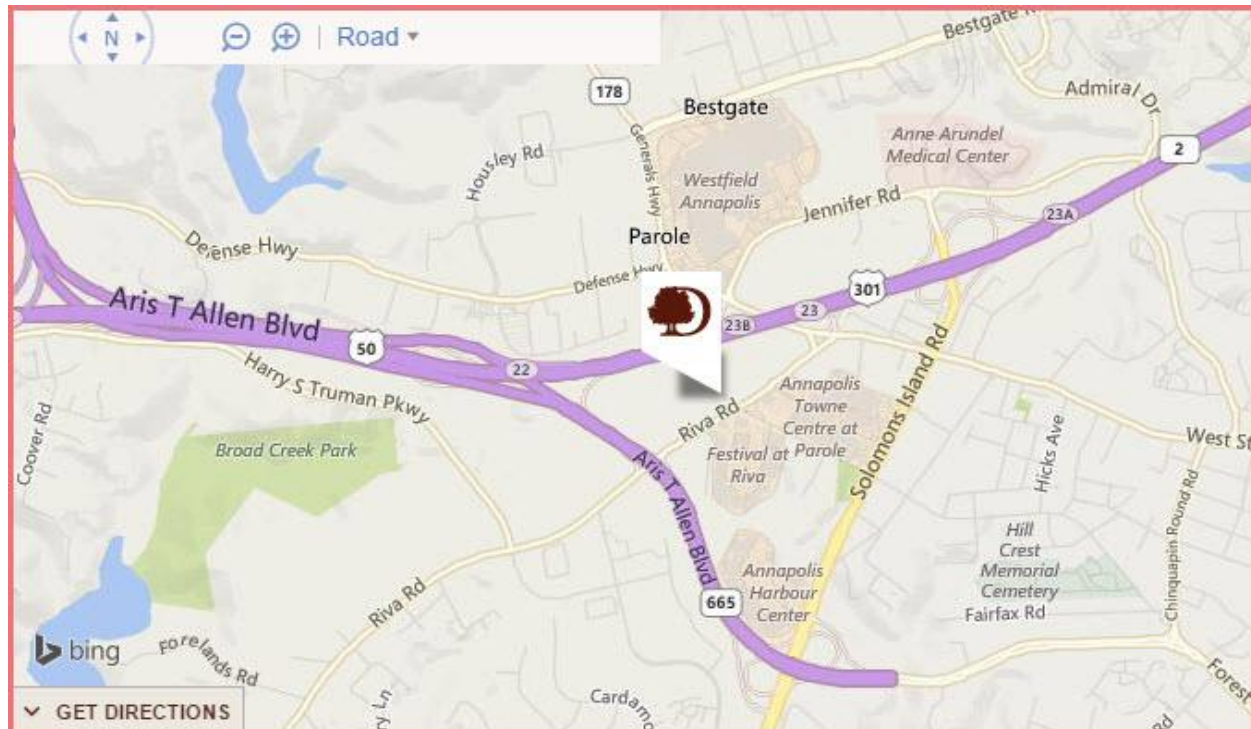
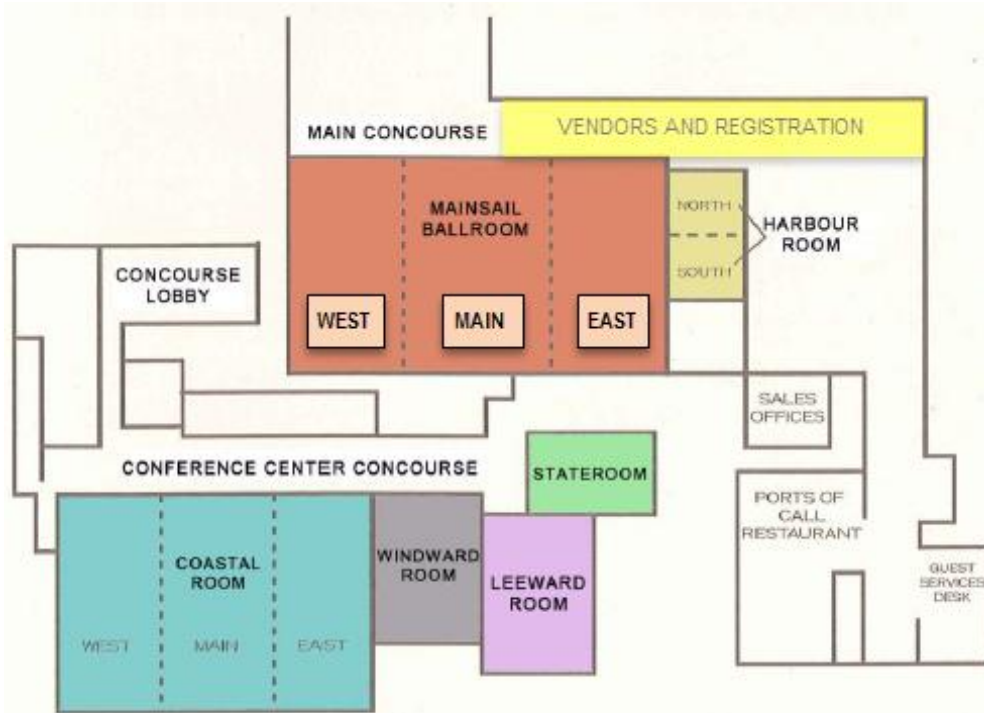
7:30 am - 8:30 am	Registration (Main Concourse)		
7:30 am - 8:30 am	Continental Breakfast (Mainsail East & Main)		
8:30 am - 10:00 am	<p style="text-align: center;"><b>FDA Keynote Addresses</b></p> <p style="text-align: center;"><b>Global Identification of Medicinal Products: Overview of the ISO Identification of Medicinal Product (IDMP) Standards</b></p> <p style="text-align: center;"><b>Vada A. Perkins: CAPT, USPHS, US FDA Deputy Associate Director (Acting), Center for Biologics Evaluation and Research (CBER)/Review Management (RM)</b></p> <p style="text-align: center;"><b>Global Substance Registration according to ISO-11238 (G-SRS) and the development of a Global Ingredient Archival System (GlnAS)</b></p> <p style="text-align: center;"><b>Larry Callahan: Ph.D. Chemist, US FDA Office of Health Informatics/Office of Chief Scientist/Office of the Commissioner</b></p> <p style="text-align: center;"><b>(Mainsail East &amp; Main)</b></p>		
10:30 am - 11:45 pm	<p><b>QbD - Taguchi Methods - quality Engineering</b> <b>C. Perini</b> <b>Ashland Specialty Ingredients</b> <b>(Mainsail East)</b></p>	<p><b>Medical Device Quality System Regulations (21 CFR Part 820)</b> <b>H. Naik</b> <b>BMS</b> <b>(Mainsail Main)</b></p>	<p><b>On-The-Job (OTJ) for GMP Cell Based Assay</b> <b>P. Kuo</b> <b>BMS</b> <b>(Mainsail West)</b></p>
12:00 pm - 1:00 pm	Lunch Break (Mainsail East & Main)		
1:15 pm - 2:45 pm	<p><b>Full Group Discussion and Comment Collation</b></p> <p>Review of <a href="#">FDA Request for Quality Metrics</a></p> <p>Draft Guidance for Industry</p> <p>Discussion Leaders - J. Lewis, T. McGinn, K. Petelinkar</p> <p><b>(Mainsail East &amp; Main)</b></p>		
3:00 pm - 4:15 pm	<p><b>Re-training: A multi-pronged approach. Innovate! Innovate!! Innovate!!!</b> <b>Sandeep Karrol</b> <b>BioGen</b> <b>(Mainsail East)</b></p>	<p><b>USP Standards</b> <b>B. Jones</b> <b>Scientific Collaboration @ DIA</b> <b>B. Ferguson</b> <b>BF Solutions LLC</b> <b>I. Salahudeen</b> <b>BMS</b> <b>(Mainsail Main)</b></p>	<p><b>Electronic Records &amp; Electronic Signatures</b> <b>D. Marquis</b> <b>BMS</b> <b>(Mainsail West)</b></p>
4:15 pm - 5:30 pm	<p><b>Why Aren't Our Employees Engaged?</b> <b>M. Pacana</b> <b>Cintas</b> <b>(Mainsail East)</b></p>	<p><b>Risk Evaluation &amp; Mitigation Strategies (REMS)</b> <b>R. Junker</b> <b>G. Donches</b> <b>Hibbert</b> <b>(Mainsail Main)</b></p>	<p><b>3D Leadership</b> <b>F. Lavallee</b> <b>Aliter Concept</b> <b>(Mainsail East)</b></p>
	Free Night - Dinner on Your Own		

Exhibits Open

**WEDNESDAY, September 30, 2015**

7:30 am - 8:30 am	Registration (Main Concourse)		
7:30 am - 8:45 am	Skipjack Buffet Breakfast (Mainsail East & Main)		
8:15 am - 8:45 am	Prize Awards (Mainsail East & Main)		
9:00 am - 10:15 am	<b>The Supplement Regulation Revolution</b> <b>J. Lewis</b> <b>Merck</b> <b>T. McGinn</b> <b>SkillPad</b> <b>(Mainsail East)</b>	<b>Regulatory Updates</b> <b>C. Gronostajski</b> <b>P. Zychowka</b> <b>BMS</b> <b>(Mainsail Main)</b>	<b>Learning Management System Basics</b> <b>K. Petelinkar</b> <b>BMS</b> <b>(Mainsail West)</b>
10:30 am - 11:45 am	<b>The Convenience Store Learner</b> <b>J. Lewis</b> <b>Merck</b> <b>(Mainsail West)</b>	<b>Preparing for Audits of Vendors and Suppliers</b> <b>D. Maines</b> <b>Managing Consultant</b> <b>Compliance Architects</b> <b>(Mainsail Main)</b>	<b>Assessment Technologies and Their Applications</b> <b>B. Bersak</b> <b>BMS</b> <b>(Mainsail West)</b>
11:45 am - 12:15 pm	<b>Closing Ceremonies</b> <b>(Mainsail East &amp; Main)</b>		

# Map of Conference Floor Plan and Location



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