14TH ANNUAL
FDA INSPECTIONS SUMMIT

WCG FDANEWS

Agenda At-A-Glance

PRE-CONFERENCE WORKSHOPS - Wednesday, Oct. 23, 2019

12:00 p.m. - 1:00 p.m.	Registration		
	Drugs & Biologics Track Pre-conference Workshop Glen Echo	**Clinical Trials Track Pre-conference Workshop Forest Glen**	**Medical Devices Track Pre-conference Workshop Oakley**
1:00 p.m. – 5:00 pm	Flawless FDA Inspection Handling and Response	ICH E6 (R2) How to Build a Sponsor Risk Management Program	Process Validation for Medical Devices: Preparing for a QSR Inspection

DAY ONE – Thursday Oct. 24, 2019

8:00 a.m. – 9:00 a.m.	Registration and Continental Breakfast				
	Plenary Session Salon G/H				
9:00 a.m. – 9:10 a.m.	Opening Comments by Chairperson				
9:10 a.m. – 10:00 a.m.	FDA and D.C. Politics: A Look at FDA Achievements and What Lies Ahead				
10:00 a.m. – 10:45 a.m.	Auditing Manufacturers: Linking Data Integrity with Quality Culture				
10:45 a.m. – 11:00 a.m.	Refreshment Break				
	Drugs & Biologics Track Salon G/H	**Clinical Trials Track Forest Glen**		**Medical Devices Track Oakley**	
11:00 a.m. – 11:10 a.m.	Moderator Comments	11:00 a.m. – 11:10 a.m.	Moderator Comments	11:00 a.m. – 11:05 a.m.	Moderator Comments
11:10 a.m. – 12:00 p.m.	Concept of Operations: FDA Facility Evaluation and Inspection Program	11:10 a.m. – 12:00 p.m.	Meeting CRO-Vendor Oversight Requirements	11:05 a.m. – 11:55 a.m.	Preparing for a MDSAP Audit: A Case Study from the Manufacturer's Perspective
12:00 p.m. – 12:45 p.m.	Audits, Inspections and Management of Suppliers in India and China	12:00 p.m. – 12:45 p.m.	Designing Data Integrity into Your Clinical Trials and Responding When an Issue Arises	11:55 a.m. – 12:55 p.m.	Panel Discussion: EU-MDR: Final Push for Compliance by the May 26, 2020 Deadline
12:45 p.m. – 1:45 p.m.	Birds-of-a-feather Lunch - Salon F	12:45 p.m. – 1:45 p.m.	Birds-of-a-feather Lunch - Salon F	12:55 p.m. – 1:45 p.m.	Birds-of-a-feather Lunch - Salon F
1:45 p.m. – 2:45 p.m.	Panel Discussion: The US/EU Mutual Recognition Agreement (MRA) for Drug GMP Inspections	1:45 p.m. – 2:45p.m.	Quality by Design – Build Quality into Clinical Trials to Proactively Identify and Mitigate Risks	1:45 p.m. – 2:45 p.m.	FDA's Shift from QSR to ISO 13485:2016: A Significant Change for Inspections
2:45 p.m. – 3:00 p.m.	Refreshment Break				
	Plenary Session Salon G/H				
3:00 p.m. – 4:30 p.m.	Panel Discussion: The 10 Best — and 10 Worst — Things to Do When FDA Staff Are on Site				
4:30 p.m. – 5:30 p.m.	Mock Inspection: Practice Makes Perfect				
5:30 p.m. – 6:30 p.m	Networking Reception - Salon B/C Foyer				

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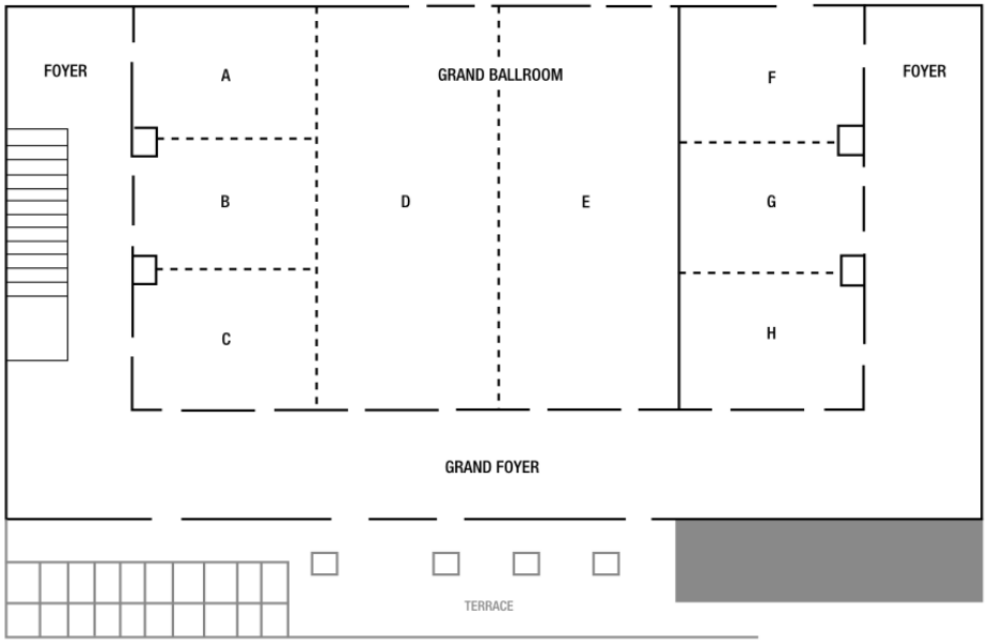
DAY TWO – Friday Oct. 25, 2019

8:30 a.m. – 9:00 a.m.	Registration and Continental Breakfast
	Plenary Session **Salon G/H**
9:00 a.m. – 9:10 a.m.	Opening Comments by Chairperson
9:10 a.m. – 10:00 a.m.	Organizing Data and Document Archives: Finding a Needle in a Haystack for FDA Inspections
10:00 a.m. – 10:45 a.m.	FDA 483 and Warning Letter Trends
10:45 a.m. – 11:00 a.m.	Refreshment Break
11:00 a.m. – 12:00 p.m.	FDA's Vision and Strategy for Field Programs
12:00 p.m.	Summit Adjourn

MAIN LEVEL



LOWER LEVEL