

Event: ISPE 2009 Annual Meeting
Session: 605 - Validating Per Annex 1
Session Leader: Vince Cebular
Dates: Wednesday, 11 November (12.45-15.45)
Location: San Diego, CA



Wednesday, 11 November

Start Time	End Time	Presentation Title	Speaker
12:45	13:00	Introduction	Cebular
13:00	13:30	Validating Cleanroom Facilities for Compliance with Annex 1: <ul style="list-style-type: none"> • General Facility Requirements Including HVAC and Pressurization • Classification of Environmental Cleanliness; "At-Rest" and "In-Operation" 	Cebular
13:30	14:00	Implementation of Annex 1 Capping Requirements: <ul style="list-style-type: none"> • Interpretation of Annex 1 Requirements • Identifying Areas of Risk and How to Mitigate • Vendors' Perspectives on Industry Direction • Short Case Study or Project Overviews on Implementation of Annex 1 Requirements 	Kline
14:00	14:30	Networking Break	
14:30	15:00	Guidance on Bio-Burden Monitoring <ul style="list-style-type: none"> • The Guidance in Annex 1 • What are the "Real Requirements" • How to Establish and Implement a Functional Compliant Environmental Program 	Bowen
15:00	15:30	Guidance on Media Simulations <ul style="list-style-type: none"> • The Guidance in Annex 1 • What are the "Real Requirements" • How to Establish and Implement a Sterile Validation Program 	Bowen
15:30	15:45	Group Question and Answer Session	Cebular Kline Bowen
15:45		Session Adjourns	

***Please Note that Agendas are Subject to Change**