

Event: WASHINGTON 2010 CONFERENCE
 Session: Barrier Isolation Technology Forum: Innovation, Updates, and New Case Studies (E01)
 Session Leader: Jack Lysfjord, Michael Porter
 Dates: Monday and Tuesday 7-8 June 2010



Monday, 7 June

Start Time	End Time	Presentation Title	Speaker
		(Speaker and Leader Breakfast 7:00)	
7:30	9:00	Breakfast	
9:00	9:10	Welcome and Introductions	Porter
9:10	9:35	Isolator History and Trends, 2010 Preliminary Data <ul style="list-style-type: none"> Review global numbers for isolators for fill finish applications View differences for different regions; Asia, Europe and North America Compare both to prior data and look at trends with isolator usage 	Lysfjord
9:35	10:15	Clinical Aseptic Processing Fill Finish Line for Liquid or Freeze Dry Products Utilizing Robotics, Various Filling Systems including Disposables and the use of RABS or Isolator for Aseptic or Aseptic Containment <ul style="list-style-type: none"> Flexibility for various filling systems including disposable systems Minimized product loss through the use of disposable filling systems Modular RABS or Isolator concept that could be used for product containment Easy to use RABS or Isolator Container transport by robotics instead of conveyor 	Bandtel Kreher
10:15	10:45	Networking Break	
10:45	11:25	Trends in the Pharmaceutical Industry and Their Influence on Isolator Technology <ul style="list-style-type: none"> Fast H₂O₂ decontamination Safe filter change H₂O₂ low PPM impact on product E-Beam technology Additional future developments 	Huber
11:25	12:05	Novel Method for In-situ Characterization of Vapor Phase Hydrogen Peroxide Processes <ul style="list-style-type: none"> Review of the key physical properties of Vapor Hydrogen Peroxide (VHP) processes for monitor and control Overview of the current methods for monitoring VHP processes Results/discussion of novel method for the simultaneous and real-time monitoring of: <ul style="list-style-type: none"> VHP dew point VHP concentration VHP temperature Concentration of VHP condensate Comparison of the current methods and recommendation for a best known method (BKM) for monitor and control of VHP processes. 	Wacinski
12:05	13:00	Lunch	
13:00	13:45	Determining the Effects of Residual Vapor Phase Hydrogen Peroxide Sterilization Cycle and the Performance Effects of an In-Line Sensor for Measuring Residual VHP in the Isolator Atmosphere <ul style="list-style-type: none"> New technology to measure low level residual vapor phase hydrogen peroxides (VPHP) Protein sensitivity to H₂O₂ VPHP cycle development at the new Genentech filling facility Gain in depth knowledge with the aeration cycle of the VPHP 	Yim
13:45	14:30	Adsorption and Desorption of Vapor Phase Hydrogen Peroxide (VPHP): Implications for Use in Barrier Systems 1. VPHP measurement technologies a. Issues with current technologies b. Improved measurement systems c. Ultra-low level VPHP measurement systems (< 0.1ppm) 2. Absorption/desorption of H ₂ O ₂ in different materials a. Experimental design for material absorption/desorption and permeation studies b. Examples of different types of absorption/desorption performance c. Summary of material performance 3. Aeration studies a. Ability to aerate isolators to very low levels (< 0.1ppm) b. Reducing aeration times i. Effect of temperature ii. Effect of materials iii. Other factors c. Potential issues for using sporicides in RABS	Walsh

14:30	15:00	Networking Break	
15:00	15:45	Case Study of a New Biotech Production Facility for Aseptic Processing of Vials with Dual Fill Finish Lines Utilizing Isolator Technology and Campaigning <ul style="list-style-type: none"> • Facility overview, product and people flow, Cost and schedule • Isolator decision vs. Cleanroom, RABS Rationale and cost analysis • Overview of the isolator filling processes, equipment selection and difference between liquid and lyo • The validation process and the use of "design of experiments" • Surprises and lessons learned 	Starkman
15:45	16:30	Placebo To Potent: Experiences of a Clinical Barrier Isolator Facility <ul style="list-style-type: none"> • Learn how clinical trial demands differ from full scale production • Debunk the myth that isolators are too rigid for clinical supply manufacturing needs • See true case studies of clinical product manufacture including highly potent an solvent-containing formulations • Review lessons learned across design, fabrication, validation, and 24 months of GMP operations 	Doshna
16:30	17:00	Q&A	
17:00		Seminar Adjourns, Reception	

Tuesday, 8 June

Start Time	End Time	Presentation Title	Speaker
7:30	9:00	Breakfast	
9:00	9:45	Low Energy E-Beam Qualification in Aseptic Processing - A Case Study <ul style="list-style-type: none"> • E-Beam processing of Prefilled Syringe (PFS) • E-Beam qualification • Decontamination of PFS tubs • First experiences with E-Beam use in aseptic manufacturing 	Bachmann
9:45	10:15	Networking Break	
10:15	11:15	Contract Manufacturing Production Aseptic Processing Fill and Finish Facility for Liquid and Freeze Dry Vials Utilizing Isolator Technology and Blow Fill Seal Technology (BFS) Liquid Niche Drug Products-A Case Study <ul style="list-style-type: none"> • Decision for isolators as opposed to RABS or conventional cleanroom technology • Restrictive space facility design In an existing multi-story office building including HVAC for isolators and BFS Equipment • Facility process and equipment for an isolated vial fill and finish line for liquid or freeze dry drug products • Facility process and equipment for BFS products • Leveraging product characteristics in process design (PAT, Consumables, Batch Size) • Lessons learned 	Kline Poisson
11:15	12:00	Aseptic Processing Contract Production Multi Product Fill Finish Facility for Vials and Syringes in Liquid or Freeze Dry Format Utilizing Isolated Process Equipment with Capability for Disposable Product Path: A Case Study <ul style="list-style-type: none"> • Facility & Line overviews including isolator decision • Process design & coordination effort • Product path options including disposables • Material and Component transfer considerations • Qualification and Validation overview • Lessons Learned 	Hawkins
12:00	13:00	Lunch	
13:00	14:30	Breakout Discussion Groups (3)	
14:30	15:00	Networking Break	
15:00	15:30	Discussion Group Presentations	
15:30	17:00	FDA Q&A Panel	Gooen, FDA Sullivan, FDA
17:00		Seminar Adjourns	
*** This is a working agenda and subject to change***			