

WORKSHOP TÉCNICAS DE PROCESSAMENTO ASSÉPTICO

PDA BRAZIL CHAPTER

18 a 22 de setembro – Conselho Regional de Química São Paulo
 eventos@pdabrazil.org - www.pda.org/brazil - Tel. 2894-9730/31



Monday 18	Class Room - CRQ
08:00 - 08:30	Introduction - PDA Brazil Board
08:30 - 09:30	Types of Aseptic Processing - David Matsuhiro - USA
09:45 - 12:00	Smoke Study Lecture - David Matsuhiro - USA
12:00 - 13:00	Welcome PDA Lunch
13:00 - 14:00	Computational Fluid Dynamics Studies - Frank Haerterich - B+S/Germany
14:00 - 17:00	Environmental Monitoring - David Matsuhiro - USA
17:00 - 18:00	Safety Training - Eurofarma/Brazil



Tuesday 19	Class Room CRQ - TEAM 1
8:00 - 08:15	PDA introduction - PDA Brazil Board
8:15 - 09:00	Aplicações de Métodos Rápidos na Indústria Farmacêutica Prof Teresinha Andreoli - BioMérieux/Brasil
09:00 - 10:00	RABS- Frank Haerterich B+S/Germany
10:15 - 12:00	Validation of Sterilizing Filtration operations using Quality by Design principles - Juan Centeno Pall/Argentina
	Implementation and Validation of Single-use Processing Systems using Quality Risk Management approach - Patrick Evrard - Pall/Belgium
	Standardized Extractables testing of polymeric materials enabling effective Risk Assessments - Patrick Evrard - Pall/Belgium
13:00 - 14:00	Debates and Challenges in Disinfectant Testing - Jim Polarine - Steris/US
14:10 - 15:00	Particle Counter - Dave Crance - PMS/USA
15:15 - 16:00	Boas Práticas de Filtração em Processos Assépticos - Roberto Uchimura - Merck/Brazil
16:00 - 16:45	Ready to fill glass container for pharmaceutical use. ISO 5 manufacturing process and sterilization with ETO and STEAM Flavia Batita Ompi/Brazil
16:45 - 17:30	Gowning / Cleaning technologies - Eiric Manrich - Elis/Brazil
17:30-18:00	Questions and Answers - all speakers

Clean Room - EUROFARMA

Conference Room EUROFARMA

Smoke Study/Water Fill - Team 2A David Matsuhiro - USA
Smoke Study/Water Fill - Team 2B David Matsuhiro - USA
Cleaning, Sanitization and Disinfectant Efficacy - Team 2A David Matsuhiro - USA
Cleaning, Sanitization and Disinfectant Efficacy - Team 2B David Matsuhiro - USA

Active-passive RABs - Media Fill Team 2B Rose Nascimento Eurofarma
Active-passive RABs & Media Fill Team 2A Rose Nascimento Eurofarma
Embalagens fármacos parenterais e considerações de integridade de fechamento (CCI) - Team 2B Deolinda Izumida West
Embalagens fármacos parenterais e considerações de integridade de fechamento (CCI) - Team 2A Deolinda Izumida West

Wednesday 20	Class Room CRQ - TEAM 2
8:10 - 08:15	PDA introduction - PDA Brazil Board
8:15 - 09:00	Aplicações de Métodos Rápidos na Indústria Farmacêutica Prof Teresinha Andreoli - BioMérieux/Brasil
09:00 - 10:00	RABS- Frank Haerterich B+S/Germany
10:15 - 12:00	Validation of Sterilizing Filtration operations using Quality by Design principles - Juan Centeno Pall/Argentina
	Implementation and Validation of Single-use Processing Systems using Quality Risk Management approach - Patrick Evrard - Pall/Belgium
	Standardized Extractables testing of polymeric materials enabling effective Risk Assessments - Patrick Evrard - Pall/Belgium
13:00 - 14:00	Debates and Challenges in Disinfectant Testing - Jim Polarine - Steris/US
14:00 - 15:00	Particle Counter - Dave Crance - PMS/USA
15:15 - 16:00	Boas Práticas de Filtração em Processos Assépticos - Roberto Uchimura - Merck/Brazil
16:00 - 16:45	Ready to fill glass container for pharmaceutical use. ISO 5 manufacturing process and sterilization with ETO and STEAM Flavia Batita Ompi/Brazil
16:45 - 17:30	Gowning / Cleaning technologies - Eiric Manrich - Elis/Brazil
17:30-18:00	Questions and Answers - all speakers

Clean Room - EUROFARMA

Conference Room EUROFARMA

Smoke Study/Water Fill - Team 1A David Matsuhiro - USA
Smoke Study/Water Fill - Team 1B David Matsuhiro - USA
Cleaning, Sanitization and Disinfectant Efficacy - Team 1A David Matsuhiro - USA
Cleaning, Sanitization and Disinfectant Efficacy - Team 1B David Matsuhiro - USA

Active-passive RABs & Media Fill Team 1B Rose Nascimento Eurofarma
Active-passive RABs & Media Fill Team 1A Rose Nascimento Eurofarma
Embalagens fármacos parenterais e considerações de integridade de fechamento (CCI) - Team 1B Deolinda Izumida West
Embalagens fármacos parenterais e considerações de integridade de fechamento (CCI) - Team 1A Deolinda Izumida West

Thursday 21	Class Room - CRQ
08:00 - 09:45	Gowning and Personnel Monitoring - David Matsuhiro - USA
10:00 - 11:45	Gowning and Personnel Monitoring - David Matsuhiro - USA
12:45 - 14:00	Perspectivas regulatórias para processo assépticos - Tatiana Oliveira - COVISA
14:00 - 15:45	Contamination Control and Aseptic Techniques - David Matsuhiro - USA
16:00 - 17:45	Risk Assessment - David Matsuhiro - USA
17:45 - 19:00	Happy Hour



A Stevanato Group Brand



Life Sciences

Friday 22	Class Room - CRQ
08:00 - 09:45	Media Fill / Media Hold - David Matsuhiro - USA
10:00 - 12:00	Media Fill failure investigation - David Matsuhiro - USA
13:00 - 14:15	Reading Plates - David Matsuhiro - USA
14:15-15:15	Regulatory Perspective - David Matsuhiro - USA
15:30-17:00	Questions and Answers - David Matsuhiro - USA