



PIC/S SEMINAR 2024 - Annex I Unveiled: Shaping the Future of Sterility

TUESDAY NOVEMBER 5		
09:00 – 18:00	First Basement	Early Seminar Registration To ensure a smooth start to the PIC/S Seminar 2024 on Wednesday, November 6, 2024, we encourage you to take advantage of our early registration opportunity the day before the event. On Tuesday, November 5, 2024, we will be available for registration from 9:00 to 18:00 at the first basement. By registering early, you can avoid long lines and save time on the morning of the seminar. Please note that on the day of the event, registration will take place from 8:00 AM to 8:30 AM. To ensure a prompt start to the seminar at 8:30 AM, we kindly ask as many of you as possible to complete your registration the day before.



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WEDNESDAY NOVEMBER 6			
Session Time	Room	Topic	Speakers/ Facilitators
08:00 – 08:30	First Basement	Seminar Registration	
08:30 – 08:45	Ipê	Welcome Address & Opening Remarks by Anvisa and PIC/S Chairperson	Romison Mota <i>(Anvisa's Director)</i> Jacques Morénas <i>(PIC/S Chairperson - ANSM France)</i>
08:45 – 08:50	Ipê	Seminar Day 1: Scene Setter	Boon Meow Hoe <i>(PIC/S Executive Bureau Member - HSA Singapore)</i>
08:50 – 09:30	Ipê	Topic A: The New Annex I in 40 minutes	Abdelaali Sarakha <i>(ANSM France)</i>
09:30 – 10:10	Ipê	Topic C: Global Perspectives On Annex 1: Trends And Issues In Sterile Manufacturing In Different Participating Authorities	Kamiya Shintaro <i>(PMDA Japan)</i> Wayne Muller <i>(SAHPRA South Africa)</i>
10:10 – 10:40	Lobby	Coffee break	
10:40 – 11:10	Ipê	Topic B: A New World for Non-Sterile: Understanding the Application of Annex I for Non-Sterile Products	Dr. Mohammed Dahhas <i>(SFDA Saudi Arabia)</i>
11:10 – 12:00	Ipê	Topic D: Inspecting risk assessments relating to aspects of the Contamination Control Strategy - key points for Inspectors to consider	Kevin O'Donnell <i>(HPRA Ireland)</i>
12:00 – 13:00	Hotel restaurant	Lunch	

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Concurrent Breakout Workshop Sessions - Four Rooms
We are hosting four parallel workshops.
Each participant will attend two workshops per day, each lasting two hours.
Workshop rooms and group assignments are listed below.

Workshop #1: The Master Plan For Contamination Prevention: Designing An Effective Ccs – Contamination Control Strategy		Edmund Mrak <i>(FDA United States)</i> Sly Mutyavaviri <i>(MCAZ Zimbabwe)</i> Lúcia Giorgis <i>(ANVISA Facilitator)</i>	
Workshop # 2: Unveiling The Human Factor: Empowering Regulators In Personnel Control For Sterile Manufacturing		David Talmage <i>(PDA US Chapter)</i> Marcia Baroni <i>(PDA BR Chapter)</i> Monick Bassi <i>(PDA US Chapter)</i> Liana Fonseca/ Mariana Collani <i>(ANVISA Facilitators)</i>	
Workshop #3: Who Wants To Be An “Inspectorpedia”: Answering The Top 10 Most Controversial Questions On Aseptic Process Simulation (Aps)		Paul Gustafson/ Nicole Proctor <i>(Health Canada)</i> Alessandra Dias/ Erieldes Silva <i>(ANVISA Facilitator)</i>	
Workshop # 4: A Stitch In Time: Verifying Aseptic Core Set-Up		Wayne Muller <i>(SAHPRA South Africa)</i> Vimal Sachdeva <i>(WHO)</i> Júlia Calatrone <i>(ANVISA Facilitator)</i>	
13:00– 15:00	Workshop #1 Group A – Breakout Room Ipê Workshop #2 Group B – Breakout Room Jacarandá Workshop #3 Group C – Breakout Room Paineira Workshop #4 Group D – Breakout Room Cambuí		
15:00 – 15:30	Lobby	Coffee break	
15:30 – 17:30	Workshop #1 Group B – Breakout Room Ipê Workshop #2 Group C – Breakout Room Jacarandá Workshop #3 Group D – Breakout Room Paineira Workshop #4 Group A – Breakout Room Cambuí		
18:30 - 21:00	Social Event: Rodízio-style Brazilian Barbecue Dinner		

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THURSDAY NOVEMBER 7			
Session Time	Room	Topic	Speakers/ Facilitators
08:30 – 08:35	Ipê	Seminar Day 2: Scene Setter	Ying-Hua (Ellen) Chen <i>(PIC/S Executive Bureau Member- TFDA Chinese Taipei))</i>
08:35 – 09:10	Ipê	Topic E : Ensuring Excellence: Inspecting Pqs For Optimal Microbial Control And Sterility In Pharmaceutical Manufacturing	Qiao Bobo <i>(US FDA)</i>
09:10 – 10:00	Ipê	Topic F : Barrier Breakthroughs: Redefining Sterility With Structural Upgrades And Smart Transfers	Lu-Jie Ferré/ Grégory Schindler <i>(ANSM France)</i>
10:00 – 10:30	Lobby	Coffee break	
10:30 – 11:20	Ipê	Topic H : Solving The Pupsit Maze: Case Studies And Best Practices In Legacy Facilities	Matthew Davis <i>(TGA Australia)</i>
11:20 – 12:00	ipê	Topic J : A Small Leak Will Sink A Great Ship: Navigating The Waters Of Container Closure Integrity (CCI) Testing	Desmond Hunt <i>(United States Pharmacopeia)</i>
12:00 – 13:00	Hotel Restaurant	Lunch	
13:00– 15:00	Workshop #1 Group C – Breakout Room Ipê Workshop #2 Group D – Breakout Room Jacarandá Workshop #3 Group A – Breakout Room Paineira Workshop #4 Group B – Breakout Room Cambuí		
15:00 – 15:30	Lobby	Coffee break	
15:30 – 17:30	Workshop #1 Group D – Breakout Room Ipê Workshop #2 Group A – Breakout Room Jacarandá Workshop #3 Group B – Breakout Room Paineira Workshop #4 Group C – Breakout Room Cambuí		
19:30 - 21:00	Cultural Event: Symphonic Orchestra Performance		

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FRIDAY NOVEMBER 8			
Session Time	Room	Topic	Speakers/ Facilitators
08:30 – 08:35	Ipê	Seminar Day 3: Scene Setter	Kathleen Sinninger (PIC/S Deputy Chairperson - US FDA)
08:35 – 09:25	Ipê	Topic K: Mastering Visual Inspection: Advancing Regulatory Oversight In The Pharmaceutical Industry	Graham Carroll (MHRA United Kingdom)
09:25–10:15	Ipê	Topic L : Inspecting the SUS: Mastering The Inspection of Single Use Systems In Sterile Manufacturing	Edmund Mrak (US FDA)
10:15 – 10:45	Lobby	Coffee break	
10:45 – 11:45	Ipê	Workshops Wrap-Up	Workshops leaders
11:45 – 12:30	Ipê	Topic M: Freeze The Risk: Innovations In Lyophilization For Sterile Manufacturing	Wayne Muller (SAHPRA South Africa)
12:30 – 12:45	Ipê	2025 Seminar Address	
12:45 – 13:00	Ipê	Closing Address & Presentation of the PIC/S Symbolic - Presented to Hong Kong SAR, China / PPBHK	Antônio Barra Torres (President Director of Anvisa)
13:00 – 13:15	Ipê	Remarks by PIC/S Chairperson	Jacques Morénas (PIC/S Chairperson)
13:15 – 14:30	Hotel Restaurant	Lunch	