



PIC/S 2025 Seminar – Advanced Technologies in Pharmaceutical Manufacturing

5 -7 November 2025, Harbour Grand Hotel, Hong Kong, China

Programme

Tuesday 4 November 2025		
16:00 – 20:00	First Floor	Early Seminar Registration
18:00 – 21:00		Welcome Reception

Wednesday 5 November 2025			
08:00 – 09:00	First Floor	Registration	
09:00 – 09:10	Grand Ballroom (1/F)	Welcome Address	Dr Ronald Lam, Director of Health/ Chairperson of PPBHK
09:10 – 09:20	Grand Ballroom	Opening remarks	Mr Jacques Morénas, PIC/S Chairperson – ANSM France
09:20 – 10:00		Latest applications of Point-of-Care (POC) manufacturing in pharmaceutical industry	Ulf Bethke (Miltényi) & Fabian Gerlinghaus (Cellares) [Remote]

10:00 – 10:50		POC manufacturing and personalised medicines – regulatory perspective	Christina Meissner (AGES)
10:50 – 11:20		<i>Coffee Break</i>	
11:20 – 12:00	Grand Ballroom	MHRA's experiences with the POC Guidelines	Martine Powell (MHRA)
12:00 – 12:30		Continuous manufacture – small molecule perspective	Nuno Matos (Hovione)
12:30 – 13:15		Continuous manufacture – large molecule perspective	Andrea Ruggiero (Merck)
13:15 – 13:30		<i>Group photo session</i>	
13:30 – 14:30		<i>Lunch Break</i>	
14:30 – 15:10	Grand Ballroom	Considerations for implementation of Continuous manufacture (CM)	Suelen Andrade Navarro (ANVISA)
15:10 – 15:45		Inspecting CM from quality risk management perspective	Kevin O'Donnell (HPRA)
15:45 – 16:15		<i>Coffee Break</i>	
16:15 – 17:45	Salon Rooms (5/F)	Concurrent Workshops (A to C)	
		Workshop A: ICH Q13 and case studies - small molecule perspective	Loi Nguyen (TGA) + Vincent LEE (PPBHK)
		Workshop B: ICH Q13 and case studies – large molecule perspective	Suelen Andrade Navarro (ANVISA) + Eddie LO (PPBHK)
		Workshop C: Point-of-care manufacturing and personalised medicines – gaps in GMP?	Christina Meissner (AGES) + Barbara Stubbe (AFMPS)

Thursday 6 November 2025			
08:50 – 09:00	Grand Ballroom	Housekeeping announcement	
09:00 – 09:30		Artificial Intelligence (AI) – latest development and its applications in pharmaceutical manufacturing	Manan Bawa (GSK) [Remote]
09:30 – 11:00	Salon Rooms	Concurrent Workshops (A to C)	
11:00 – 11:30		<i>Coffee Break</i>	
11:30 – 13:00	Salon Rooms	Concurrent Workshops (A to C)	
13:00 – 14:00		<i>Lunch Break</i>	
14:00 – 14:45	Grand Ballroom	Key features of Annex 22	Ib Alstrup (DKMA) [Remote]
14:45 – 14:55		Break	
14:55 – 15:30		AI – How to inspect?	Ib Alstrup (DKMA) [Remote]
15:30 – 16:00		<i>Coffee Break</i>	
16:00 – 17:15		Workshop D: Practical approach to inspection of AI application	Ib Alstrup (DKMA) [Remote]

18:00 – 21:00		<i>Seminar Dinner</i>
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Friday 7 November 2025			
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09:00 – 09:05	Grand Ballroom	Housekeeping announcement	
09:05 – 09:40		Challenges and current situation of Japanese manufacturing sites in implementation automation and AI	Yuki Marumo (PMDA)
09:40 – 10:20		3D printing	Speaker from (?) [Remote?]
10:20 – 10:40		EMA QIG and STA in Belgium – European experiences on advanced technologies	Karin Froidbise (AFMPS) and Barbara Stubbe (AFMPS)
10:40 – 11:10		<i>Coffee Break</i>	
Wrapping Up			
11:10 – 12:00		Outcome of Workshops	Workshop moderators
12:00 – 12:15		2026 Seminar Address	TMMDA
12:15 – 12:30		Closing Address and Presentation of the PIC/S Flag	
12:30 – 12:45		Closing Remarks by PIC/S Chairperson	Mr Jacques Morénas, PIC/S Chairperson – ANSM France
12:45 – 14:00		<i>Farewell Lunch</i>	

