



**PIC/S 50<sup>th</sup> ANNIVERSARY SYMPOSIUM**

*Thriving at 50 and Striving Forward*

**4 OCTOBER 2022**

VENUE: Radisson Blu Royal Hotel, Golden Lane, Dublin, Ireland

**PROGRAMME**

**SESSION 1**

**Moderator: Ms. Susan Laska, PIC/S Deputy Chairperson and SCSD<sup>1</sup> Chair, US FDA**

**INTERNATIONAL INFLUENCE AND CHANGE**

Abstract: Session 1 focuses on navigating the complexity of providing access to safe, quality medicines with regulations that are in keeping with innovation

**Start time: 9:00**

9:00-9:05 5 mins	Welcome remarks	Lorraine Nolan HPRA
9:05 – 9:25 20 minutes	'Celebrating 50 Years' PIC/S Strategic Plan 2023 – 2027	Paul Gustafson Health Canada PIC/S Chairman
9:25 - 9:45 20 minutes	Evolution: Pharma industry and PIC/S	Susan Laska US FDA
9:45 - 10:10 25 minutes	Convergent Innovation in the Pharma Industry	Jan Rosier University College Dublin
10:10 - 10:30 20 minutes	<b>Keynote Speaker</b> Striving for better international relationships and collaboration	Emer Cooke European Medicines Agency (EMA)
10:30-10:45 15 mins	Q & A	
10:45 – 11:15 30 mins	Break	

<sup>1</sup> PIC/S Sub-Committee on Strategic Development (SCSD)



## SESSION 2

**Moderator: Mr. Jacques Morénas, PIC/S SCT<sup>2</sup> Chair, France / ANSM**

### THE CHANGING FRAMEWORK FOR REGULATORY GMP INSPECTIONS

Abstract: Session 2 aims to increase awareness and stimulate conversations around the developments and initiatives that impact on GMP inspections, such as the PIC/S Inspectorates' Academy (PIA) and the International Coalition of Medicines Regulatory Authorities' (ICMRA's) pharmaceutical quality knowledge management system (PQKMS)

11:15 – 11:20 5 mins	Scene setting	Jacques Morénas ANSM
11:20 – 11:35 15 mins	Overview of PIC/S' involvement in ICH Q12 implementation	Jacques Morénas ANSM
11:35 – 11:50 15 mins	Pharmaceutical quality knowledge management capability to support regulator and manufacturer agility (PQ KMS)	Theresa Mullin US FDA
11:50 – 12:05 15 mins	Q & A	
12:05 – 12:50 45 mins	Panel discussion: Heads of Agencies' priorities on the changing framework for GMP regulatory inspections	Facilitator: Paul Gustafson  Panellists: <ul style="list-style-type: none"> <li>○ Lorraine Nolan, HPRA</li> <li>○ Stefania Trombetti, Health Canada</li> <li>○ Judith McMeekin, US FDA</li> <li>○ Uzu Shinobu, PMDA</li> <li>○ Christelle Ratignier Carbonneil, ANSM</li> </ul>
12:50-13:50 60 mins	Lunch	
13:50 – 14:10 20 mins	Group photograph	

<sup>2</sup> PIC/S Sub-Committee on Training (SCT)



### SESSION 3

**Moderator: Mr. Meow Hoe Boon, former PIC/S Chairperson (2018-2019), Singapore / HSA**

#### WHAT THE FUTURE HOLDS FOR INDUSTRY AND PIC/S

Abstract: Session 3 seeks to increase awareness and facilitate discussion on the capabilities that inspectorates will need to keep pace with developments

14:10 – 14:15 5 mins	Scene setting	Meow Hoe Boon HSA
14:15 – 15:25 70 mins	<b>Advanced Manufacturing</b>  Technologies impacting the way future inspections will be conducted	
14:15 – 14:55	- Digitalised pharmaceutical manufacturing	Thomas Hartman & Thomas Zimmer, ISPE
14:55 – 15:25	- Point of care manufacturing	Ian Rees, MHRA
15:25 – 15:45 20 mins	Q & A	
15:45- 16:05 20 mins	Break	
16:05 – 16:50 45 mins	Panel discussion with Heads of Inspectorates: Ensuring GMP inspections are fit for purpose in the 21 <sup>st</sup> Century	Facilitator: Gráinne Power, HPR  Panellists: o Ana Carolina Moreira Marino Araujo, ANVISA o Christian Schärer, SwissMedic o Elizabeth Miller, US FDA o James Pound, MHRA o Johanna Gouws, WHO
16:50 – 17:00 10 mins	Conclusion & official closing of symposium	Paul Gustafson PIC/S Chairman

**End Time: 17:00**



### Celebration Dinner (Invitation Only)

17:40 – 17:45	Bus Departure to Clontarf Castle
18:30 – 22:30	Celebratory 50th Anniversary Dinner in the Great Hall at Clontarf Castle
22:30 – 22:35	Bus Departure to Radisson Blu Hotel
23:00	Arrival at Radisson Blu Hotel