GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5115: Principles and Frameworks for Pharmacovigilance

11 October 2021 – 15 October 2021

Venue: Zoom

Overall objectives of the Workshop

- Explain the guidelines and principles behind the regulatory frameworks and processes for pharmacovigilance and risk management plan
- Describe the ideal conditions, processes and systems to optimise data collection, collation and signal generation
- List the platforms and initiatives that is supporting pharmacovigilance and risk management, both regionally and globally
- Describe strategies for improving risk communication and stakeholder engagement

Learning outcomes

- Compare roles and processes of pharmacovigilance from both regulator's and industry perspective
- Establish foundational knowledge on pharmacovigilance frameworks, its operations and standards, as well as the application of life cycle approach
- Apply concepts of critical thinking for regulatory decision-making in pharmacovigilance
- Appreciate the future direction for pharmacovigilance

Graduate Certificate in Health Products Regulation

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Day 1 – 11 October, Mon

	Topic	Speaker/ Organisation
9.00am	**Zoom briefing**	**Mr Osman Mohamad** Senior Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School Singapore
9.10am	**Welcome**	**Professor John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School Singapore
9.20am	**Overview of workshop** • Scope of module • Conduct of workshop and assessment	
9.30am	**Networking**	
10.00am	**Refreshment Break**	
Session 1: The Pharmacovigilance Systems		
11.00am	**50 years of evolution of pharmacovigilance system** • Key processes and stakeholders in pharmacovigilance • Key documents used in PV: CTD, RMP, PBRER	**Dr Jean-Christophe Delumeau** Head Pharmacovigilance Policy Strategy (Global) Bayer
12.00pm	**Pharmacovigilance in innovation medicines**	**Ms Ayn Nova Celo** Patient Safety Head (Singapore, Myanmar, Vietnam) Novartis Asia Pacific Pharmaceuticals Pte Ltd
12.30pm	**Lunch**	
2.00pm	**Overview of pharmacovigilance processes by industry and product licence holder**	**Dr Jean-Christophe Delumeau** Bayer
3.00pm	**Refreshment Break**	
3.30pm	**Overview of a National Regulatory Authority's pharmacovigilance system:** • An ASEAN country's perspective	**Ms Adena Lim** Deputy Director Vigilance and Compliance Branch Health Sciences Authority (HSA), Singapore
4.15pm	**Overview of a National Regulatory Authority's pharmacovigilance system:** • UK perspective	**Mr Patrick Batty** UK Alternate delegate EU Pharmacovigilance Risk Assessment Committee (PRAC) Vigilance and Risk Management of Medicines Medicines and Healthcare products Regulatory Agency (MHRA), UK
5.00pm	**End**	

Day 2 – 12 October, Tue

	Topic	Speaker/ Organisation
9.00am	**Individual and Group Assessment I**	
Session 2:	**Signal Detection**	
10.00am	**Methodologies in ADR Reporting** • Reporting systems • ICSR • Limitations of data sources	**Dr Ruth Savage** Consultant & Senior Advisor Uppsala Monitoring Centre (UMC); Senior Lecturer University of Otago, New Zealand
11.00am	**Refreshment Break**	
11.30am	**Case Discussion** **Signal generation: A framework for reporting** • Ways to improve quantity and quality of safety data fueling subsequent PV activities • Cultivating a positive **reporting culture**	**Dr Ruth Savage** Consultant & Senior Advisor Uppsala Monitoring Centre (UMC); Senior Lecturer University of Otago, New Zealand **Dr Joseph Mitchell** Pharmacovigilance Scientist Uppsala Monitoring Centre (UMC)
12.00pm	**Medications errors and promoting appropriate use of medicines** • Using ICSR to educate on non-rational prescribing	**Dr Ruth Savage** Consultant & Senior Advisor Uppsala Monitoring Centre (UMC); Senior Lecturer University of Otago, New Zealand
1.00 pm	**Lunch**	
Session 3:	**Signal Management and Assessment**	
2.00pm	**Evaluation of Pharmacovigilance data** • Statistical signal detection • Causality assessment and definitions • Case series evaluations • Signal and trends - Signal detection, validation and confirmation	**Dr Ruth Savage** Consultant & Senior Advisor Uppsala Monitoring Centre (UMC); Senior Lecturer University of Otago, New Zealand
3.00pm	**Practicum I** • Causality Assessment and Signal Detection	
3.30pm	**Refreshment Break**	
4.00pm	**Practicum I (cont'd)** • Signal detection and assessment	
5.30pm	**End**	

Day 3 – 13 October, Wed

	Topic	Speaker/ Organisation
9.00am	**Individual and Group Assessment II**	
Session 4:	**Benefit-Risk Assessment and Management**	

10.00am	**Benefit-Risk Assessment for Pharmacovigilance**
	• General Principles and Limitations
	• Source of safety data through product lifecycle
	• Benefit-Risk Assessment: Points to consider
	  ○ Benefit Evaluation
	  ○ Risk Evaluation
		Dr Han Phey Yen
		Senior Regulatory Specialist
		Vigilance and Compliance Branch
		Health Sciences Authority (HSA), Singapore

11.00am	**Refreshment Break**	
11.30am	**Case Discussion** **Benefit-risk assessment** • Apply a multi-criteria approach to benefit-risk profiling • Articulate the basis of the benefit-risk decision	**Dr Han Phey Yen** **Ms Christine Ho** HSA [Facilitated by CoRE]
12.30pm	**Lunch**	
1.30pm	**Risk Management Planning** • Principles of Risk Management Planning • Routine and Additional risk minimisation methods • Elements to consider for deciding and selecting risk minimization methods • Planning to address gaps in knowledge	**Mr Patrick Batty** MHRA
2.30pm	**Practicum II** Adapting RMPs to different healthcare systems in ASEAN	**Dr Jean-Christophe Delumeau** Bayer [Facilitated by CoRE]
3.30pm	**Refreshment Break**	
4.00pm	**Practicum II (cont'd)**	
5.30pm	**End**	

Day 4 –14 October, Thurs

	Topic	Speaker/ Organisation
9.00am	**Individual and Group Assessment III**	
Session 5 – Risk Communication		
10.00am	**Approaches in Risk Communications**	**Ms Peck Li Fung** Senior Regulatory Specialist Vigilance and Compliance Branch Health Sciences Authority (HSA), Singapore
11.00am	**Refreshment Break**	
11.30am	**Case Discussion** • Effective engagement of stakeholders in risk communications	**Ms Adena Lim** **Ms Peck Li Fung** HSA
12.30pm	**Lunch**	
Session 6 – Pharmacovigilance Operations		
(self-study)	**Post-approval safety decision-making and regulatory actions** • Options for regulatory action • Measuring effectiveness of regulatory actions	**Mr Patrick Batty** MHRA
1.30pm	**Quality Management Systems in Pharmacovigilance** • Quality Assurance • Quality Management • Quality Control	**Dr Jean-Christophe Delumeau** Bayer
2.15pm	**Post-approval product safety and regulatory actions** • Pharmacovigilance Audits and Inspections • Dealing with non-compliance • Common inspection findings	**Ms Mandeep Rai** Global Head of PV Audits & Inspections Kyowa Kirin International plc
3.00pm	**Refreshment Break**	
3.30pm	**Practicum III** Preparing for a Pharmacovigilance inspection	
5.30pm	**End**	

Day 5 – 15 October, Fri

	Topic	Speaker/ Organisation
9.00am	End-of-Module (EOM) Assessment	
10.00am	Refreshment Break	
10.30am	Discussion of EOM	
11.00am	Preparation for panel discussion	
11.45am	**Expectations – Perspectives from patients on safe use of medicines**	**Dr Christopher Knight** Founder, Alliance for Safe Medicine Asia Everett Knight (Asia Pacific) Pte Ltd
12.30pm	Lunch	
Session 7: Regulating IVD products - Challenges and Opportunities		
2.00pm	**Utility of Real World Data and Evidence in Pharmacovigilance**	**Mr Hiren Thakkar** Principal, Real World Solutions, SEA IQVIA Asia Pacific
2.45pm	**Harnessing social media to reduce misinformation**	**Ms Alexandra Hoegberg** Head of Global Communications UMC
3.30pm	Refreshment Break	
4.00pm	**Panel Discussion** **Seamless pharmacovigilance processes through product life cycle**	
4.45pm	**Graduate Certificate Workshop Conclusion**	**A/Prof Silke Vogel** Senior Associate Dean Graduate Studies Duke-NUS Medical School Deputy Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School Singapore
5.00pm	End	