GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5116 Post-Market Activities for Pharmaceuticals

5 – 9 May 2025

WORKSHOP PROGRAMME

Learning outcomes

At the end of this workshop, participants should be able to

- Summarise the role and importance of risk-management and pharmaceutical quality management systems in post-market activities
- Explain the role of good manufacturing practices (GMP) and good storage and distribution practices (GSDP) in safeguarding the quality of pharmaceutical products across the product lifecycle
- Describe the post-market surveillance and enforcement activities to monitor and ensure the quality and safety of pharmaceutical products
- Describe the 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

Target Audience

- Early to mid-career professionals: regulatory affairs professionals in pharmaceutical companies, healthcare professionals, academic researchers in life sciences and regulators in national (health/drug) regulatory authorities.

Graduate Certificate in Health Products Regulation

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Day 1 – 5 May, Mon

Time	Topic	Speaker/Organisation
8.00am	**Registration**	
8.30am	**Welcome and Workshop Briefing**	**Dr Rathi Saravanan** Lead Education Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.15am	**Group activity/ Bright Space and Assessment Familiarisation**	**Mr Osman Mohamad** Senior Education Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
Session 1: Ensuring pharmaceutical product quality across supply chain- Supporting Best Practices and Systems		
9.30am	**Role and importance of Pharmacovigilance in Post-market**	**Asst Prof James Leong** Head, Health Products and Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.50am	**Introduction to Risk Management and compliance in post-market activities** • Risk Management (RM) principles and methodology • Risk assessment tools • QMS Elements and standards (ISO:2015/ICH Q10) • Role of RM and QMS in achieving quality compliance across supply chain	**Dr Rathi Saravanan** Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
10.15am	**Tea Break**	
10.30am	**Good Manufacturing Practices (GMP) in quality assurance of pharmaceuticals** • GMP Principles • Types of GMP inspections • Risk-based categorisation of deficiencies • Specific product deficiencies (e.g., Biologics, CTGTPs)	TBC
11.15am	**Being GMP Compliant: Operational considerations, planning and preparation for post-approval inspections** • Proactive compliance & Inspection readiness • Approaches and systems supporting inspection • Roles and responsibility of management	TBC
12.00pm	**Lunch**	
1.00pm	**Overview of Good Storage Distribution Practice in supply chain integrity of medicinal products**	TBC

	• Importance of GSDP • Best practices and principles on GSDP • Case examples needs and Challenges in vaccine Cell & Gene therapy supply chain • Enhanced Safety monitoring measures	
1.45pm	**Maintaining a secure pharmaceutical supply chain** • Threats and Challenges • Supply chain security measures • Handling of supply chain security breaches • Detection technologies with focus on suspected substandard and falsified pharmaceutical products	TBC
2.30pm	**Root Cause Analysis and CAPA: An Overview**	**Asst Prof James Leong** Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
3.00pm	**Tea Break**	
3.15pm	**Case Discussion: CAPA**	**CoRE Education Team**
5.15pm	**Debrief**	
5.30pm	**End**	

Day 2 – 6 May, Tue

Time	Topic	Speaker/Organisation
8.00am	**Registration**	
Session 2: Ensuring pharmaceutical product quality and supply chain - Post-market surveillance activities for approved medicinal products		
8.30am	**Pharmaceutical quality surveillance in Singapore** • Purposes • Sampling criteria • Laboratory testing	**TBC**
9.15am	**Reporting of therapeutic product defects and recall** • Classification of product quality defects • Level of recalls • Investigation, corrective and preventive actions	**TBC**
10.00am	**Tea Break**	
10.15am	**Practicum I: Management of pharmaceutical product quality surveillance for out-of-specifications (OOS) and product quality defects**	
12.30pm	**Lunch**	
1.30pm	**Practicum I (continued)**	
Session 3: Ensuring pharmaceutical product quality and supply chain security – Surveillance activities for Counterfeit, Substandard and Falsified medicinal products		
2.00pm	**Trend Observation on Counterfeits (CF), Substandard and Falsified (SF) Medicines in the Asia-Pacific Region** • What are CF and SF medicines • Hot spot areas in the Asia-Pacific region and the contributory factors • Impact of CF and SF medicines to public health	**TBC**
2.45pm	**Global enforcement efforts against SF and illegal sales of medicinal products** • Magnitude of issues worldwide • Strategies to combat existing and emerging global threat	**TBC**
3.30pm	**Tea Break**	
3.45pm	**Case Discussion: Detection of SF medicinal product**	**CoRE Education Team**
5.15pm	**Debrief**	
5.30pm	**End**	

Day 3 – 7 May, Wed

Time	Topic	Speaker/Organisation
8.00am	**Registration**	
Session 5: Pharmacovigilance Systems and Signal detection		
8.30am	**Overview of a National Regulatory Authority's pharmacovigilance system:** • An ASEAN country's perspective	**TBC**
9.15am	**Overview of pharmacovigilance processes by industry and product licence holder** • QMS in PV • Single Case Management Guidelines & Regulations	**TBC**
10.00pm	**Tea Break**	
10.15am	**Methodologies in ADR Reporting** • Reporting systems • ICSR • Limitations of data sources	**TBC**
11.15am	**Case Discussion Signal Generation**	**CoRE Education Team**
12.30pm	**Lunch**	
1.30pm	**Evaluation of Pharmacovigilance data** • Statistical signal detection • Causality assessment and definitions • Case series evaluations • Signal and trends - Signal detection, validation and confirmation	**TBC**
Session 6: Benefit-Risk Assessment		

2.30pm	**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
		TBC

3.30pm	**Tea Break**	
3.45pm	**Case Discussion: Benefit-risk assessment** • Apply a multi-criteria approach to benefit-risk profiling • Articulate the basis of the benefit-risk decision	**CoRE Education Team**
5.00pm	**Panel Discussion Preparation**	
5.15pm	**Debrief**	
5.30pm	**End**	

Day 4 – 8 May, Thur

Time	Topic	Speaker/Organisation
8.00am	**Registration**	
Session 7: Risk Management and Risk Communication		
8.30am	**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	TBC
9.30am	**Practicum II: Adapting RMPs to different healthcare systems in ASEAN**	**CoRE Education Team**
10.00am	**Tea Break**	
10.15am	**Practicum II (continued)**	
12.30pm	**Lunch**	
1.30pm	**Approaches in Risk Communications**	TBC
2.15pm	**Post-approval product safety and regulatory actions** • Pharmacovigilance Audits and Inspections • Dealing with non-compliance • Common inspection findings	TBC
3.00pm	**Tea Break**	
3.15pm	**Case Discussion: PV Inspection**	**CoRE Education Team**
5.15pm	**Debrief**	
5.30pm	**End**	

Day 5 – 9 May, Fri

Time	Topic	Speaker/Organisation
9.00am	**End-of-Module (EOM) Assessment**	**CoRE Education Team**
10.00am	**Tea Break**	
10.15am	**Discussion for EOM**	**CoRE Education Team**
Session 8: Trending topics in Pharmacovigilance and Pharmaceutical Surveillance		
10.45am	**Role of Pharmacogenomics in Pharmacovigilance of medicinal products**	TBC
11.30pm	**Lunch**	
12.30pm	**Utility of Real-World Data and Evidence in Pharmacovigilance**	**TBC**
1.15pm	**Looming Crisis of Counterfeit Drugs**	**TBC**
2.00pm	**Capacity building for resilient supply chains** • Global and LMIC Case examples	**TBC**
2.45pm	**Regulatory systems strengthening for supply chain integrity and security**	**TBC**
3.30pm	**Tea Break**	
3.45pm	**Panel discussion** **Facilitating a regional approach to combatting substandard and falsified medicines and impact on access and global health**	
5.00pm	**Workshop Conclusion**	**Prof Silke Vogel** Senior Associate Dean Graduate Studies Deputy Director Centre of Regulatory Excellence Head Centre for Lifelong Learning Duke-NUS Medical School
5.30 pm	**End**	