GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION
GMS5116 POST-MARKET ACTIVITIES FOR PHARMACEUTICALS

25 September – 29 September 2023

Overall objectives of the workshop

- Build and enhance capability for the key activities and roles essential for effective post-market control of pharmaceutical products.
- Promote opportunities for optimisation of post-market surveillance networks and collaboration, handling of substandard and falsified pharmaceuticals within ASEAN region.

Learning outcomes

- Describe the post-market surveillance and enforcement activities to monitor and ensure the quality and safety of pharmaceutical products
- Explain the role of good manufacturing practices (GMP) and good storage and distribution practices (GSDP) in safeguarding the quality of approved pharmaceutical products across the product lifecycle
- List the national and international platforms and initiatives that are supporting post-market regulatory activities to enhance supply chain integrity of pharmaceutical products and facilitate timely interventions

The programme is accurate as of 20 September 2023 and may be subjected to further refinement if necessary before the actual event.

Graduate Certificate in Health Products Regulation

GMS5116 Post-Market Activities for Pharmaceuticals

25 - 29 September 2023

Day 1 – September 25, Mon

Time	Agenda	Faculty
8.30 am	Welcome and workshop briefing	**Dr. Rathi Saravanan** Lead Education Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.00 am	Group activity/ Bright Space and Assessment Familiarisation	**Mr Osman Mohamad** Senior Associate CoRE, Duke-NUS Medical School
Session 1: Post-Market Surveillance Overview & Supporting Best Practices and Systems		
9.30 am	**Post-market surveillance programme: Role in ensuring pharmaceutical product quality across supply chain** • Objectives and stakeholder responsibilities • Applicable General principles (e.g.GMP and GSDP) • Sampling and quality control testing	**Asst Prof James Leong** Head, Health Products and Regulatory Science CoRE, Duke-NUS Medical School
10.00 am	**Break**	
10:15 am	**Quality Management System (QMS) in ensuring pharmaceutical product quality and reliability of supply chain.** • QMS Elements • QMS Regulations and standards (ISO 9001:2015/ICH Q10) • Role of QMS in achieving quality compliance across supply chain	**Ms. Teo Jing Yi** CMC Regulatory MSD International GmbH
11:15 am	**Quality Risk Management (QRM) as part of supply chain integrity and control** • QRM principles (ICH Q9 (R1) • QRM methodology • Role of QRM in achieving quality compliance across supply chain	**Ms. Teo Jing Yi** CMC Regulatory MSD International GmbH
12.30pm	**Lunch**	
Session 2: Ensuring pharmaceutical product quality across supply chain - GMP		
1.30 pm	**Role of Good Manufacturing Practices (GMP) in quality assurance of pharmaceutical products across supply chain** • Basic Principles of GMP • GMP requirements for quality control	**Mr Vimal Sachdeva** Technical Officer – Senior Inspector Inspection Services Group Prequalification Team (PQT) World Health Organization (WHO)
2.15 pm	**Types of GMP inspections and classification of deficiencies** • Risk-based categorization of deficiencies • Specific product deficiencies (e.g., Biologics, CTGTPs) • Communication of Inspection Report	**Mr Vimal Sachdeva** WHO
3.00 pm	**Break**	

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3.15 pm	**Being GMP Compliant: Operational considerations, planning and preparation for post-approval inspections** • Proactive compliance & Inspection readiness • Approaches and systems supporting inspections • Roles and responsibility of management	**Dr. Stephen Hsu** Regional Head Quality Assurance Alcon, Singapore
4.30 pm	**Co-operation and mutual reliance in GMP Inspections** • Global supply chain complexities & importance of inspection reliance in quality compliance and assurance • PIC/S inspection reliance initiatives • ASEAN MRA on GMP inspections	**Mr. Boon Meow Hoe** Deputy Director Senior GMP Auditor Audit & Licensing Division Health Products Regulation Group Health Sciences Authority (HSA) Singapore
5.30 pm	**End**	

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Day 2 – September 26, Tue

Time	Agenda	Faculty
8.30 am	Individual and Group Assessment I	**CoRE Education team**
Session 3: Ensuring pharmaceutical product quality across supply chain – GSDP		
9.30 am	**Overview of Good Storage Distribution Practice in supply chain integrity of medicinal products** • Importance of GSDP • Best practices and principles on GSDP	**Mr. Brett Marshall** Vice President – Quality & HSSE Zuellig Pharma Holdings Pte Ltd
10.00 am	**Break**	
10.15 am	**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	**Mr. Brett Marshall** Zuellig Pharma
11.00 am	**Ensuring quality and integrity of vaccines across supply chain** • Freezing threat and cold chain management • Tools and approaches for temperature monitoring • Enhanced Safety monitoring measures	**Mr. Brett Marshall** Zuellig Pharma
11.30 am	**Good Storage and Distribution Practices for ATMPs** • Needs and Challenges in Cell & Gene therapy Supply Chain • Supporting operations & infrastructure • Best practices ensuring supply chain integrity	**Ms. Cathleen E. Afable** CQA, CMQ/OE (ASQ) Regional Director, International Markets Cell Therapy Operations, Novartis Singapore
12. 00 noon	**Lunch**	
1.00 pm	**Case Discussion I: CAPA**	**Asst Prof James Leong** CoRE
3.00 pm	**Break**	
3.15 pm	**Practicum I: GMP**	**Content Expert** **Mr Vimal Sachdeva** WHO
5.30 pm	**End**	

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Day 3 – September 27, Wed

Time	Agenda	Faculty
8.30am	Individual and Group Assessment II	**CoRE Education team**
9.30 am	Peer Learning and Sharing	**CoRE Education team**
10. 00 am	**Break**	
Session 4: Ensuring pharmaceutical product quality and supply chain security- Post-market surveillance activities for approved medicinal products		
10.15 am	**Pharmaceutical quality surveillance in Singapore** • Purposes • Sampling criteria • Laboratory testing	**Ms Yang Silin** Senior Regulatory Specialist Vigilance and Compliance Branch Health Products Regulation Group HSA, Singapore
11.30 am	**Reporting of therapeutic product defects and recall** • Classification of product quality defects • Level of recalls • Investigation, corrective and preventive actions	**Mr Choong Chih Tzer** Senior Regulatory Specialist HSA, Singapore
12.30 noon	**Lunch**	
1.30 pm	**Practicum II: Management of pharmaceutical product quality surveillance for out-of-specifications (OOS) and product quality defects**	**Content Experts** **Ms Yang Silin** HSA, Singapore **Mr Choong Chih Tzer** HSA, Singapore
3.30 pm	**Break**	
3.45 pm	**Practicum II: Discussion**	
4.30 pm	**Risk-Based Post-Market Product Quality Surveillance** • Considerations for effective post-market surveillance • Guidance for establishing and implementing risk-based surveillance tool	**Ms Ruth Lee** Associate Director Public Policy and Regulatory Affairs Global External Affairs, APAC United States Pharmacopeial Convention (USP)
5.30pm	**End**	

Day 4 – September 28, Thurs

Time	Agenda	Faculty
8.30am	Individual and Group Assessment III	**CoRE Education team**
Session 5: Ensuring pharmaceutical product quality and supply chain security – Surveillance activities for Counterfeit, Substandard and Falsified medicinal products		
9.30 am	**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	**Mr Ramesh Raj Kishore** Regional Director – Asia Pacific Pharmaceutical Security Institute Singapore
10.15 am	**Break**	
10.30 am	**Practicum III: Detection of SF medicinal product**	**Content Expert** **Mr Ramesh Raj Kishore** Pharmaceutical Security Institute Singapore
12.30 pm Lunch		
Session 6: Ensuring pharmaceutical product quality and supply chain security – Enforcement activities		
1.30 pm	**Enforcement efforts against SF and illegal sales of medicinal products in ASEAN** • Magnitude of issue in ASEAN landscape • Types of operations carried out • Collaboration with other agencies intra- and inter-countries	**Mr. Jonathan Selvasegaram** Asia Pacific Manager and Legal Counsel React
2. 30 pm	**Global enforcement efforts against SF and illegal sales of medicinal products** • Magnitude of issues worldwide • Strategies to combat existing and emerging global threat	**Ms Ruth Lee** USP
3.30 pm	**Break**	
3.45 pm	**Case discussion II: Enforcement operations against SF medicines**	**CoRE Education team**
5.15 pm	**Group Activity – Preparation for panel discussion/ EOM preparation**	**CoRE Education team**
5.30pm	**End**	

Day 5 – September 29, Fri

Time	Agenda	Faculty
9.00am	End-of-Module (EOM) assessment	**CoRE Education team**
10.00 am	Discussion for EOM	**CoRE Education team**
10.30 am	**Break**	
Session 7: Emerging Technologies in Pharmaceutical supply chain management and Regulatory Systems strengthening		
10.45 am	**Regulatory Systems Strengthening to mitigate issues of Substandard and Falsified medicines**	**Dr. Valerio Reggi** Visiting Expert, CoRE Consultant, Drug Regulatory Matters & Pharmaceutical Policy
11.45 am	**Block chain enabled end-to-end traceability and supply chain resilience**	**Associate Prof. Sunil Tiwari** ESSCA School of Management France
12.30 pm	**Lunch**	
1.30 pm	**Capacity building for resilient vaccine supply chains** • Global and LMIC Case examples	**Mr. Brett Marshall** Zuellig Pharma
2.30 pm	**Regulatory systems strengthening for supply chain integrity and security**	**Ms Ruth Lee** USP
3.30 pm	**Panel discussion** **Facilitating a regional approach to combatting substandard and falsified medicines and impact on access and global health**	**Panellist** **Ms Ruth Lee** USP **Mr. Brett Marshall**, Zuellig Pharma **Moderator** **Mr Ramesh Raj** Pharmaceutical Security Institute
4.45 pm	**Workshop conclusion**	**A/Prof Silke Vogel** Senior Associate Dean, Graduate Studies Deputy Director, CoRE Head, Centre for Lifelong Learning Duke-NUS Medical School
4.50 pm	**High-Tea and Networking Session**	**Faculty, Participants and CoRE Members**
5.30 pm	**End**	

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