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

21 February – 25 February 2022

Conducted via Zoom

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 17 February 2022 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

21 - 25 February 2022

Day 1 – February 21, Mon

Time	Agenda	Faculty
8.30am	Welcome and workshop briefing	**Asst Prof James Leong** Head, Health Products and Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.00am	Group activity	**Mr Osman Mohamad** Senior Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.30am	**Break**	
10.00am	Role of post-market surveillance programme to ensure quality and supply chain integrity of pharmaceutical products • Supporting infrastructures (e.g. application of GMP principles, GSDP, national/international surveillance) • Product sampling and testing strategy	**Dr Souly Phanouvong** Senior Technical Advisor Regulatory Systems Strengthening United States Pharmacopeial Convention (USP)
Session 1: Ensuring pharmaceutical product quality and supply chain security - GMP		
11.15pm	Role of Good Manufacturing Practices (GMP)	**Mr Vimal Sachdeva** Technical Officer (Expert Inspector) Prequalification Team World Health Organization (WHO)
12.30pm	**Lunch**	
1.30pm	Good Practices in Production and Quality Control • Active Pharmaceutical Ingredient • Finished Pharmaceutical Product	**Mr Vimal Sachdeva** WHO
2.30pm	Type of GMP inspections	**Mr Vimal Sachdeva** WHO
3.00pm	**Break**	
3.30pm	WHO Prequalification Programme (WHO PQP) • Background of PQP • WHO efforts towards harmonizing cGMP inspection procedures worldwide • WHO role in facilitating regulatory reliance for cGMP inspection • WHO current GMP and supplementary guidelines	**Mr Vimal Sachdeva** WHO
4.30pm	A global effort to improve GMP standards – Initiatives from PIC/S	***TBC***
5.30pm	**End**	

The programme is accurate as of 17 February 2022 and may be subjected to further refinement if necessary before the actual event.

Day 2 – February 22, Tue

Time	Agenda	Faculty
9.00am	Individual and Group Assessment I	**CoRE Education team**
10.00am	**Break**	
Session 2: Ensuring pharmaceutical product quality and supply chain security – GSDP		
10.30am	Maintaining supply chain security • Supply chain security programmes • Handling of supply chain security breaches • Detection technologies with focus on suspected substandard and falsified pharmaceutical products	**Dr Souly Phanouvong** USP
11.30am	Laboratory support and capacity building	**Dr Souly Phanouvong** USP
12.30pm	**Lunch**	
1.30pm	Case discussion: Corrective Actions and Preventive Actions (CAPA)	**Asst Prof James Leong** CoRE
3.30pm	**Break**	
4.00pm	Practicum I: GMP	**Content Expert** **Mr Vimal Sachdeva** WHO
5.30pm	**End**	

Day 3 – February 23, Wed

Time	Agenda	Faculty
9.00am	Individual and Group Assessment II	**CoRE Education team**
10.00am	**Break**	
Session 3: Ensuring pharmaceutical product quality and supply chain security – Post-market surveillance activities for approved medicinal products		
10.30am	Pharmaceutical quality surveillance in Singapore • Purposes • Sampling criteria • Laboratory testing	**Ms Yang Silin** Senior Regulatory Specialist Vigilance and Compliance Branch (VCB) Health Products Regulation Group (HPRG) Health Sciences Authority (HSA) Singapore
11.15am	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 Vigilance and Compliance Branch (VCB) Health Products Regulation Group (HPRG) Health Sciences Authority (HSA) Singapore
12.00pm	**Lunch**	
1.30pm	Practicum II: Handling of pharmaceutical product quality defects	**Content Experts** **Ms Yang Silin** HSA, Singapore **Mr Choong Chih Tzer** HSA, Singapore
3.30pm	**Break**	
4.00pm	Product Quality Surveillance	**Ms Ruth Lee** Associate Director Public Policy and Regulatory Affairs Global External Affairs, APAC United States Pharmacopeial Convention (USP)
5.00pm	Case Discussion: Considerations for preparing a sampling list	**Asst Prof James Leong** CoRE
5.30pm	**End**	

The programme is accurate as of 17 February 2022 and may be subjected to further refinement if necessary before the actual event.

Day 4 – February 24, Thurs

Time	Agenda	Faculty
9.00am	Individual and Group Assessment III	**CoRE Education team**
10.00am	**Break**	
10.30am	Case Discussion: Considerations for preparing a sampling list	**Asst Prof James Leong** CoRE
Session 4: Ensuring pharmaceutical product quality and supply chain security – Surveillance activities for Counterfeit, Substandard and Falsified medicinal products		
11.30am	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
12.30pm	**Lunch**	
1.30pm	Practicum III: Detection of SF medicinal product	**Content Expert** **Mr Ramesh Raj Kishore** Pharmaceutical Security Institute
3.30pm	**Break**	
4.00pm	Regulatory systems strengthening to mitigate issues of SF	**Dr Valerio Reggi** Visiting Expert CoRE, Consultant Drug Regulatory Matters & Pharmaceutical Policy
4.45pm	Group Activity – Preparation for panel discussion	**CoRE Education team**
5.30pm	**End**	

Day 5 – February 25, Fri

Time	Agenda	Faculty
Session 4: Ensuring pharmaceutical product quality and supply chain security – Enforcement activities		
9.00am	End-of-Module (EOM) assessment	**CoRE Education team**
10.00am	Discussion for EOM	**CoRE Education team**
10.30am	**Break**	
11.00am	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
11.30am	Global enforcement efforts against SF and illegal sales of medicinal products • Magnitude of issues worldwide • Role of INTERPOL • Strategies to combat existing and emerging global threat	**Ms Ruth Lee** USP
12.30pm	**Lunch**	
2.00pm	Case discussion: Enforcement operations against SF medicines	**CoRE Education team**
3.30pm	**Break**	
4.00pm	Panel discussion – Facilitating a regional approach in tackling SF issues	**Panellist** **Ms Ruth Lee** USP **Mr Ramesh Raj** Pharmaceutical Security Institute **Mr Jonathan Selvasegaram** React
5.00pm	Workshop conclusion	**A/Prof Silke Vogel** Senior Associate Dean Graduate Studies Deputy Director Centre of Regulatory Excellence, Head Centre for Lifelong Learning, Duke-NUS Medical School
5.30pm	**End**	

The programme is accurate as of 17 February 2022 and may be subjected to further refinement if necessary before the actual event.