



DukeNUS
Medical School



Centre of
Regulatory Excellence

GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5116 Post-Market Activities for Pharmaceuticals

5 – 9 May 2025

Venue: Duke NUS, Room 5C

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

GMS5116 Post-Market Activities for Pharmaceuticals

5 – 9 May 2025

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	Team introductions/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 <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • GMP Principles • Types of GMP inspections • Risk-based categorisation of deficiencies • Specific product deficiencies (e.g., Biologics, CTGTPs) 	Dr. Stephen Hsu Regional Head Quality Assurance Alcon, Singapore
11.15am	Being GMP Compliant: Operational considerations, planning and preparation for post-approval inspections <ul style="list-style-type: none"> • Proactive compliance & Inspection readiness • Approaches and systems supporting inspection • Roles and responsibility of management 	Dr. Stephen Hsu Regional Head Quality Assurance Alcon, Singapore
12.00pm	Lunch	



1.00pm	Overview of Good Storage Distribution Practice in supply chain integrity of medicinal products <ul style="list-style-type: none">• 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	Mr. Brett Marshall, Former Vice President, Zuellig Pharma Quality Assurance, HSSE
1.45pm	Maintaining a secure pharmaceutical supply chain <ul style="list-style-type: none">• 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, Former Vice President, Zuellig Pharma Quality Assurance, HSSE
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 <ul style="list-style-type: none"> • Purposes • Sampling criteria • Laboratory testing 	Ms Yang Silin Specialist Consultant Vigilance and Compliance Branch (VCB) Health Products Regulation Group (HPRG) Health Sciences Authority (HSA) Singapore
9.15am	Reporting of therapeutic product defects and recall <ul style="list-style-type: none"> • Classification of product quality defects • Level of recalls • Investigation, corrective and preventive actions 	Mr Choong Chih Tzer Regulatory Consultant HSA, Singapore
10.00am	Tea Break	
10.15am	Practicum I: Management of pharmaceutical product quality surveillance for out-of-specifications (OOS) and product quality defects	<u>Content Experts</u> Ms Yang Silin HSA, Singapore Mr Choong Chih Tzer HSA, Singapore
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 <ul style="list-style-type: none"> • What are CF and SF medicines • Magnitude of issues worldwide • Hot spot areas in the Asia-Pacific region and the contributory factors • Impact of CF and SF medicines to public health • Strategies to combat existing and emerging SF and illegal sales threat 	Mr Ramesh Raj Kishore Regional Director – Asia Pacific Pharmaceutical Security Institute Singapore
3.00 pm	Tea Break	
3.15pm	Case Discussion: Detection of SF medicinal product	Mr Ramesh Raj Kishore & CoRE Education Team
5.15pm	Debrief	
5.30pm	End	



Day 3 – 7 May, Wed

Time	Topic	Speaker/Organisation
8.00am	Registration	
Session 4: Pharmacovigilance Systems and Signal detection		
8.30am	Overview of a National Regulatory Authority's pharmacovigilance system: <ul style="list-style-type: none"> An ASEAN country's perspective 	Ms. Adena Lim Deputy Director Vigilance and Compliance Branch Health Sciences Authority (HSA), Singapore
9.30am	Tea Break	
9.45am	Methodologies in ADR Reporting <ul style="list-style-type: none"> Reporting systems ICSR Limitations of data sources 	Dr Ruth Savage Consultant & Senior Advisor Uppsala Monitoring Centre (UMC); Senior Lecturer University of Otago, New Zealand
10.45am	Case Discussion: Signal Generation	CoRE Education Team
12.30pm	Lunch	
1.30pm	Evaluation of Pharmacovigilance data <ul style="list-style-type: none"> 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
Session 5: Benefit-Risk Assessment		
2.15pm	Benefit-Risk Assessment for Pharmacovigilance <ul style="list-style-type: none"> General Principles and Limitations Source of safety data through product lifecycle Benefit-Risk Assessment: Points to consider <ul style="list-style-type: none"> Benefit Evaluation Risk Evaluation 	Dr Han Phey Yen Regulatory Consultant Vigilance and Compliance Branch Health Sciences Authority (HSA), Singapore
3.00pm	Tea Break	
3.15pm	Case Discussion: Benefit-risk assessment <ul style="list-style-type: none"> Apply a multi-criteria approach to benefit-risk profiling Articulate the basis of the benefit-risk decision 	Dr Han Phey Yen and 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 6: Risk Management and Risk Communication		
8.30am	Risk Management Planning <ul style="list-style-type: none"> • 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 UK Alternate delegate EU Pharmacovigilance Risk Assessment Committee (PRAC) Vigilance and Risk Management of Medicines Medicines and Healthcare products Regulatory Agency (MHRA), UK
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	Ms Peck Li Fung Regulatory Consultant Vigilance and Compliance Branch Health Sciences Authority (HSA), Singapore
2.15pm	Post-approval product safety and regulatory actions <ul style="list-style-type: none"> • Pharmacovigilance Audits and Inspections • Dealing with non-compliance • Common inspection findings 	Ms. Mandeep Rai Global Head PV Performance Excellence Kyowa Kirin International plc
3.00pm	Tea Break	
3.15pm	Case Discussion: PV Inspection	Ms. Mandeep Rai and CoRE Education Team
5.15pm	Debrief	
5.30pm	End	



Day 5 – 9 May, Fri

Time	Topic	Speaker/Organisation
8.30am	Registration	
9.00am	End-of-Module (EOM) Assessment	CoRE Education Team
10.00am	Tea Break	
10.15am	Discussion for EOM	CoRE Education Team
Session 7: Trending topics in Pharmacovigilance and Pharmaceutical Surveillance		
10.45am	Role of Pharmacogenomics in Pharmacovigilance of medicinal products	Dr. Michael Winther Senior Director, Target Discovery Engine Biosciences Pte Ltd
11.30am	Lunch	
12.30pm	Utility of Real-World Data and Evidence in Pharmacovigilance	Mr. Hiren Thakkar Senior Director, Project Operations, RWS, APAC, ICON Plc
1.15pm	Importance of Patient Engagement in Pharmacovigilance	Asst.Prof. Khoo Yoong Khean Centre for Outbreak Preparedness Singhealth Duke-NUS Global Health Institute (SDGHI)
2.00pm	Capacity building for resilient supply chains <ul style="list-style-type: none"> • INTERPOL's role in tackling pharmaceutical crime • Global and LMIC Case examples 	Mr. Perry NG Criminal Intelligence Officer Criminal Networks Public Health and Pharmaceutical Crime, INTERPOL
2.45pm	Regulatory systems strengthening for supply chain integrity and security	Ms. Ruth Lee Associate Director Public Policy and Regulatory Affairs Global External Affairs, APAC United States Pharmacopeial Convention (USP)
3.30pm	Tea Break	
3.45pm	<u>Panel discussion</u> Facilitating a regional approach to combatting substandard and falsified medicines and impact on access and global health	<u>Panellist</u> Mr. Brett Marshall, Mr. Perry Ng <u>Moderator</u> Mr Ramesh Raj Pharmaceutical Security Institute
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	