

## **GRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION**

### **GMS5116 Post-Market Activities for Pharmaceuticals**

*13 – 17 April 2026*

Venue: White Space Room (Level 2), Academia,  
20 College Road, Singapore 169856

### **WORKSHOP PROGRAMME**

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#### **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 Pharmaceutical Regulation

### GMS5116 Post-Market Activities for Pharmaceuticals

13 – 17 April 2026

#### Day 1 – 13 April, Mon

Time	Topic	Speaker/Organisation
8.00am	Registration	
8.30am	Welcome and Workshop Briefing	<b>Dr Rathi Saravanan</b> Lead Education Associate Lead, Graduate Certificate Programmes Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.05am	<b>Ice-breaker Activity</b> <ul style="list-style-type: none"> <li>• Brightspace Familiarization</li> <li>• Introduction of team members</li> <li>• Goal setting</li> </ul>	<b>Education Team</b>
9.25am	<b>Photo-taking Session: Faculty &amp; Participants</b>	<b>Education Team</b>
<b>Session 1: Ensuring pharmaceutical product quality across supply chain- Supporting Best Practices and Systems</b>		
9.30am	<b>Role and importance of Pharmacovigilance in Post-market</b>	<b>Asst Prof James Leong</b> Head, Health Products and Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
10.00am	<b>Introduction to Risk Management and compliance in post-market activities</b> <ul style="list-style-type: none"> <li>• Risk Management (RM) principles and methodology</li> <li>• Risk assessment tools</li> <li>• QMS Elements and standards (ICH Q10)</li> <li>• Role of RM and QMS in achieving quality compliance across supply chain</li> </ul>	<b>Dr Rathi Saravanan</b> Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
10.30am	<b>Tea Break</b>	
10.45am	<b>Good Manufacturing Practices (GMP) in quality assurance of pharmaceuticals</b> <ul style="list-style-type: none"> <li>• GMP Principles</li> <li>• Types of GMP inspections</li> <li>• Risk-based categorisation of deficiencies</li> <li>• Specific product deficiencies (e.g., Biologics, CTGTPs)</li> </ul>	<b>Dr. Stephen Hsu</b> Regulatory and Quality Consultant ATTOPOLIS@ARQon-Asia Pte Ltd Singapore
11.30am	<b>Being GMP Compliant: Operational considerations, planning and preparation for post-approval inspections</b> <ul style="list-style-type: none"> <li>• Proactive compliance &amp; Inspection readiness</li> <li>• Approaches and systems supporting inspection</li> <li>• Roles and responsibility of management</li> </ul>	<b>Dr. Stephen Hsu</b> Regulatory and Quality Consultant ATTOPOLIS@ARQon-Asia Singapore

<b>12.30pm</b>	<b>Lunch</b>	
<b>1.30pm</b>	<b>Case Discussion I: GMP</b>	<b>Dr. Stephen Hsu</b> and <b>CoRE Education Team</b>
<b>3.00pm</b>	<b>Tea Break</b>	
<b>3.15pm</b>	<b>Case Discussion II: CAPA</b> •With a brief overview to Root Cause Analysis and CAPA	<b>Asst Prof James Leong</b> Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
<b>4.45 pm</b>	<b>Overview of Good Storage Distribution Practice in supply chain integrity of medicinal products</b> <ul style="list-style-type: none"> <li>• Importance of GSDP</li> <li>• Best practices and principles on GSDP</li> <li>• Case examples needs and Challenges in vaccine Cell &amp; Gene therapy supply chain</li> <li>• Enhanced Safety monitoring measures</li> </ul>	<b>Dr. Waqas Ahmed</b> Head of International Regulatory Policy and Intelligence United States Pharmacopeial Convention (USP)
<b>5.30pm</b>	<b>End</b>	

**Day 2 – 14 April, Tue**

Time	Topic	Speaker/Organisation
8.00am	Registration	
<b>Session 2: Ensuring pharmaceutical product quality and supply chain - Post-market surveillance activities for approved medicinal products</b>		
8.30am	<b>Pharmaceutical quality surveillance in Singapore</b> <ul style="list-style-type: none"> <li>Purposes</li> <li>Sampling criteria</li> <li>Laboratory testing</li> </ul>	<b>Ms Yang Silin</b> Specialist Consultant Vigilance and Compliance Branch (VCB) Health Products Regulation Group (HPRG) Health Sciences Authority (HSA) Singapore
9.15am	<b>Reporting of therapeutic product defects and recall</b> <ul style="list-style-type: none"> <li>Classification of product quality defects</li> <li>Level of recalls</li> <li>Investigation, corrective and preventive actions</li> </ul>	<b>Mr Choong Chih Tzer</b> Regulatory Consultant HSA, Singapore
10.00am	Tea Break	
10.15am	<b>Practicum I: Management of pharmaceutical product quality surveillance for out-of-specifications (OOS) and product quality defects</b>	<b>Content Experts</b> <b>Ms Yang Silin</b> HSA, Singapore  <b>Mr Choong Chih Tzer</b> HSA, Singapore
12.30pm	Lunch	
<b>Session 3: Ensuring pharmaceutical product quality and supply chain security – Surveillance activities for Counterfeit, Substandard and Falsified medicinal products</b>		
2.00pm	<b>Trend Observation on Counterfeits (CF), Substandard and Falsified (SF) Medicines in the Asia-Pacific Region</b> <ul style="list-style-type: none"> <li>What are CF and SF medicines</li> <li>Magnitude of issues worldwide</li> <li>Hot spot areas in the Asia-Pacific region and the contributory factors</li> <li>Impact of CF and SF medicines to public health</li> <li>Strategies to combat existing and emerging SF and illegal sales threat</li> </ul>	<b>Mr. Ramesh Raj Kishore</b> Regional Director - Asia Pacific Pharmaceutical Security Institute Singapore
3.00 pm	Tea Break	
3.15pm	<b>Case Discussion III: Detection of SF medicinal product</b>	<b>Mr. Ramesh Raj Kishore</b> and <b>CoRE Education Team</b>
5.15pm	Debrief	
5.30pm	End	

### Day 3 – 15 April, Wed

Time	Topic	Speaker/Organisation
8.00am	Registration	
<b>Session 4: Pharmacovigilance Systems and Signal detection</b>		
8.30am	Individual and Group Assessment	CoRE Education Team
9.30am	<b>Overview of a National Regulatory Authority's pharmacovigilance system:</b> <ul style="list-style-type: none"> <li>An ASEAN country's perspective</li> </ul>	<b>Ms. Adena Lim</b> Deputy Director Vigilance and Compliance Branch Health Sciences Authority (HSA), Singapore
10.30am	Tea Break	
10.45am	<b>Methodologies in ADR Reporting</b> <ul style="list-style-type: none"> <li>Importance of AE reporting</li> <li>Sources of AEs and Types of AE reports</li> <li>Steps in AE reporting</li> </ul>	<b>Ms Tham Mun Yee</b> Regulatory Consultant Adverse Event Management Unit Health Sciences Authority (HSA), Singapore
11.30am	<b>Evaluation of Pharmacovigilance data</b> <ul style="list-style-type: none"> <li>Causality assessment</li> <li>Signal detection</li> <li>Signal validation and regulatory actions</li> </ul>	<b>Ms Tham Mun Yee</b> Regulatory Consultant Adverse Event Management Unit Health Sciences Authority (HSA), Singapore
12.30pm	Lunch	
1.30pm	<b>Case Discussion: Causality Assessment and Signal Detection</b>	<b>Ms Tham Mun Yee</b> and <b>CoRE Education Team</b>
3.00 pm	Tea Break	
<b>Session 5: Benefit-Risk Assessment</b>		
3.15pm	<b>Benefit-Risk Assessment for Pharmacovigilance</b> <ul style="list-style-type: none"> <li>General Principles and Limitations</li> <li>Source of safety data through product lifecycle</li> <li>Benefit-Risk Assessment: Points to consider</li> </ul>	<b>Ms Leng Xue Zhen</b> Senior Regulatory Specialist Vigilance and Compliance Branch Health Sciences Authority (HSA), Singapore
4.00pm	<b>Case Discussion: Benefit-risk assessment</b> <ul style="list-style-type: none"> <li>Apply a multi-criteria approach to benefit-risk profiling</li> <li>Articulate the basis of the benefit-risk decision</li> </ul>	<b>Ms Leng Xue Zhen</b> and <b>CoRE Education Team</b>
5.15pm	Debrief	
5.30pm	End	

**Day 4 – 16 April, Thur**

Time	Topic	Speaker/Organisation
8.00am	Registration	
<b>Session 6: Risk Management and Risk Communication</b>		
8.30am	<b>Risk Management Planning</b> <ul style="list-style-type: none"> <li>Principles of Risk Management Planning</li> <li>Routine and Additional risk minimisation methods</li> <li>Elements to consider for deciding and selecting risk minimization methods</li> <li>Planning to address gaps in knowledge</li> </ul>	<b>Mr. Byron Romero</b> Patient Safety Country Cluster Lead Product Development Safety, International Patient Safety Roche Singapore Pte Ltd
9.30am	<b>Practicum II: Adapting RMPs to different healthcare systems in ASEAN</b>	<b>Mr. Byron Romero</b> and <b>CoRE Education Team</b>
10.00am	Tea Break	
10.15am	Practicum II (continued)	
12.30pm	Lunch	
1.30pm	<b>Approaches in Risk Communications</b>	<b>Ms Peck Li Fung</b> Regulatory Consultant Vigilance and Compliance Branch Health Sciences Authority (HSA) Singapore
2.30pm	<b>Post-approval product safety and regulatory actions</b> <ul style="list-style-type: none"> <li>Pharmacovigilance Audits and Inspections</li> <li>Dealing with non-compliance</li> <li>Common inspection findings</li> </ul>	<b>Mr. Byron Romero</b> Patient Safety Country Cluster Lead Product Development Safety, International Patient Safety Roche Singapore Pte Ltd
3.30pm	Tea Break	
3.45pm	<b>Case Discussion: PV Inspection</b>	<b>Mr. Byron Romero</b> and <b>CoRE Education Team</b>
5.15pm	Debrief	
5.30pm	End	

**Day 5 – 17 April, 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
<b>Session 7: Trending topics in Pharmacovigilance and Pharmaceutical Surveillance</b>		
10.45am	Role of Artificial Intelligence (AI) in Pharmacovigilance	<b>Mr. Byron Romero</b> Patient Safety Country Cluster Lead Product Development Safety, International Patient Safety Roche Singapore Pte Ltd
11.45am	Utility of Real-World Data and Evidence in Pharmacovigilance	<b>Mr. Hiren Thakkar</b> Senior Director, Project Operations, RWS, APAC, ICON Plc
12.30pm	Lunch	
1.30pm	Importance of Patient Engagement in Pharmacovigilance	<b>Asst.Prof. Khoo Yoong Khean</b> Centre for Outbreak Preparedness Singhealth Duke-NUS Global Health Institute (SDGHI)
2.15pm	Global enforcement efforts against counterfeit medicinal products	<b>Mr. Andy Chua</b> Director, Global Brand Protection, Asia Pacific, Johnson & Johnson
3.00pm	Tea Break	
3.15pm	Regulatory systems strengthening for supply chain integrity and security	<b>Ms Ruth Lee</b> Associate Director Public Policy and Regulatory Affairs Global External Affairs, APAC United States Pharmacopeial Convention (USP)
4.00pm	Reflection & Peer Sharing	<b>Dr. Rathi Saravanan</b> Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
5.00pm	Workshop Conclusion	<b>Asst Prof James Leong</b> Head, Health Products and Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
5.30pm	End	