

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

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

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Day 1 – 13 April, Mon

| Time | Topic | Speaker/Organisation |
|--|--|---|
| 8.00am | Registration | |
| 8.30am | Welcome and Workshop Briefing | Dr Rathi Saravanan Lead Education Associate Lead, Graduate Certificate Programmes Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School |
| 9.05am | Ice-breaker Activity <ul style="list-style-type: none"> Brightspace Familiarization Introduction of team members Goal setting | Dr. Uttara Soumyanarayanan Senior Education Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School |
| 9.25am | Photo-taking Session: Faculty & Participants | Education Team |
| 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 |
| 10.00am | 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 (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 |
| 10.30am | Tea Break | |
| 10.45am | 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 Regulatory and Quality Consultant ATTOPOLIS@ARQon-Asia Pte Ltd Singapore |
| 11.30am | 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 Regulatory and Quality Consultant ATTOPOLIS@ARQon-Asia Singapore |

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| 12.30pm | Lunch | |
| 1.30pm | Case Discussion I: GMP | Dr. Stephen Hsu and CoRE Education Team |
| 3.00pm | Tea Break | |
| 3.15pm | Case Discussion II: CAPA •With a brief overview to Root Cause Analysis and CAPA | Asst Prof James Leong Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School |
| 4.45 pm | 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 | Dr. Waqas Ahmed Head of International Regulatory Policy and Intelligence United States Pharmacopeial Convention (USP) |
| 5.30pm | End | |

Day 2 – 14 April, 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 | Content Experts Ms Yang Silin HSA, Singapore Mr Choong Chih Tzer HSA, Singapore |
| 12.30pm | Lunch | |
| 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 III: Detection of SF medicinal product | Mr. Ramesh Raj Kishore and CoRE Education Team |
| 5.15pm | Debrief | |
| 5.30pm | End | |

Day 3 – 15 April, Wed

| Time | Topic | Speaker/Organisation |
|--|--|---|
| 8.00am | Registration | |
| Session 4: Pharmacovigilance Systems and Signal detection | | |
| 8.30am | Individual and Group Assessment | CoRE Education Team |
| 9.30am | 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 |
| 10.30am | Tea Break | |
| 10.45am | Methodologies in ADR Reporting <ul style="list-style-type: none"> Reporting systems ICSR Limitations of data sources | Ms Tham Mun Yee Regulatory Consultant Adverse Event Management Unit Health Sciences Authority (HSA), Singapore |
| 11.30am | 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 | Ms Tham Mun Yee Regulatory Consultant Adverse Event Management Unit Health Sciences Authority (HSA), Singapore |
| 12.30pm | Lunch | |
| 1.30pm | Case Discussion: Causality Assessment and Signal Detection | Ms Tham Mun Yee and CoRE Education Team |
| 3.00 pm | Tea Break | |
| Session 5: Benefit-Risk Assessment | | |
| 3.15pm | 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 | Ms Leng Xue Zhen Senior Regulatory Specialist Vigilance and Compliance Branch Health Sciences Authority (HSA), Singapore |
| 4.00pm | 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 | Ms Leng Xue Zhen and CoRE Education Team |
| 5.15pm | Debrief | |
| 5.30pm | End | |

Day 4 – 16 April, Thur

| Time | Topic | Speaker/Organisation |
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| 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. Byron Romero Patient Safety Country Cluster Lead Product Development Safety, International Patient Safety Roche Singapore Pte Ltd |
| 9.30am | Practicum II: Adapting RMPs to different healthcare systems in ASEAN | Mr. Byron Romero and 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 |
| 2.30pm | Post-approval product safety and regulatory actions <ul style="list-style-type: none"> • Pharmacovigilance Audits and Inspections • Dealing with non-compliance • Common inspection findings | Mr. Byron Romero Patient Safety Country Cluster Lead Product Development Safety, International Patient Safety Roche Singapore Pte Ltd |
| 3.30pm | Tea Break | |
| 3.45pm | Case Discussion: PV Inspection | Mr. Byron Romero and CoRE Education Team |
| 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 |
| Session 7: Trending topics in Pharmacovigilance and Pharmaceutical Surveillance | | |
| 10.45am | Role of Artificial Intelligence (AI) in Pharmacovigilance | Mr. Byron Romero 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 | Mr. Hiren Thakkar Senior Director, Project Operations, RWS, APAC, ICON Plc |
| 12.30pm | Lunch | |
| 1.30pm | Importance of Patient Engagement in Pharmacovigilance | Asst.Prof. Khoo Yoong Khean Centre for Outbreak Preparedness Singhealth Duke-NUS Global Health Institute (SDGHI) |
| 2.15pm | Global enforcement efforts against counterfeit medicinal products | Mr. Andy Chua Director, Global Brand Protection, Asia Pacific, Johnson & Johnson |
| 3.00pm | Tea Break | |
| 3.15pm | 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) |
| 4.00pm | Reflection & Peer Sharing | Dr. Rathi Saravanan Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School |
| 5.00pm | Workshop Conclusion | Asst Prof James Leong Head, Health Products and Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School |
| 5.30pm | End | |