

# WHO-UMC-HSA Inter-Regional Pharmacovigilance Training Workshop

Partnerships to Protect Public Health

15 - 17 August 2018

## DAY 1 – 15 AUGUST 2018

8:30AM

Registration

9.00AM

Welcome and Introduction

**Dr Mimi Choong**

Chief Executive Officer  
Health Sciences Authority  
Singapore

**A/Prof Silke Vogel**

Deputy Director  
Centre of Regulatory Excellence  
Senior Associate Dean  
Graduate Studies (PhD and Accredited Programmes)  
Duke-NUS Medical School  
Singapore

9.15AM

Pharmacovigilance (PV) and Public Health Programmes: Updates from the WHO

**Dr Viola Macolic Sarinic**

Technical Officer  
Essential Medicines and Health Products  
Regulation of Medicines and other Health Technologies  
Safety and Vigilance  
World Health Organization  
Geneva  
Switzerland

10.00AM

The Role of Pharmacovigilance in Ensuring Health Product Safety: Singapore's Experience

**Ms Jalene Poh**

Director  
Vigilance and Compliance Branch  
Vigilance, Compliance & Enforcement Cluster  
Health Products Regulation Group  
Health Sciences Authority  
Singapore

10.45AM

Tea Break

11.10AM

Vaccine Safety: A Clinician's Perspective

**Adj Associate Professor Thoon Koh Cheng**

Head and Senior Consultant  
Infectious Disease Service, Department of Paediatrics  
KK Women's and Children's Hospital

**11.50AM Lunch & Photo Taking Session**

**1.45PM Epidemiological Studies on Vaccine Safety**

**Dr Yung Chee Fu**

Consultant  
Infectious Disease Service, Department of Paediatrics  
KK Women's and Children's Hospital  
Singapore

**2.30PM Current and Future Trends in Vaccine Development**

**Dr Philippe Buchy**

Director  
Scientific Affairs & Public Health Intercontinental Region  
GlaxoSmithKline Vaccines

**3.00PM Tea Break**

**3.30PM SAPHIRE – A Partnership of Regulators, Scientists and Clinicians**

**Ms Ang Pei San**

Regulatory Consultant  
Vigilance and Compliance Branch  
Health Products Regulation Group  
Health Sciences Authority  
Singapore

**4.10PM Panel Discussion: Partnerships to Protect Public Health - Challenges and Opportunities in Asia**

**Moderator:**

**Dr Philippe Buchy**

Director  
Scientific Affairs & Public Health Intercontinental Region  
GlaxoSmithKline Vaccines

**Panel:**

**Ms Ang Pei San**

Regulatory Consultant  
Vigilance and Compliance Branch  
Health Products Regulation Group  
Health Sciences Authority  
Singapore

**Ms Sally Soh**

Regulatory Consultant  
Adverse Event Management Unit  
Vigilance and Compliance Branch  
Health Products Regulation Group  
Health Sciences Authority  
Singapore

**Mr Sanjiv Navangul**

Managing Director  
Janssen  
India

**5:00PM End of Day 1**

## DAY 2 – 16 AUGUST 2018

|                |   |
|----------------|---|
| <b>8:30AM</b>  | <b>Registration</b>   |
| <b>9:00AM</b>  | <b>Welcome</b>  |
| <b>9:10AM</b>  | <b>Managing Vaccine Safety Events, From Risk Detection to Risk Communication</b>  |
|                | <p><b>Ms Sally Soh</b><br/>Regulatory Consultant<br/>Adverse Event Management Unit<br/>Vigilance and Compliance Branch<br/>Health Products Regulation Group<br/>Health Sciences Authority<br/>Singapore</p> |
| <b>10.00AM</b> | <b>Stakeholder Communication</b>  |
|                | <p><b>Ms Geraldine Ang</b><br/>Deputy Director<br/>Service Management<br/>Stakeholder Engagement Office<br/>Health Products Regulation Group<br/>Health Sciences Authority<br/>Singapore</p>                |
| <b>10.45AM</b> | <b>Tea Break</b>  |
| <b>11.10AM</b> | <b>Adverse Drug Reactions (ADRs) and Individual Case Study Reports (ICSRs)</b>  |
|                | <p><b>Dr Ruth Savage</b><br/>Consultant &amp; Senior Medical Advisor, Research<br/>Uppsala Monitoring Centre<br/>Uppsala<br/>Sweden</p>   |
| <b>12.00PM</b> | <b>Lunch</b>  |
| <b>1.00PM</b>  | <b>Principles of Causality Assessment: Single Case Safety Report Assessment</b>   |
|                | <p><b>Dr Ruth Savage</b></p>  |
| <b>2.00PM</b>  | <b>Principles of Causality Assessment: Case Series Assessment</b>   |
|                | <p><b>Dr Ruth Savage</b></p>  |
| <b>3.00PM</b>  | <b>Tea Break</b>  |
| <b>3.30PM</b>  | <b>Hands-on Work: Causality Assessment Exercises</b>  |
|                | <p><b>Dr Ruth Savage</b></p>  |
| <b>5.00PM</b>  | <b>End of Day 2</b>   |

## DAY 3 – 17 AUGUST 2018

**8:30AM** Registration

**9:00AM** Welcome

**9:10AM** Principles of Signal Detection

**Mr Daniele Sartori**

Research Pharmacist  
Uppsala Monitoring Centre  
Uppsala  
Sweden

**10.00AM** For Regulators:  
VigiLyze and Other  
Pharmacovigilance Tools and  
Methods

**Mr Daniele Sartori**

Research Pharmacist  
Uppsala Monitoring Centre  
Uppsala  
Sweden

**For Industry:  
Updates on Requirements to Ensure Product Safety  
Topics:**

- Reporting of product defects
- Reporting of product recalls

**Mr Choong Chih Tzer**

Senior Regulatory Specialist  
Vigilance and Compliance Branch  
Health Products Regulation Group  
Health Sciences Authority  
Singapore

**10.45AM** Tea Break

**11.15AM** For Regulators:  
Pharmacovigilance Tools and  
Methods (Hands-On Work)

**Mr Daniele Sartori**

Research Pharmacist  
Uppsala Monitoring Centre  
Uppsala  
Sweden

**For Industry:  
Updates on Requirements to Ensure Product Safety  
Topics:**

- Medical advertisements
- Risk management plans (RMPs)

**Ms Yang Silin**

Senior Regulatory Specialist  
Vigilance and Compliance Branch  
Health Products Regulation Group  
Health Sciences Authority  
Singapore

**Ms Christine Ho**

Regulatory Consultant  
Vigilance and Compliance Branch  
Health Products Regulation Group  
Health Sciences Authority  
Singapore

**12.30PM** Lunch

**1.30PM** Future Trends and Challenges

**Dr Viola Macolic Sarinic**

Technical Officer  
Essential Medicines and Health Products  
Regulation of Medicines and other Health Technologies  
Safety and Vigilance  
World Health Organization  
Geneva  
Switzerland

**1.50PM****Panel Discussion: Working Together to Address Future Trends and Challenges for Pharmacovigilance****Moderator:****Dr Viola Macolic Sarinic**

Technical Officer  
Essential Medicines and Health Products  
Regulation of Medicines and other Health Technologies  
Safety and Vigilance  
World Health Organization  
Geneva  
Switzerland

**Panel:****Mr Daniele Sartori**

Research Pharmacist  
Uppsala Monitoring Centre  
Uppsala  
Sweden

**Dr Ruth Savage**

Consultant & Senior Medical Advisor, Research  
Uppsala Monitoring Centre  
Uppsala  
Sweden

**Ms Jalene Poh**

Director  
Vigilance and Compliance Branch  
| Vigilance, Compliance & Enforcement Cluster  
Health Products Regulation Group  
Health Sciences Authority  
Singapore

**2.40PM****Closing Remarks and Certificate Presentation****Dr Mimi Choong**

Chief Executive Officer  
Health Sciences Authority  
Singapore

**3.00PM****End of Workshop**