DCVMN-Sinopharm Workshop: Vaccine Safety and Pharmacovigilance
8-12 May 2017, Novotel Xinqiao Beijing, China

DAY 1, Monday 8th May 2017- Welcome and Introduction		
Time	Topic	Speaker
8h30 – 9h00	Registration	
9h00 – 9h30	Welcome and introduction by CNBG	Yuntao Zhang, CNBG
9h30 – 10h30	It Takes a Program to Vaccinate Safely and Efficiently	Lawrence Everett Rodewald, WHO
10h30 – 11h00	Coffee break	
11h00 – 12h00	Introduction of PATH and CVIA	Michael Wang and Dexiang Chen, PATH
12h00 – 12h30	Test 1	
12h30 – 13h30	Lunch	
13h30 – 14h30	DCVMN Introduction	DCVMN
14h30 – 15h30	Humidity control for controlling microbial growth	Martin Ginty, Munters
15h30 – 16h00	Coffee break	
16h00 – 17h00	Viral Safety for Vaccines from cell line to finished product	Kate Smith, Principle Scientist, BioReliance, Merck
17h00 – 17h30	Q&A	
17h30	Adjourn	
18h00	Welcome Dinner	Sinopharm

DAY 2, Tuesday 9th May 2017- Introduction and Basic Principles of Pharmacovigilance (PV)		
Time	Topic	Speaker
8h30 – 9h00	Introduction of participants	
9h00 – 9h30	Introduction to the workshop	Thomas Verstraeten and Andrea Lohée
9h30 – 10h00	Lecture 1.1: The importance of PV	
10h00 – 10h30	Coffee break	
10h30 – 12h00	Lecture 1.2: The legal framework of PV: Europe, US, WHO and China	Thomas Verstraeten and Andrea Lohée
12h00 – 12h30	Lecture 1.3: Specifics of vaccine PV	Thomas Verstraeten
12h30 – 13h30	Lunch	
13h30 – 14h00	Lecture 1.4: Basic elements of a PV system	Andrea Lohée
14h00 – 15h30	Group exercise 1.1: Illustrate the importance of PV in your daily work	Thomas Verstraeten and Andrea Lohée
15h30 – 16h00	Coffee break	
16h00 – 17h30	Group exercise 1.2: Practical exercises of basic PV understanding (real life examples)	Thomas Verstraeten and Andrea Lohée
17h30	Adjourn	

DAY 3, Wednesday 10th May 2017- Clinical Safety and Post-Marketing PV: Part 1: Passive PV		
Time	Topic	Speaker
8h30 – 9h00	Lecture 2.1: European and US specific requirements:	Andrea Lohée
9h00 – 10h30	Lecture 2.2: The principles of Clinical safety - Types of clinical safety information - Individual clinical safety reports: collection, evaluation and reporting	Thomas Verstraeten and Andrea Lohée
10h30 – 11h00	Coffee break	
11h00 – 12h30	Lecture 2.3: The principles of Post-marketing PV: Part 1- passive PV - Different sources of post-marketing safety information - Individual post-marketing PV reports: collection, evaluation and reporting	Thomas Verstraeten and Andrea Lohée
12h30 – 13h30	Lunch	
13h30 – 15h00	Group exercise 2.1: Review and create a few individual clinical and post-marketing PV case reports	Thomas Verstraeten and Andrea Lohée
15h00 – 15h30	Coffee break	
15h30 – 17h00	Group exercise 2.3: Review scientific articles to identify safety reports	Thomas Verstraeten and Andrea Lohée
17h00 – 17h30	Q&A	
17h30	Adjourn	

DAY 4, Thursday 11th May 2017- Post-marketing PV : Part 2		
Time	Topic	Speaker
8h30 – 10h30	Lecture 3.1: Post-marketing PV - Part 2: Active pharmacovigilance - The principles of active PV - Basic notions of pharmaco-epidemiology - Post-authorization studies	Thomas Verstraeten
10h30 – 11h00	Coffee break	
11h00 – 11h30	Lecture 3.2: Signal detection – principles and models	Thomas Verstraeten
11h30 – 12h30	Lecture 3.3: Aggregate post-marketing PV reporting	Andrea Lohée
12h30 – 13h30	Lunch	
13h30 – 14h30	Group exercise 3.1: Design a pharmaco-epidemiological study	Thomas Verstraeten and Andrea Lohée
14h30 – 15h30	Group exercise 3.2: Review a report of a pharmaco-epidemiological study	Thomas Verstraeten and Andrea Lohée
15h30 – 16h00	Coffee break	
16h00 – 17h00	Group exercise 3.3: Write/review sections of a PSUR	Thomas Verstraeten and Andrea Lohée
17h00 – 17h30	Q&A	
17h30	Adjourn	

DAY 5, Friday 12th May 2017- Various Topics		
Time	Topic	Speaker
8h30 – 10h00	Lecture 4.1: Practical considerations in establishing a PV department - Supporting tools - Professional profiles - Subcontracting PV activities: when and what - Safety data exchange agreements: basic principles	Andrea Lohée
10h00 – 10h30	Lecture 4.2: Quality management in PV	Andrea Lohée
10h30 – 11h00	Coffee break	
11h00 – 11h30	Lecture 4.3: Aggregate clinical reporting (DSUR)	Andrea Lohée
11h30 – 12h00	Lecture 4.4: Monitoring of scientific and medical literature	
12h00 – 12h30	Test 2	
12h30 – 13h30	Lunch	
13h30 – 14h30	Group exercise 4.1: Role plays in a PV audit	All participants
14h30 – 15h30	Group exercise 4.2: Search for potential scientific literature with safety information	
15h30 – 16h00	Coffee break	
16h00 – 17h30	Workshop evaluation and wrap up	Andrea Lohée and DCVMN
17h30	Adjourn	

Thomas Verstraeten graduated as MD from Ghent University in 1987 and obtained a degree in Tropical Medicine from the Institute of Tropical Medicine in Antwerp in 1988. After about 10 years working in the field in emergency relief in Africa and HIV/STD research and surveillance in both Belgium and Africa, he went back to school to obtain a Masters in biostatistics from the University of Limburg in 1999. Following this, he was selected for a 2-year fellowship as Epidemiology Intelligence Service officer at the Centers for Disease Control where he was stationed within the Vaccine Safety Branch of the National Immunization Program. From 2001 to 2011, he was employed by GlaxoSmithKline where he was first responsible for the vaccine epidemiology group, for another 5 years in charge of the company's vaccine safety group. He is currently the managing director of P95. Andrea Lohée is graduated in psychomotricity and started working about 20 years ago within the drug safety and pharmacovigilance department at GlaxoSmithkine where she was mainly involved in all operational aspects of pharmacovigilance. Since 2009, she is owning her own company and offers services related to the operational aspects in pharmacovigilance, from case entry to establishing a full PV system.