

Training Workshop on Vaccine Safety monitoring and Pharmacovigilance tools 16-19 March, 2020 in Shanghai, China

Objectives:

This Advanced Pharmacovigilance Workshop covers in-depth training on

- Best practices in core Pharmacovigilance activities
- Presentation and communication of vaccine safety data with internal and external stakeholders
- Handling vaccine safety crisis with interactive exercises

Participants profile:

Safety professionals most likely to benefit from this training have advanced experience in the vaccine safety arena. The course would be advantageous to professionals with multifunction responsibilities or medical directors who manage teams in the various disciplines.

Expected Outcome:

- Demonstrate Good Pharmacovigilance Practice by implementing of best practices in accordance with regulatory requirements
- Develop competencies to present and communicate vaccine safety issues to National Regulatory Authorities and other official bodies
- Capability and competency to handle pharmacovigilance audits

The workshop will be in English and there will be no translation service as our workshop is an activity to foster international integration and cooperation.

DAY 1, Monday 16 March 2020		
Time	Topic	Speaker
08:30-09:00	Registration	DCVMN
09:00-09:15	Welcome and introduction	Host company
09:15-10:00	Welcome and introduction Updates on initiatives, objectives and expected outcomes	S. Pagliusi, DCVMN
10:00-10:30	Coffee Break	Group photo
10:30-11:00	Short introduction in Pharmacovigilance basics	K. Hartman, DCVMN
11:00-12:30	Best practices in case management	K. Hartman, DCVMN
12:30-13:30	Lunch Break	
13:30-15:30	Training on AEFI case management and discussion on safety databases	K. Hartman, DCVMN
15:30-16:00	Coffee Break	
16:00-16:30	Handling of product quality complaints with respective safety implications	K. Hartman, DCVMN
16:30-17:00	Bill Gates Video	DCVMN
17:00-17:30	Discussion, Q&A and Adjourn	All participants

DAY 2, Tuesday 17 March 2020		
Time	Topic	Speaker
09:00-10:30	Best practices in aggregate reporting (PSURs, DSURs) and Best practices in Signal and Risk Management	K. Hartman, DCVMN
10:30-11:00	Coffee Break	
11:00-12:30	Best practices in Vaccine Safety Communication	K. Hartman, DCVMN
12:30-13:30	Lunch Break	
13:30-15:30	Exercises in communicating and presenting vaccine safety data within the company	K. Hartman, DCVMN
15:30-16:00	Coffee Break	
16:00-17:00	Communicating and presenting vaccine safety data with different external stakeholders	K. Hartman, DCVMN
17:00-17:30	Discussion, Q&A and Adjourn	All participants

DAY 3, Wednesday 18 March 2020		
Time	Topic	Speaker
09:00-10:30	Best practices in Pharmacovigilance Quality Management System (QMS)	K. Hartman, DCVMN
10:30-11:00	Coffee Break	
11:00-12:30	Best practices in Pharmacovigilance Quality Management System (QMS)	K. Hartman, DCVMN
12:30-13:30	Lunch Break	
13:30-15:30	Discussion of a PV audit checklist for facilitating internal PV System gap analyses (PV audits)	K. Hartman, DCVMN
15:30-16:00	Coffee Break	
16:00-17:00	Vaccine Crisis Case Studies: Vaccine confidence crisis in China	K. Hartman, DCVMN
17:00-17:30	Discussion, Q&A and Adjourn	All participants

DAY 4, Thursday 19 March 2020		
Time	Topic	Speaker
09:00-10:30	Vaccine Crisis Case Studies	K. Hartman, DCVMN
10:30-11:00	Coffee Break	
11:00-12:30	Joint discussion and conclusion	K. Hartman, DCVMN
12:30-13:30	Lunch Break	
13:30-15:30	Working group discussions	
15:30-16:00	Coffee Break	
16:00-17:00	Working group discussions	
17:00-17:30	Conclusion, next meeting and adjourn	All participants