Developing Countries Vaccine Manufacturers Network

Mini E-workshop (via WebEx) on Vaccine Safety monitoring and Pharmacovigilance tools 16-18 March 2020

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 E-workshop is an activity to foster international integration and cooperation.

DAY 1, Monday 16 March 2020		
Time	Topic	Speaker
08:30-09:00 (CET)	Registration & Introduction	DCVMN
09:00-09:45 (CET)	Best practices in AEFI case management, incl safety databases	K. Hartman, DCVMN
09:45-10:00 (CET)	Q&A on the chat box	K. Hartman, DCVMN
10:00-10:15 (CET)	Break	
10:15-11:00 (CET)	Best practices in aggregate reporting (PSURs, DSURs)	K. Hartman, DCVMN
11:00-11:15 (CET)	Q&A on the chat box	K. Hartman, DCVMN
11:15- (CET)	Adjourn	All participants

DAY 2, Tuesday 17 March 2020		
Time	Topic	Speaker
08:30-09:00 (CET)	Registration & Recap	DCVMN
09:00-09:45 (CET)	Handling of product quality complaints with respective safety implications	K. Hartman, DCVMN
09:45-10:00 (CET)	Q&A on the chat box	K. Hartman, DCVMN
10:00-10:15 (CET)	Break	
10:15-11:00 (CET)	Best practices in Signal and Risk Management	K. Hartman, DCVMN
11:00-11:15 (CET)	Q&A on the chat box	K. Hartman, DCVMN
11:15- (CET)	Adjourn	All participants

DAY 3, Wednesday 18 March 2020		
Time	Topic	Speaker
08:30-09:00 (CET)	Registration & Recap	DCVMN
09:00-09:45 (CET)	Best practices in Pharmacovigilance Quality Management System (QMS)	K. Hartman, DCVMN
09:45-10:00 (CET)	Q&A on the chat box	K. Hartman, DCVMN
10:00-10:15 (CET)	Break	
10:15-11:00 (CET)	Proposal for a PV audit checklist for facilitating internal PV System gap analyses (PV audits)	K. Hartman, DCVMN
11:00-11:15 (CET)	Q&A on the chat box	K. Hartman, DCVMN
11:15- (CET)	Adjourn	All participants