

1st DCVMN Pharmacovigilance e-Workshop on Inspection/Audit Readiness for Post-Marketing Vaccine Pharmacovigilance 15-16 March 2021 via WebEx

Objectives:

At the end of this workshop, participants should be able to:

- Understand the importance and specificities of vaccine pharmacovigilance with reference to global regulatory expectations.
- Understand the importance and benefits of documenting pharmacovigilance processes using a standard template.

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 15 th March 2021		
Time	Topic	Speaker
11:00-11:45 (CET)	Specificities of vaccine pharmacovigilance	Katharina Hartmann, DCVMN
11:45-11:50 (CET)	Break	
11:50-12:35 (CET)	Pharmacovigilance from industry perspective: pre- and post-licensure	Katharina Hartmann, DCVMN
12:35-13:00 (CET)	Q&A	All participants, Katharina Hartmann, DCVMN

DAY 2, Tuesday 16 th March 2021		
Time	Topic	Speaker
11:00-11:45 (CET)	The PV System Master File (PSMF): Purpose & content	Varun Sharma, PATH
11:45-11:50 (CET)	Break	
11:50-12:10 (CET)	The PV System Master File (PSMF): Purpose & content (continued)	Varun Sharma, PATH
12:10-12:30 (CET)	Q&A	All participants, Varun Sharma, PATH