Developing Countries Vaccine Manufacturers Network

E-workshop (via WebEx) on Regulatory Pathways and changes in Vaccine Testing 27-29 April 2020

Objectives:

The objective of the workshop is two-fold:

A) Familiarize participants with available regulatory pathways for registration of vaccines, in particular those offered by WHO will be the focus of the training
B) Discuss challenges faced for the review and approval of variations in countries using imported vaccines and proposals for improvements
C) Reflect on validation, implementation and acceptance 3Rs opportunities.
D) Get updates on the 3Rs opportunities (Replacement of the Rabbit Pyrogenicity Test, Replacement of NIH for Rabies vaccines, Refinement of whole-cell Pertussis challenge).

Participants profile:

Participants are staff from regulatory affairs, Quality Assurance or Quality Control Departments from vaccine manufacturing companies having a good level of spoken and written English and closely involved with the preparation of dossier submissions to regulatory agencies.

Expected Outcome:

A) Understanding of the work carried out by DCVMN in the field of regulatory convergence, the activities carried out in relation to challenges for variations review and approvals and of the proposals made by the DCVMN regulatory working group to improve the situation.
B) Understanding of differences between variations guidelines and review procedures across countries
C) Engagement of participants in fostering internal and external communication around the proposals of this initiative, including when discussing with vaccine partners and regulatory authorities.
D) Understanding the impact of a testing strategy that includes 3Rs opportunities.

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 27 April 2020		
Time	Topic	Speaker
08:45-09:00 (CET)	Registration & Introduction	DCVMN
09:00-09:45 (CET)	Available regulatory Pathways for WHO PQ and for the registration of vaccines in importing countries	N. Dellepiane, DCVMN
09:45-10:00 (CET)	Q&A	N. Dellepiane, DCVMN
10:00-10:15 (CET)	Break	
10:15-11:00 (CET)	Introducing the DCVMN regulatory working group (RWG), its aims and activities Briefing on work done on vaccines registration challenges and opportunities for improvement	N. Dellepiane, DCVMN
11:00-11:15 (CET)	Q&A	N. Dellepiane, DCVMN
11:15- (CET)	Adjourn	All participants

DAY 2, Tuesday 28 April 2020		
Time	Topic	Speaker
08:45-09:00 (CET)	Registration & Recap	DCVMN
09:00-09:45 (CET)	Introduction to post-approval changes/variations regulatory landscape: challenges and opportunities for improvement	N. Dellepiane, DCVMN
09:45-10:00 (CET)	Q&A	N. Dellepiane, DCVMN
10:00-10:15 (CET)	Break	
10:15-11:00 (CET)	Validation, implementation and acceptance 3Rs opportunities. Special 3Rs considerations for a COVID19 vaccine	L. Viviani, DCVMN
11:00-11:15 (CET)	Q&A	L. Viviani, DCVMN
11:15- (CET)	Adjourn	All participants

DAY 3, Wednesday 29 April 2020		
Time	Topic	Speaker
08:45-09:00 (CET)	Registration & Recap	DCVMN
09:00-09:45 (CET)	Updates: Replacement of the Rabbit Pyrogenicity Testing; Replacement of NIH for Rabies.	L. Viviani, DCVMN
09:45-10:00 (CET)	Q&A	L. Viviani, DCVMN
10:00-10:15 (CET)	Break	
10:15-11:00 (CET)	TBC: PSPT Project	L. Viviani, DCVMN
11:00-11:15 (CET)	Q&A	L. Viviani, DCVMN
11:15- (CET)	Adjourn	All participants