Developing Countries Vaccine Manufacturers Network

E-workshop (via WebEx)
Regulatory Pathways: Part II
30 September – 1 October 2020

Objectives:

The objective of the workshop is to:

A. Inform participants and their respective companies about strategies to increase implementation by vaccine importing countries of the WHO collaborative registration procedure,

B. Familiarize participants with the use of the WHO Emergency Use Listing Procedure for COVID 19 vaccines

C. ICH CTD preparation (EU guidelines) and conversion into eCTD format

Participant 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. Communicating to participants and through them reaching relevant stakeholders in their respective companies on how manufacturers can foster acceptance of the WHO CRP in countries and through its use improved alignment in dossier format. Engagement of participants in fostering internal communication around the proposed strategy,

B. In the present COVID 19 pandemic situation, many member companies are engaged in the development of candidate COVID vaccines. This session will be focused on discussing the use of the WHO EUL mechanism as a means to obtain a temporary approval for use of the candidate vaccines in importing countries (avoiding lengthy review procedures at local level). The experience obtained during the recent Ebola epidemic will be shared,

C. Experience from big pharma on how to prepare a good CTD dossier. What is required to convert a paper based CTD into an eCTD dossier.

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.

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DAY 1, Wednesday 30 September 2020		
Time	Topic	Speaker
12:15-12:30 (CET)	Connections & Introduction	DCVMN
12:30-13:00 (CET)	Strategies to improve CRP implementation and alignment	N. Dellepiane, DCVMN
13:00-13:30 (CET)	Q&A (type questions in Q&A box)	All participants
13:30-13:45 (CET)	Break	
13:45-14:15 (CET)	Hints on the WHO EUL procedure	N. Dellepiane, DCVMN
14:15- 14:45 (CET)	Merck, Sharp & Dohme's experience of using EUL for Ebola vaccine	Mic Mc. Goldrick, IFPMA
14:45-15:00 (CET)	Q&A (type questions in Q&A box)	All participants
15:00-15:30 (CET)	End of training questionnaire	All participants

DAY 2, Thursday 1st October 2020		
Time	Topic	Speaker
12:00-12:30 (CET)	Connections and Introduction	DCVMN
12:30-13:00 (CET)	Preparation of ICH CTD (EU guidelines)	Norbert de Clercq, IFPMA
13:00-13:15 (CET)	Q&A (type questions in Q&A box)	All participants
13:5-13:30 (CET)	Break	
13:30-14:00 (CET)	Conversion of paper ICH CTD into eCTD, GSK's experience	Norbert de Clercq, IFPMA
14:00:14:15 (CET)	Q&A (type questions in Q&A box)	All participants
14:15- 14:45 (CET)	End of training questionnaire	All participants
14:45 (CET)	Adjourn	All participants