Advanced Training Workshop:
Building a CTD for registration of vaccines globally
27th – 28th March 2019, Singapore

Objectives

1) The objective of the first day of the training (27th) is for manufacturers to review the building blocks of technical documents and information required to register vaccines in different countries and regions, voluntarily share their experiences and explore any potential for collaboration.
2) The objective of the second day of the training (28th) is to work with regulatory experts focusing on challenges faced regarding the review and registration of vaccines in importing countries and consider approaches to support a registration dossier, e.g. expert reports and pre-submission meetings.
3) The workshop is aimed at collaborators working on regulatory dossiers for submission to NRAs and professionals closely involved in gathering product information for registration dossiers (e.g. QC, CMC, clinical, production, supply)

Expected outcomes

1) To understand the key building blocks of CTDs and explore potential areas for improvement
2) To help registration professionals to establish a method to efficiently coordinate a registration dossier

Wednesday 27 March- CTD training session		
Time	Topic	Speaker
9:00-10:30	CTD, history, format and contents, comparison between ASEAN and ICH CTD, manufacturers proposals for alignment Q & A	Presentation by Dr. N.Dellepiane Moderated by Dr N.Dellepiane
10:30-11:00	Coffee Break	
11:00-12:00	Model application form with example	Iin Susanti, BioFarma Discussion moderated by Dr. N.Dellepiane
12:00-13:00	Lunch	
13:00-15:00	PQ Module 1: What is the required information, why? How to prepare this info for PQ	Prashant Akut, Serum Institute of India
15:00-15:30	Coffee Break	

15:30-16:30	Country specific requirements (legalisations, translations, labelling, national agent, etc): How to address them	Shubhangi Ghadge, Serum Institute of India and Sebastian Comellas-Sinergium Biotec
16:30-17:30	Role of Regulatory team in management of registration and variations. Key functions	Sebastian Comellas, Sinergium Biotec

Thursday 28 March- CTD training session		
Time	Topic	Speaker
9:00-10:30	How to prepare for a pre-submission meeting (Nora) and how to address questions Discussion	Presentation by Dr N. Dellepiane Discussion moderated by Dr N. Dellepiane
10:30-11:00	Coffee Break	
11:00-12:00	Issues with building a CTD Modules 2-5 Which information is the most difficult to address: 1) Pre-clinical 2) Clinical data 3) CMC 4) Pharmacovigilance plan/data	Establishment of four working groups to address. List the issues and propose ideas to overcome them
12:00-13:00	Lunch	
13:00-15:00	What are the problems you face? Participants should come prepared to the meeting with their examples to give their own experiences. Where do they have problems and what do they do to solve them?	Working groups continued
15:00-15:30	Coffee Break	
15:30-16:30	Presentation by Working groups	15 minutes each
16:30-17:30	Discussion and conclusions	All