

First DCVMN 3Rs Experts Working Group Meeting

December 2nd, 2019 - Bangkok

In vivo tests have represented the gold standard for routine batch release for the majority of vaccines, including the extremely important vaccines for tetanus, diphtheria, pertussis (and their combination), and the rabies vaccines. They are mandated by regulatory authorities as means to assess vaccines' potency and safety before their release to the market.

Animal (and animal testing) are also employed in research and development, preclinical safety and sometimes also for the product manufacturing.

Animal models and in vivo challenge studies cannot, as yet, be completely eliminated in the research and development phase of vaccines, due to the need to establish the correlates of protection. But their use for lot release testing is increasingly being called into question, with some alternative methods already developed, validated and accepted by regulatory agencies and international standardization organizations.

This first DCVMN 3Rs Working Group Meeting in Bangkok is organized as a one day only event meant as a follow up of the workshop *Chemistry, Manufacturing & Controls (CMC) in fostering implementation of vaccine release test methods aimed at reducing animal use (3Rs)* held in Hyderabad in June 10th-13th 2019, where DCVMN members agreed to initiate a specific working group dedicated to the promotion of the implementation of 3Rs (Reduce, Replace, Refine animal testing) and the regulatory acceptance and harmonization of alternative methods for some specific vaccines: whole-pertussis, tetanus, diphtheria, and rabies.

The objectives of this first 3Rs WG meeting are:

- Learn more about the *whole-cell* Pertussis Serological Potency Test (PSPT);
- Introduce the Monocyte Activation Test and discuss its use;
- Learn more about the possibility to replace animal use in the manufacturing processes;
- Establish the Working Group's priorities and define an action plan for 2020 and beyond;
- Define the operations and the governance of the Working Group.

Target audience:

- company representatives (maximum one per company), fulfilling the Working Group requirements already shared (companies that have proposed nominees are encouraged to join);
- representatives from Thai companies working on 3Rs relevant projects;
- representatives from companies that have experience in lot release of DTP-containing products and of rabies vaccines are encouraged to participate;

Local Thai companies may have two 2 delegates attending.

Agenda

Time	Topic	Speaker	Affiliation
	Meeting Opening		
9:00 – 9:15	Welcome Opening Remarks	L. Viviani I. K. Poredi	On behalf of DCVMN BioNet-Asia, Thailand
9:15 – 9:45	Introduction of DCVMN Meeting objectives and nomination of the Chair and Co-chair	B. Hayman L. Viviani	On behalf of DCVMN
9:45 – 10:00	Review of the Report of the CMC Workshop Hyderabad June 2019 for future publication	L. Viviani Chair Co-Chair	
10:00 – 10:30	Experience in acellular Pertussis Batch Release Testing	I. K. Poredi	BioNet-Asia, Thailand
10:30 – 10:45	<i>Coffee Break</i>		
	Invited Experts Session		
10:45 – 11:15	Whole-cell Pertussis – Presentation of the PSPT study	C. Hendriksen	Intravacc, The Netherlands
11:15 – 11:45	Rabbit Pyrogenicity Test and Monocyte Activation Test	M. Etna	ISS, Italy
11:45 -12:15	Replacing animals in manufacturing process: JE case study	D. T. Dat	Vabiotech, Vietnam
12:15 – 12:45	An overview of Rabies Batch Release testing	R. Chozhavel	Zydus Cadila, India
12:45 – 13:45	<i>Lunch</i>		
	Establish Key Priorities for the DCVMN 3Rs Working Group		
13:45 – 14:45	Project Specific Action Plan, Roles and Responsibilities	L. Viviani Chair/Co-Chair All	
14:45 – 15:45	Discussion on the <i>DT-wP</i> pilot project – first step: PSPT study	L. Viviani Chair/Co-Chair All	
15:45 – 16:00	<i>Coffee Break</i>		
16:00 – 16:30	Wrap-up. Propose the next 3Rs WG meeting date. Nomination of chair and co- chair for the next year activities.	L. Viviani Chair/Co-Chair All	
16:30	Video		
18:30	<i>Informal dinner</i>		