

Workshop :
Chemistry Manufacturing and Controls in
fostering implementation of vaccine release test methods
aimed at reducing animal use (3Rs)

The Chemistry, Manufacturing & Controls (CMC) landscape of vaccines and biologics is undergoing rapid development and constant change. Complex processes yielding complex products such as biologics and biopharmaceuticals demand numerous, non-compendial, and sometimes complex QC test methods to confirm manufacturing consistency and product quality.

It is important for a manufacturer to have an effective CMC regulatory compliance strategy that can meet both local and international requirements and expectations.

ICH regulatory guidance's have been adopted broadly and are driving the biopharmaceutical industry to a higher performance, including Quality by Design (QbD), Quality Risk Management (QRM) and Pharmaceutical Quality System (PQS).

The first part of this workshop will provide an overview of the international requirements and expectations for test method validation of such assays, including in-process, release and stability assays commonly used by QC in biological and biopharmaceutical manufacturing. E.g.

- cell-based potency bioassays,
- immunochemical binding impurity assays
- adventitious agent assays

The second part of the workshop (days 2 and 3) will focus on alternative testing methods developed and standardized with view at reducing or replacing the use of laboratory animals. The objective of this 3Rs part of the workshop is to initiate a DCVMN activity targeted at encouraging the implementation of alternative testing methods among vaccine manufacturers in developing countries for selected priority vaccines.

Target audience: professionals performing, supervising, managing, audit, or overseeing the validation of test methods for the quality control of vaccines and biopharmaceutical products, including professionals working in Analytical Development, Quality Control, Quality Assurance, and Validation groups. Senior Management, Project Managers, Regulatory Affairs, responsible for the strategic alignment of local and global operations, as well present and future operations.

DAY 1, 10 June 2019

Time	Topic	Speaker
7:30 – 8:30	Breakfast for non-residential participants	
8:30-9:00	Registration	DCVMN
9:00-9:30	Welcome and introductions Objectives, Initiatives and expected outcomes	DCVMN
9:30-10:00	Introduction to Analytical Method Validation for Vaccines, Biopharmaceuticals and Other Bioproducts	D. Wilkinson NIBSC
10:00-10:30	Coffee Break	Group photo
10:30-11:30	Validation and re-validation of assays	D. Wilkinson NIBSC
11:30-12:30	Group exercise Case studies & assays validation	Working Groups
12:30-13:30	Lunch Break	
13:30-14:30	Case studies and feedback	Working Groups
14:30-15:30	Strengthening QC labs and efforts on building QC lab networks	S. Yadlapalli USP
15:30-16:00	Coffee Break	
16:00-17:00	Types of stainless steel and welding controls applied in the pharmaceutical industry for product-contact areas.	S. Simon Biozeen
17:00-17:30	Bill Gates video & discussion	
17:30	Adjourn	

DAY 2, Tuesday 11 June 2019		
Time	Topic	Speaker
7:30– 8:30	Breakfast for non-residential participants	
8:30 - 9:00	Introduction to the 3Rs initiatives: Objectives and expected outcomes	N. Dellepiane for DCVMN
9:00 - 9:30	Importance of 3Rs in lot release testing for vaccines. Progress in acceptance of alternative assays	A.Vissala CDSCO
9:30 – 10:00	Q&A	
10:00-10:30	Coffee Break	Group photo
10:30-11:00	USP Pharmacopeia activities in the vaccine area	D. Saha USP Pharmacopoeia
11:00-11:30	Q&As on Pharmacopoeia session Discussion	All participants
11:30-12:00	Alternative tests for DTP containing vaccines: an overview	C. von Hunolstein. Istituto Superiore di Sanità
12:00-12:30	Collaborative study for the establishment of harmonized Hib testing methodology	C. von Hunolstein. Istituto Superiore di Sanità
12:30-13:30	Lunch	
13:30-14:00	Experience with harmonized Hib testing methodology in India	S. Singh NIB
14:00-14:30	Q & As on Hib vaccine testing Discussion	All participants
14:30- 15:00	3R methods applicable to control the quality of tetanus and diphtheria vaccine components	G. Singh Bharat Biotechnology
15:00-15:30	3R methos applicable to control the quality of tetanus and diphtheria vaccine components	S. Goel Serum Institute of India
15:30-16:00	Coffee Break	
16:00-16:30	Alternative testing methods for pertussis vaccine	C. von Hunolstein. Istituto Superiore di Sanità
16:30-17:00	Alternative testing methods for pertussis vaccine	S. Goel Serum Institute of India
17:00-17:30	Q & As on D, T and P containing vaccines testing Discussion	All participants
17:30	Adjourn and Welcome Reception	All participants

DAY 3, Wednesday 12 June 2019		
Time	Topic	Speaker
7:45 – 8:45	Breakfast for non-residential participants	
9:00-10:00	WHO initiative on alternative testing method for rabies vaccine: international collaborative study design	U. Roskopf WHO (by video)
10:00-10:30	Considerations on alternative testing for rabies vaccine I	T.M. Chozhavel Rajanathan Zydus Cadila
10:30-11:00	Coffee Break	
11:00-11:30	Considerations on alternative testing for rabies vaccine II	S. Goel Serum Institute of India
11:30- 12:30	Q & A on rabies vaccine testing Discussion on the collaborative study design	All participants
12:30-13:30	Lunch Break	
13:30-15:30	Establishing an initiative to move forward the use of alternative test methods	Working groups on specific vaccines: Rabies Pertussis DT Others?
15:30-16:00	Coffee break	
16:00-17:00	Feedback and joint discussion	
17:30	Conclusion and Adjourn	

DAY 4, Thursday 13 June 2019		
Time	Topic	Speaker
7:45 – 8:45	Breakfast for non-residential participants	
9:00-10:00	Presentation of proposals by working groups: how to accelerate lot release and reduce animal use	Working groups
10:00-10:30	Final discussions and agreement on next step(s)	All participants
10:30-11:00	Coffee Break	
11:00-11:30	Application of combo filling line for vaccine sterile production	P.Peng Tofflon, India
11:30- 12:00	Q & A and adjourn	All participants
12:00-13:30	Lunch	All participants
13:30	Departure individually	