

DCVMN 3Rs Workshop
Implementing the Diphtheria-Tetanus Single Dilution Assay for
Potency Calculation
27 January 2022 12:00-14:45 PM (CET) - Zoom

Chair: *Christina Von Hunolstein*
Panelists: *Christina Von Hunolstein*
Sunil Gairola, Samir Desai, Pradip Das, Varma Bhupathiraju
Organizers: *Laura Viviani and Sivashen Cunden*

Rationale and Objectives

The single dilution assay for the potency calculation of Diphtheria-Tetanus containing vaccines reduce the number of animals required for the serological potency assay. The single dilution is performed when the potency of the test vaccine consistently and significantly exceeds minimum requirements (i.e. the potency of the test vaccine is significantly greater than the minimum requirement per human dose for the product under test) and when parallelism between test and reference vaccine has been demonstrated over time. An amendment to the diphtheria and tetanus sections of wP containing vaccines concerning single dilution and in vitro potency assays was adopted by the Expert Committee on Biological Standardization in 2004 (c.f. *Requirements for Diphtheria, tetanus, pertussis and combined vaccines. In: WHO Expert Committee on Biological Standardization. Fortieth report. Geneva, World Health Organization, 1990, Annex 2 - WHO Technical Report Series, No. 800*) and the single dilution is included into the Tetanus and Diphtheria TRS 980 and into the WHO Manual for Quality Control of Diphtheria, Tetanus and Pertussis Vaccines (IVB 11.11, 2013).

The objectives of the workshop are:

- A) Introduce the opportunity for the implementation of the single dilution assay for DT-containing vaccines, via the experience of DCVMN members
- B) Discuss about DCVMN opportunities to support the implementation among the network

Live Survey to assess implementation of single dilution assay within DCVMN -

PSPT Project Workshop Participants profile:

DCVMN secretariat and project management.
DCVMN 3Rs WG members and DCVMN members with TD containing vaccines
DCVMN Regulatory WG members and DCVMN members with TD containing vaccines
PSPT Consortium Members

The workshop will be in English and there will be no translation service.

27th of January, 2022

Time	Topic	Speaker
12:00-12:10	Opening remarks	<i>C. von Hunolstein</i> <i>Sunil Gairola</i>
12:10-13:40	Implementation of DT Single Dilution assay <ul style="list-style-type: none">- Background of SDA- Quality Control- Regulatory Perspective- Benefits- Summary	Pradip Das & Varma Bhupathiraju / Biological E
10-20 min? Dependent on complexity on questions	Live poll of Interest and Implementation Have there been any difficulties in implementation within your company	
	Opportunities for DCVMN	L.Vivani
	Expert Panel Q&A	Open Discussion
	Closing remarks	<i>C. von Hunolstein</i>