

**E-workshop (via WebEx) on
Statistical Analysis of Stability Testing
21st April 2020
6 AM EST – 12 PM CET – 04:30 PM IST**

Objectives:

The objectives of the workshop are:

- A) Familiarize with the basic principle of stability;
- B) Learn about the vaccine stability study design and analysis aimed for product licensure and how to maintain vaccine stability through annual stability and comparability studies;
- C) Review DCVMN viewpoints on technical and administrative issues in stability testing of vaccines.

Participants profile:

Participants are staff from Quality Assurance Quality Control, and Regulatory Affairs Departments from vaccine manufacturing companies having a good level of spoken and written English and closely involved with stability testing.

Suggested Pre-readings

Elsevier and the journal Biologicals granted one year access to the special issue on "[Stability Evaluation of Vaccines](#)" (Edited by Timothy Schofield, Philip R. Krause, Volume 37, Issue 6, pages 355-444, November 2009).

Among that issue you're invited to read the following papers.

[Basic principles of stability](#), William Egan, Timothy Schofield, Pages 379-386

[Vaccine stability study design and analysis to support product licensure](#), Timothy Schofield, Pages 387-396

[Maintenance of vaccine stability through annual stability and comparability studies](#), Timothy Schofield, Pages 397-402

[Stability testing of vaccines: Developing Countries Vaccine Manufacturers' Network \(DCVMN\) perspective](#), Suresh S. Jadhav, Vikas Dogar, Manish Gautam, Sunil Gairola, Pages 360-363

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.

Wednesday April 21 st 2021		
Time	Topic	Speaker
11:30-12:00 (CET)	Registration & Introduction	DCVMN
12:00-12:45 (CET)	Basic principle of stability, study design and analysis for product licensure	T. Schofield, CMC Sciences
12:45-12:55 (CET)	Q&A on the chat box	T. Schofield, CMC Sciences
12:55-13:05 (CET)	Break	
13:05-13:50 (CET)	Maintenance of vaccine stability through annual stability and comparability studies	T. Schofield, CMC Sciences
13:50-14:05 (CET)	Q&A on the chat box	T. Schofield, CMC Sciences
14:05-14:15 (CET)	Break	
14:15-15:00 (CET)	Stability testing for vaccines: DCVMN perspective	P. Tyagi, Serum Institute of India
15:00-15:15	Q&A on the chat box	P. Tyagi, Serum Institute of India
15:15	Adjourn	

Speakers

Timothy Schofield, owner and consultant at CMC Sciences (US)

Parikshit Tyagi, DGM – Quality Control, Serum Institute of India (India)