



**In collaboration with HSI
IABS Webinar**

Global availability of critical reagents for biologicals testing. Current status, challenges and possible solutions

Webinar

July 2nd, 2024

The issue of availability and affordability of critical reagents and standards to be used for vaccines and other biologicals production and release testing has been reported to be one of the main bottlenecks to be solved for new methods' implementation, validation and acceptance, in particular within the various countries and regions. The topic has been discussed in many occasions in the last years but a dedicated discussion is much needed between all the stakeholders, in light of the ongoing global initiatives and of the country and regional challenges, needs and priorities. The workshop will better define the issue and provide possible solutions.

Scientific Committee

Representatives from

IABS: Joris Vandeputte, Carmen Jungbäck

HSI/ScEthiQ: Laura Viviani

HealthCanada: Dean Smith

EDQM: Catherine Milne

WHO: Dianliang Lei

MHRA: Paul Stickings

PATH: Kutub Mahmood

DCVMN: Sunil Kumar Goel

IFPMA: Lyne Le Palair

Consultant for HSI: Blaise Descampe

Webinar Agenda – Tuesday, July 2nd, 2024

Times are indicated CEST

- 12:30pm **Welcome from IABS and HSI**
Joris Vandeputte – IABS & Laura Viviani – SciEthiQ/HSI
- 12:35pm **Scientific Considerations for the Lifecycle Management of Vaccine Reference Standards and the Impact of Animal Assay Use**
Dean Smith – HealthCanada

Session 1: An overview of successful examples of collaborations on reagents production, availability and affordability.

- 1:00pm **Case study: DTP reagents**
Emmanuelle Coppens – Sanofi on behalf of the VAC2VAC Consortium
- 1:30pm **Case study: influenza vaccine potency reagents**
Maryna Eichelberger – CBER FDA, USA
- 2:00pm **Case study: NGS standards for adventitious virus detection**
Arifa Khan - USFDA
- 2:30pm **Case study: PATH efforts on universal reagents and reference standard development**
Kutub Mahmood - PATH

Session 2: Describing the challenges: stakeholder's perspectives

- 3:00pm **Developing Countries Vaccine Manufacturers Network perspective**
Sunil Goel – Serum Institute of India on behalf of DCVMN
- 3:30pm **Non animal based reagents manufacturers perspective**
Esther Wenzel – Abcalis
- 4:00pm **Critical Reagents in China**
Le Sun – Abmax, China
- 4:30pm **The EU/EEA OCABR network; maximising resources through work sharing and mutual recognition**
Catherine Milne – EDQM
- 5:00pm **The South Africa example on the application of the reliance principle**
Quinton Meyer – South Africa National Control Laboratory for Biological Products
- 5:30pm **Roundtable: Reagents availability and affordability. What kind of solutions can be implemented to remove current barriers?**
Panelists: All speakers and Mic McGoldrick – Merck Sharp & Dohme, LLC on behalf of IFPMA
Chair: Laura Viviani (SciEthiQ for HSI)
Co-Chair: Dean Smith (HealthCanada)
- 6:00pm **Closing Remarks**
Joris Vandeputte – IABS & Laura Viviani – SciEthiQ/HSI
- 6:05pm *End of the meeting*