



IABS Next Generation Sequencing Webinar

September 25 & 26, 2024

Virtual

The IABS NGS webinar will give an introduction to Next Generation Sequencing (NGS) technologies and their applications in the viral safety testing package of biological products. It will particularly cover a review of the sources of introducing adventitious viral agent contamination in the biomanufacturing process, reports of cases of contamination with adventitious viral agents, considerations for using NGS as an alternative method for the current adventitious virus detection assays, and an overview of the different steps in the NGS workflow.

The talks and discussions focus on enhancing viral safety of biologics. The webinar will also provide an overview of the Advanced Virus Detection Technologies Working group (AVDTWG) activities and an update of the regulatory landscape from various regions.

The webinar is addressed to all manufacturers and regulators who want to learn about NGS applications for adventitious viral agent detection in biological products following its recent introduction in the ICHQ5A (R2) guideline and the publication for comment of the new EDQM/Ph. Eur general chapter 2.6.41 “High-Throughput Sequencing for the detection of viral extraneous agents

SCIENTIFIC COMMITTEE

- **Arifa S. KHAN** – U.S. Food and Drug Administration, Center for Biologics Evaluation and Research FDA-CBER (FDA) – U.S.A. – Co-Chair
- **Laurent MALLET** – European Directorate for the Quality of Medicines & HealthCare (EDQM) – France – Co-Chair
- **Pieter NEELS** – International Alliance for Biological Standardization (IABS) – Chair, Human Vaccine Scientific Committee – Belgium
- **Johannes BLÜMEL** – Paul-Ehrlich Institut (PEI) – Germany
- **Noémie DENEYER** – GlaxoSmithKline (GSK) Vaccines – Belgium
- **Sigrid DE KEERSMAECKER** – Sciensano – Belgium
- **Blandine DE SAINT-VIS** – Boehringer Ingelheim – France
- **Ivana KNEZEVIC** – World Health Organization (WHO) – Switzerland
- **Carine LOGVINOFF** – Sanofi – France
- **Marie MURPHY** – Eli Lilly & Co – Ireland
- **Siemon NG** – Notch Therapeutics Canada
- **Yoji SATO** – National Institute of Health Sciences – Japan
- **Michael WALL** – Health Canada

PROVISIONAL AGENDA

DAY 1 – WEDNESDAY 25 OF SEPTEMBER, 2024

Times are indicated CEST

Moderator: *Laurent MALLET, EDQM, France*

- 12.00pm** Welcome Remarks from IABS – **Rick HILL**, IABS President
Welcome Remarks from Chairs
- 12.10pm** **Viral Safety of Biologics**
45' **Arifa KHAN**, USFDA, FDA-CBER, U.S.A.
- 12.55pm** Q&A Session
10'
- 1.05pm** **Cases of contamination with adventitious viral agents in Biological Products**
30' **Carine LOGVINOFF**, Sanofi, France
- 1.40pm** Q&A Session
10'
- 1.50pm** *Break*
10'
- 2.00pm** **What is NGS?**
45' **Siemon NG**, Notch Therapeutics, Canada
- 2.45pm** Q&A Session
10'
- 2.55pm** **Panel Discussion**
60'
 - **Arifa KHAN**, USFDA, FDA-CBER, U.S.A.
 - **Carine LOGVINOFF**, Sanofi, France
 - **Siemon NG**, Notch Therapeutics, Canada
 - **Sigrid DEKEERSMAECKER**, Sciensano, Belgium
 - **Ken KONO**, NIHS, Japan
 - **Johannes BLÜMEL**, PEI, Germany
- 4.00pm** *End of Day 1*

DAY 2 – THURSDAY 26 OF SEPTEMBER, 2024

Times are indicated CEST

Moderator: *Siemon NG, Notch Therapeutics, Canada*

- 12.00pm** Welcome Remarks: IABS & Chairs
- 12.10pm** **Advanced Virus Detection Technologies Working Group (AVDTWG) overview**
45'
Siemon NG, Notch Therapeutics, Canada
Noémie DENEYER, GlaxoSmithKline (GSK) Vaccines, Belgium
- 12.55pm** Q&A Session
10'
- 1.05pm** **Regulatory Landscape**
20'
20'
20'
- **Overview of ICHQ5A (R2)** - **Johannes BLÜMEL**, PEI, Germany
- **EDQM Perspectives** - **Laurent MALLET**, EDQM, France
- **FDA Perspectives** – **Arifa KHAN**, USFDA, FDA-CBER (FDA), U.S.A.
- 2.05pm** *Break*
15'
- 2.15pm** **Regulatory Landscape**
20'
- **WHO Perspectives** – **Ivana KNEZEVIC**, WHO, Switzerland
- 2.35pm** **Panel Discussion: Regulatory Expectations and Industry Perspectives**
60'
- **Arifa KHAN**, USFDA, FDA-CBER (FDA), U.S.A.
- **Carine LOGVINOFF**, Sanofi, France
- **Laurent MALLET**, EDQM, France
- **Johannes BLÜMEL**, PEI, Germany
- **Ivana KNEZEVIC**, WHO, Switzerland
- **Michael WALL**, Health Canada
- **Marie MURPHY**, Eli Lilly & Co, Ireland
- **Noémie DENEYER**, GlaxoSmithKline (GSK) Vaccines, Belgium
- **Blandine DE SAINT VIS**, Boehringer Ingelheim, France
- **Ryutaro HIRASAWA**, Daiichi Sankyo Co., Japan
- **Industry Representative**
- 3.35pm** Conclusion
15'
- 3.50pm** *End of Webinar*