



Training Workshop on Next Generation Sequencing for Adventitious Virus Detection in Biologics for Humans and Animals

December 3rd, 2024 - Frankfurt, Germany

2024 is a key year for globally considering NGS implementation with the recent publication of the revised ICHQ5A(R2) guideline and the upcoming draft chapter on NGS from the EDQM/European Pharmacopoeia. The 4th NGS meeting will continue to highlight current scientific data and knowledge with focus on NGS implementation for adventitious virus detection in biological products. Discussions will include capabilities of NGS for virus detection in different matrices and validation of the technical and bioinformatics steps involved in NGS for its applications in characterization and safety evaluation of biologics such as vaccines for human and veterinary use, gene and cell therapy products, and biotherapeutics. The meeting will bring together representatives from industry, academia, technology providers, and international regulatory bodies for discussing the current applications of NGS for detection of adventitious viruses in biologics.

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** – GSK – 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 – Ireland
- **Siemon NG** – Notch Therapeutics Canada
- **Yoji SATO** – National Institute of Health Sciences – Japan
- **Michael WALL** – Health Canada

Tuesday 3rd of December 2024

- 8.30am** *Registration & Welcome Coffee*
- 9.00am** Welcome Remarks: IABS & Chairs
Laurent MALLET – European Directorate for the Quality of Medicines & HealthCare (EDQM) – France – Co-Chair
- 9.10am** **General Overview of the NGS**
Carine LOGVINOFF, Sanofi, France
Siemon NG, Notch Therapeutics, Canada
- 9.55am** Q&A Session
- 10.10am** *Coffee Break*
- 10.40am** **Sequencing Instrument Presentations**
- **Illumina**
Felix KROMBHOLZ
- 11.05am** - **Nanopore**
Veronica FOWLER
Tim WALKER
- 11.30am** - **PacBio**
Felix WOLTER
Natalie KAHN
- 11.55am** Round Table & Q&A
Illumina, Nanopore, PacBio
- 12.15pm** *Lunch break*
- 1.15pm** **Sample and Library Preparation (Challenges, Specific examples)**
Siemon NG, Notch Therapeutics, Canada
- 2.00pm** Q&A Session

- 2.15pm** **Bioinformatics (different tools, targeted/non targeted, reference database)**
Pei-Ju CHIN, USFDA, U.S.A.
- 3.15pm** Q&A Session
- 3.30pm** *Coffee break*
- 4.00pm** **Follow-up investigations**
Christophe LAMBERT, GSK, Belgium
- 4.30pm** Q&A Session
- 4.45pm** **Panel Discussion – Technical Challenges for Using NGS for Adventitious Virus Detection**
Perspectives from presenters and participants
Carine LOGVINOFF, Sanofi, France
Siemon NG, Notch Therapeutics, Canada
Pei-Ju CHIN, USFDA, U.S.A.
Christophe LAMBERT, GSK, Belgium
Sigrid DE KEERSMAECKER, Sciensano, Belgium
Blandine DE SAINT-VIS, Boehringer Ingelheim Animal Health, France
Johannes BLÜMEL – Paul-Ehrlich Institut (PEI) – Germany
- 5.45pm** *Closing remarks*
Arifa S. KHAN – U.S. Food and Drug Administration, Center for Biologics Evaluation and Research FDA-CBER (FDA) – U.S.A. – Co-Chair
End of Training Workshop
- 5.45pm**
6.45pm **Meet & Greet: Advanced Virus Detection Technologies Working Group (AVDTWG)**
Open to all on-site attendees of the Training workshop and the 4th NGS Conference
[Link to the Working Group presentation at the IABS Webinar \(September 25-26, 2024\)](#)