



4th Conference on Next Generation Sequencing for Adventitious Virus Detection in Biologics for Humans and Animals: Validation and Implementation of NGS

**December 4 & 5, 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 as an alternative method for replacing or supplementing the current conventional assays 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** – 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

DAY 1 – WEDNESDAY 4 OF DECEMBER 2024

8.30am *Registration & Welcome Coffee*

9.00am Welcome Remarks: IABS & Chairs

Rick Hill, IABS, USA

Arifa 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

INTRODUCTION

9.10am **Introduction** – Summary of Previous Meetings and Goal of the 4th meeting

Arifa 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

SESSION 1 – Current Perspectives on Using NGS for Adventitious Virus Testing

Moderators: Laurent Mallet & Arifa Khan

9.30am Next Generation Sequencing and ICH Q5A(R2)

Johannes BLÜMEL, Paul-Ehrlich Institute (PEI), Germany

10.00am EDQM/Ph. Eur. perspectives on NGS/HTS

Laurent MALLET, Co-Chair & **Gwenael CIREFICE**, European Directorate for the Quality of
Medicines & HealthCare (EDQM), France

10.30am FDA

Arifa KHAN, U.S. Food and Drug Administration, Center for Biologics Evaluation and Research
FDA-CBER (FDA), U.S.A. – Co-Chair

11.00am WHO

Ivana KNEZEVIC, World Health Organization (WHO), Switzerland

11.30am *Coffee break*

12.00pm Perspectives from the CAACB on the Current Benefits and Challenges of NGS Adoption for Viral
Safety Testing

Charles SWOFFORD, MIT Center for Biomedical Innovation

12.30pm EFPIA's Perspectives on the Validation and Implementation of Next Generation Sequencing for Virus Safety Testing of Biological Products
Noémie DENEYER, GSK, Belgium, Member of the EFPIA WG

1.00pm *Lunch*

2.00pm **Panel Discussion**
Johannes BLÜMEL, Paul-Ehrlich Institute (PEI), Germany
Laurent MALLET, Co-Chair, European Directorate for the Quality of Medicines & HealthCare (EDQM), France
Gwenael CIREFICE, European Directorate for the Quality of Medicines & HealthCare (EDQM), France
Arifa KHAN, U.S. Food and Drug Administration, Center for Biologics Evaluation and Research FDA-CBER (FDA), U.S.A. – Co-Chair
Ivana KNEZEVIC, World Health Organization (WHO), Switzerland
Charles SWOFFORD, MIT Center for Biomedical Innovation
Noémie DENEYER, GSK, Belgium, Member of the EFPIA WG
Juliati DAHLAN, National Agency of Drugs and Food Control, Indonesia (Virtual)
Hadeer ABOSALEM, Egyptian Drug Authority EDA, Egypt (Virtual)
Hamida BEGUM, Bangladesh (Virtual)

SESSION 2 – Reference Materials, NGS Qualification and Validation

Moderators: Sigrid De Keersmaecker, Johannes Blümel

2.45pm Transcriptomic NGS assay of cells as a substitute for conventional virus testing techniques
Marc ELOIT, Pathoquest, France

3.10pm Matrix effects on Limit of Detection for NGS-based Adventitious Virus Detection Assays
Bradley HASSON, MilliporeSigma, U.S.A.

3.35pm AVDTWG Spiking Study 4 - Evaluation of Long-Read Sequencing for Adventitious Virus Detection in a Low Complexity Viral Background
Valeria ZANDA, Merck, Italy

4.00pm *Coffee Break*

4.30pm Head-to-head comparison of NGS with in vivo animal assays and in vitro cell culture assays for adventitious virus detection
Alison ARMSTRONG, Merck KgAG on behalf of NIIMBL PC3.1-305 project team

4.55pm Refinement Efforts on CBER's Reference Virus Database (RVDB) to Enhance Accuracy and Specificity of Virus Detection
Pei-Ju CHIN, US FDA, U.S.A.

- 5.20pm** Next Generation Sequencing: Validation, Regulatory Approval and Implementation of NGS as an alternative *In Vivo* Testing for Live Attenuated Influenza Vaccine
Alice ALSTON, AstraZeneca (*Virtual*)
- 5.50pm** **Panel Discussion**
- 6.30pm** *End of Day 1*

DAY 2 – THURSDAY 5 OF DECEMBER 2024

- 8.00am** *Registration & Welcome Coffee*

SESSION 3 – NGS Applications

Moderators : Michael Wall, Blandine de Saint-Vis

- 8.30am** Comparison of Non-Targeted and Broad-Spectrum Targeted NGS for Adventitious Virus Detection
Gibran Horemheb RUBIO QUINTANARES, Paul Ehrlich Institute, Germany
- 8.55am** Comparison of Long- and Short-Read Sequencing Methods for Recombinant Adeno-Associated Virus Sequence and Adventitious Agent Identification in a GMP Environment
Megan GURA, Regeneron, U.S.A.
- 9.20am** Selecting and developing approaches for adventitious virus detection by HTS, contrasting release testing with investigational follow-up
Carine LOGVINOFF, Sanofi, France
Song SUN, Sanofi, Canada
- 9.45am** *Coffee Break – POSTER SESSION*
- 10.30am** Current status for testing of adventitious agents by NGS at Serum Institute of India Pvt. Ltd. and way forward
Subhashis CHATTERJEE, Serum Institute of India, India
- 10.55am** BLOODVIR – Surveillance system for novel viruses based on next generation sequencing and artificial intelligence
Martin MACHYNA, Paul Ehrlich Institute, Germany
- 11.20am** **Panel Discussion**
- 12.20pm** *Lunch*

SESSION 4 - Strategies for Optimization of NGS Virus Detection and Follow-up of NGS Signal

Moderators: Siemon Ng, Marie Murphy

- 1.30pm** Rapid alignment-free detection of adventitious agents using next-generation sequencing
Tom J.B. DE MAN, Millipore Sigma, U.S.A.
- 1.55pm** Viral metagenomic analysis to complement the viral risk assessment and adventitious agent testing of live virus vaccines
Vanessa V. SARATHY, Merck, U.S.A.
- 2.20pm** Evolution of a bioinformatics pipeline for adventitious agent detection
Robert L. CHARLEBOIS, Sanofi, Canada
- 2.45pm** **Panel Discussion**
- 3.20pm** *Coffee Break*

SESSION 5 – Implementation of NGS in Biologics

Moderators: Ivana Knezevic, Laurent Mallet, Arifa Khan

- 3.50pm** **Final Panel Discussion (Regulators, Industries and CROs)**
Johannes BLÜMEL, Paul-Ehrlich Institut (PEI), Germany
Ken KONO, National Institute of Health Sciences, Japan
Marc ELOIT, Pathoquest, France
Alison ARMSTRONG, Merck KgAG
Carine LOGVINOFF, Sanofi, France
Blandine DE SAINT-VIS, Boehringer Ingelheim Health Animal, France
Marie MURPHY, Eli Lilly & Co, Ireland
Siemon NG, Notch Therapeutics, Canada
Christophe LAMBERT, GSK, Belgium
Gwenael CIREFICE, European Directorate for the Quality of Medicines & HealthCare (EDQM)
Pei-Ju CHIN, US FDA, U.S.A.
Ajmeer RAMKISHAN, Ministry of Health & Family Welfare, India (Virtual)
Koji ISHII, National Institute of Infectious Diseases, Japan (Virtual)
Igishie USHIE, National Agency For Food And Drug Administration And Control (NAFDAC, Nigeria (Virtual)
- 5.20pm** Summary & Conclusion
- 5.30pm** Closing Remarks
- 5.40pm** *End of meeting*