3rd Conference on Next Generation Sequencing for Adventitious Virus Detection in Biologics for Humans and Animals

University of Maryland –
Institute for Bioscience and Biotechnology Research (IBBR)
Rockville, Maryland, U.S.A.
September 27 - 28, 2022

This face-to-face meeting will focus on the recent expansion of scientific data and the current applications of next generation sequencing technologies for adventitious virus detection in biological products. This will include presentations on standardization and validation of the technical and bioinformatics steps involved in the NGS workflow and applications of different NGS strategies for characterization and safety evaluation of biologics, including human and animal vaccines, as well as gene therapy, and therapeutic products Current regulatory expectations will be discussed. The meeting will bring together representatives from industry, academia, contract research organizations, and international regulatory bodies for developing a scientific consensus regarding recommendations for using NGS for detection of adventitious viruses.

Scientific Committee

Name	Organization
Arifa S. KHAN	U.S. Food and Drug Administration, Center for Biologics Evaluation and Research FDA-CBER, U.S.A. Co-Chair, U.S.A.
Laurent MALLET	European Directorate for the Quality of Medicines & HealthCare (EDQM) – Co-Chair, France
Pieter NEELS	International Alliance for Biological Standardization (IABS) Chair, Human Vaccine Scientific Committee, Belgium
Johannes BLÜMEL	Paul-Ehrlich Institut (PEI), Germany
Jean-Pol CASSART	GlaxoSmithKline (GSK) Vaccines, Belgium
Miia JAKAVA-VILJANEN	Finnish Food Authority
Ivana KNEZEVIC	World Health Organization (WHO), Switzerland
Carine LOGVINOFF	Sanofi, France
Siemon NG	Notch Therapeutics, Canada
Michael WALL	Health Canada

AGENDA

Day 1 - Tuesday, September 27, 2022

8:00 am Registration & Welcome Coffee

8:30 am Welcome Remarks:
Rick HILL, IABS President
Pieter NEELS, Chair, IABS Human Vaccine Committee

8:45 am **Introduction** – Summary of Previous Meetings and Goals of the 3rd meeting
Arifa KHAN, U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (FDA-CBER), U.S.A.
Laurent MALLET, European Directorate for the Quality of Medicines & HealthCare (EDQM), France

9:15 am **Keynote**
Latest Advances in Next Generation Sequencing and Their Impact on Biological Product Control
Domenico GENOVESE, Istituto Superiore di Sanità (ISS), Italy

Session 1 - Regulatory and Health Authority Perspectives on Using NGS for Adventitious Virus Testing

Chairpersons: **Robin LEVIS,** U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (FDA-CBER), USA
& Johannes BLÜMEL, Paul-Ehrlich-Institut, Germany

9:45 am FDA Perspectives and Ongoing Efforts on Next Generation Sequencing for Adventitious Virus Detection
Arifa KHAN, U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (FDA-CBER), U.S.A.

10:15 am EDQM Achievements and Perspectives on Next Generation Sequencing
Laurent MALLET & Gwenael CIREFICE, European Directorate for the Quality of Medicines & HealthCare (EDQM), France

10:45 am **Coffee break**

11:15 am Use of NGS in Adventitious Virus Screening of Biological Medicinal Products: Regulatory Requirements
Koen BRUSSELMANS, Sciensano, Belgium

11:45 am PMDA's Perspective and Discussion Points in Replacing Conventional Methods with NGS for Virus Testing in the Manufacturing Process of Pharmaceutical Products
Akira SAKURAI, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

12:15 pm **Lunch**

1:15 pm High Throughput Sequencing for Detection of Adventitious Agents in Biological Products: WHO Approach
Ivana KNEZEVIC, World Health Organization (WHO), Switzerland *(virtual)*

1:45 pm **Panel Discussion**

2:30 pm **Break**

Session 2 - Reference Materials, NGS Qualification and Validation

Chairpersons: **Kathryn KING,** U.S. Food and Drug Administration, Center for Drugs Evaluation and Research (FDA-CDER)
& Jean-Pol CASSART, GlaxoSmithKline (GSK) Vaccines, Belgium

3:00 pm Updates on NGS Efforts in the Advanced Virus Detection Technologies Interest Group (AVDTIG)
Siemon NG, Notch Therapeutics, Canada

3:25 pm Reference Materials for Adventitious Virus Detection by NGS: Establishment of WHO International Reference Virus Reagents and Update on CBER's Reference Virus Database (RVDB)
Pei-Ju CHIN, U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (FDA-CBER), U.S.A.

3:50 pm RNA Next-generation Sequencing Transcriptomics Analysis: A Validated Method to Assess Viral Safety of Cell Substrates
Pascale **BEURDELEY**, PathoQuest, France

4:15 pm **Break**

4:40 pm Towards the Use of NGS to Control Veterinary Master Seeds: A Challenging Method to Validate
Blandine De SAINT-VIS, Boehringer Ingelheim, France

5:05 pm Next Generation Sequencing Application for Adventitious Virus Testing: Limit of Detection Study in an Influenza Vaccine Background
Bradley HASSON, MilliporeSigma, U.S.A.

5:30 pm **Panel Discussion**

6:00 pm **Poster Presentation & Reception**

7:15 pm **End of Day 1**

Day 2 – Wednesday, September 28, 2022

8:00 am Registration & Welcome Coffee

Session 3 - NGS Applications for Adventitious Virus Testing

Chairpersons: **Robert CHARLEBOIS,** Sanofi, Canada
& Christophe LAMBERT, GlaxoSmithKline, Belgium

8:30 am Next Generation Sequencing Transcriptomics Analysis: An Alternative Method to Replace in Vivo Tests for Assessing the Viral Safety of Cells
Marc ELOIT – PathoQuest, France

8:55 am Developing Sample-tailored Procedures for In-Depth Analysis of Gene Therapy Products Using High-Throughput Sequencing
Katarina BAČNIK, National Institute of Biology, Slovenia

9:20 am Development of a Sample Preparation Pipeline Using Oxford Nanopore Technologies (ONT) Sequencing for the Rapid Detection of Adventitious Agents
Charles A. SWOFFORD, Massachusetts Institute of Technology, U.S.A.

9:45 am NGS Implementation Strategy for Adventitious Virus Detection in an Adenovirus Vaccine
Aurora SIGNORAZZI, Janssen Vaccines & Prevention B.V., Netherlands

10:10 am **Break**

10:35 am Next Generation Sequencing to Unravel a Positive Signal in QC Investigation: Pitfalls and Learnings
Noemie DENEYER, GSK Vaccines, Belgium

11:00 am Sensitivity of Latent Endogenous Virus Detection Using High-Throughput Genome Sequencing
Sandra FUENTES, U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (FDA-CBER), U.S.A.

11:25 am LABRADOR – a GMP Validated Workflow for Virus Detection
Izabela FABIANSKA, IDT Biologika GmbH, Germany *(virtual)*

11:50 am **Panel Discussion**

12:05 **Lunch**

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

Chairpersons: **Alison ARMSTRONG,** MilliporeSigma, U.S.A.
& Siemon NG, Notch Therapeutics, Canada

1:05 pm Overview: Strategies to Optimize Next Generation Sequencing (NGS) Bioinformatics Pipelines for Virus Detection
Christophe LAMBERT, GSK Vaccines, Belgium

1:30 pm Overview: Deciding on Actionable Signals from an HTS-based Adventitious Virus Detection Assay
Robert CHARLEBOIS, Sanofi, Canada

1:55 pm NGS for Adventitious Agent Detection: Analysis Options and Consequences
Qiu RUAN, Genedata, Switzerland

2:20 Break

2:30 pm Reducing the Haystack to Find the Needle: Improved HTS Assay Sensitivity by Host Depletion in Biological Samples
Song SUN, Sanofi, Canada

2:55 pm Host RNA Depletion for Increased Sensitivity of Random Amplification for Next Generation Sequencing
David SUAREZ, Southeast Poultry Research Laboratory, Agricultural Research Service, USDA-ARS-SAA-SEPRL, U.S.A.

3:20 pm Panel discussion

3:35 pm **Break**

Session 5 – Expectations for NGS Implementation

Chairpersons: **Arifa KHAN,** U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, (FDA-CBER), U.S.A.
& Laurent MALLET, European Directorate for the Quality of Medicines & HealthCare (EDQM)

3:55pm **Panel discussion**

Alison ARMSTRONG	MilliporeSigma, U.S.A.
Johannes BLÜMEL	Paul-Ehrlich Institut (PEI), Germany
Koen BRUSSELMANS	Sciensano, Belgium
Jean-Pol CASSART	GlaxoSmithKline, Belgium
Gwenael CIREFICE	European Directorate for the Quality of Medicines & HealthCare (EDQM)
Marc ELOIT	PathoQuest, France
Ivana KNEZEVIC	World Health Organization (WHO), Switzerland (*virtual*)
Robin LEVIS	U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (FDA-CBER), U.S.A.
Robert CHARLEBOIS	Sanofi, Canada
Siemon NG	Notch Therapeutics, Canada
Blandine de SAINT-VIS	Boehringer Ingelheim, France
Akira SAKURAI	Pharmaceuticals and Medical Devices Agency, Japan
Michael WALL	Health Canada (*virtual*)

5:25 pm **Summary & Conclusion**
Arifa **KHAN,** U.S. Food and Drug Administration, Center for Biologics Evaluation and Research (FDA-CBER), U.S.A.
Laurent **MALLET,** European Directorate for the Quality of Medicines & HealthCare (EDQM**),** France

5:35 pm **Closing Remarks**
Pieter **NEELS**, International Alliance for Biological Standardization (IABS), Belgium

5:45 pm **End of meeting**