

Europe



2nd Conference on Next Generation Sequencing for Adventitious Virus Detection in Biologics for Humans and Animals

November 13-14, 2019

Het Pand, Ghent University, Belgium

This meeting will focus on the current scientific data and knowledge related to the use of next generation sequencing technologies for adventitious virus detection in biological products. Discussions will include ongoing efforts and future needs toward standardization and validation of the technical and bioinformatics steps involved in NGS for its applications in characterization and safety evaluation of biologics, including human and animal vaccines. The meeting will bring together representatives from industry, academia, technology providers, and international regulatory bodies for developing a scientific consensus regarding readiness of NGS for detection of adventitious viruses in biologics.

Scientific Committee

Name	Organization
Dieter Deforce	Ghent University, Federal Agency for Medicines and Health Products of Belgium
Sebastiaan Theuns	Ghent University
Arifa S. Khan	U.S. Food and Drug Administration (FDA)
Pieter Neels	International Alliance for Biological Standardization (IABS)
Sven Arnouts	Ghent University, PROVAXS
Johannes Blümel	Paul-Ehrlich Institut (PEI)
Carmen Jungbäck	International Alliance for Biological Standardization (IABS)
Ivana Knezevic	World Health Organization (WHO)
David Mackay	Advisor Veterinary Vaccinology
Laurent Mallet	Sanofi Pasteur
Gerald Schumann	Paul-Ehrlich Institut (PEI)
William Egan	GlaxoSmithKline
Joseph Victoria	Boehringer Ingelheim

AGENDA

Day 1 - Wednesday, November 13, 2019

08:30 Registration & Welcome Coffee

Session 1 - Introduction & Perspectives on NGS for adventitious virus detection

Chairpersons: Johannes Blümel, Paul-Ehrlich-Institut
William Egan, GlaxoSmithKline

- 09:00 Welcome & opening of the meeting by the organizers
Pieter Neels, Chair, IABS Human Vaccine Committee
- 09:10 Summary of the 1st NGS meeting in 2017 & progress since then
Arifa Khan, co-Chair; U.S. Food and Drug Administration
- 09:50 Goals of NGS as envisioned by the human and veterinary vaccine industry
Laurent Mallet, Sanofi Pasteur
- 10:15-10:45 Coffee break
- 10:45 Efforts of the Advanced Virus Detection Technologies Interest Group (AVDTIG) for NGS applications in biologics
Jean-Pol Cassart, GlaxoSmithKline
- 11:10 State of the art in bioinformatics analyses of viral next-generation sequencing data and consequences on follow-up investigation strategies
Robert Charlebois, Sanofi Pasteur
- 11:35-12:00 Q&A and Discussion
- 12:00-13:00 Lunch

Session 2 - Regulatory aspects

Chairpersons: Marion Gruber, U.S. Food and Drug Administration
David Mackay, Advisor in veterinary vaccinology

- 13:00 FDA Perspectives on using NGS for human vaccines
Robin Levis, US Food and Drug Administration
- 13:25 WHO approach for detection of AAs: scientific advances and regulatory challenges with NGS
Ivana Knezevic, World Health Organization

- 13:50 Perspective on NGS for adv virus detection at production of human biotherapeutics and ATMPs
Johannes Blümel, Paul-Ehrlich-Institut
- 14:15 Detection of extraneous agents in biological products using NGS: Regulatory aspects from a veterinary perspective
Javier Pozo Gonzalez, EMA
- 14:40-15:10 Q&A and Discussion
- 15:10-15:30 Coffee break

Session 3 - Standardization of next-generation sequencing

Chairpersons: **Laurent Mallet**, Sanofi Pasteur
Ivana Knezevic, World Health Organization

- 15:30 Outcomes of the NIST/FDA Workshop on Standards for NGS Detection of Viral Adventitious Agents in Biologics and Biomanufacturing
Megan Cleveland, National Institute of Standards and Technology
- 15:55 FDA references for NGS virus detection: virus stocks & viral database
Arifa Khan, U.S. Food and Drug Administration
- 16:20 NGS in the context of WHO standardization / NIBSC
Edward Mee, National Institute for Biological Standards and Control
- 16:45 Current Studies in the AVDTIG on Next Generation Sequencing (NGS) Standardization for Adventitious Virus Detection
Siemon Ng, Sanofi
Cassandra Braxton, Biogen
- 17:10 OIE: Standardization of NGS for animal health applications
Fredrik Granberg, Swedish University of Agricultural Sciences (SLU)
- 17:35-18:00 Q&A and Discussion

Day 2 - Thursday, November 14, 2019

08:00 Registration & Welcome Coffee

Session 4 - Validation & Applications of NGS for Adventitious Virus Testing

Chairpersons: **Dieter Deforce** - University of Ghent

Jelle Matthijssens - Rega Institute, KU Leuven

- 08:30 Welcome back
- 08:35 Advances in next-generation sequencing technologies
Sebastiaan Theuns, Ghent University
- 09:00 Validation of an NGS adventitious virus detection assay for a viral seed matrix
Siemon Ng, Sanofi Pasteur
- 09:25 Validation data to support NGS purity testing of veterinary master seeds
Blandine de Saint-Vis, Boehringer Ingelheim Animal Health
- 09:50-10:15 Coffee break
- 10:15 Hunting for the needle in the needlestack
Dawid Walas, Merckgroup, U.K.
- 10:40 Specific identification of cell infection: analysis of the cell transcriptome by stranded RNA analysis and/or metabolic labelling of RNAs
Marc Eloit, Institut Pasteur / Pathoquest
- 11:00 Dead or alive? Or How NGS can help make the difference between inert viral nucleic acids and replicative viruses
Audrey Brussel, LFB, Les Ulis
- 11:20 NGS Transcriptome as Read-out of Infectivity Assays to Specifically Detect Live Viruses
Jean-Pol Cassart, GlaxoSmithKline
- 11:40 Developing sample-tailored procedures for determination of adventitious viruses and non-product DNA in different biologicals (*Selected abstract*)
Katarina Bacnik, National Institute of Biology, Slovenia
- 12:00-12:15 Q&A
- 12:15-13:00 Lunch

Session 5 - Case studies: Follow-up of NGS signal detection

Chairpersons: **Carmen Jungbäck**, IABS
Joseph Victoria, Boehringer Ingelheim, Germany

- 13:00 Examples of usage and consequences of NGS in early R&D for animal health
Joseph Victoria, Boehringer Ingelheim
- 13:25 OHEJP-METASTAVA: Joint efforts in standardization and analytical validation of diagnostic metagenomics approaches in public (animal) health laboratories.
Steven Van Borm, Sciensano

13:50 NGS for viral vaccine testing - Dealing with (false) positive results
Mark Kerstjens, Janssen

14:05-14:35 Q&A - discussion

14:35-15:00 Coffee Break

Session 6 - Panel discussion/Conclusions and way forward

Chairpersons: **Arifa Khan**, U.S. Food and Drug Administration
Laurent Mallet, Sanofi Pasteur

Panelists

15:00-16:00 **Blandine De Saint-Vis**, Boehringer Ingelheim Animal Health

Simone Olgiati, Merckgroup

Emmanuelle Charton, EDQM

Ivana Knezevic, WHO

Johannes Blümel, PEI

Marc Eloit, Institut Pasteur

Marion Gruber, U.S. FDA

Siemon Ng, Sanofi Pasteur

William Egan, GlaxoSmithKline

Celine Lorteau, ANSES

16:00 **Closing remarks**
Sebastiaan Theuns, Ghent University