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

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