

*Europe*



# **2<sup>nd</sup> Conference on Next Generation Sequencing for Adventitious Virus Detection in Human and Veterinary Biologics**

**November 13-14, 2018  
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**

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

# AGENDA

## Day 1 - Wednesday, November 13, 2018

08:30 Registration & Welcome Coffee

### **Session 1 - Introduction & state of the art in the field of next-generation sequencing**

- 09:00 Welcome & opening of the meeting by the organizers
- 09:10 Summary of the 1st NGS meeting, 2017 & progress made since then
- 09:50 Goals of NGS as envisioned by the human and veterinary vaccine industry
- 10:15 Coffee break
- 10:45 Efforts of the Advanced Virus Detection Interest Group (AVDTIG) for NGS applications in biologics.
- 11:10 State of the art in bioinformatics analyses of viral next-generation sequencing data and consequences on follow-up investigation strategies
- 11:35 Q&A and Discussion
- 12:05 Lunch

### **Session 2 - Regulatory aspects**

- 13:00 FDA Perspectives on using NGS for Human Vaccines
- 13:25 WHO approach for detection of AAs: Scientific advances and regulatory challenges with NGS
- 13:50 Regulatory aspects from a veterinary perspective
- 14:15 Perspective from the Official Medicines Control Laboratory
- 14:40 Q&A and Discussion
- 15:10 Coffee break

## **Session 3 - Standardization of next-generation sequencing**

- 15:30 Summary of the workshop on NIST NGS Standards
- 15:55 FDA References for NGS Virus Detection: Virus Stocks & Viral Database
- 16:20 NGS in the context of WHO standardization / NIBSC
- 16:45 Current Studies in the AVDTIG on NGS Standardization for Adventitious Virus Detection
- 17:10 OIE: Standardization of NGS for Animal health applications
- 17:35 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**

- 08:30 Welcome back
- 08:35 Advances in next-generation sequencing technologies
- 09:00 Validation of an NGS Adventitious Virus Detection assay for a viral seed matrix
- 09:25 NGS for adventitious virus testing: veterinary applications
- 09:50 Coffee break
- 10:20 Title of talk
- 10:45 Title of talk
- 11:10 Selected abstract 1
- 11:25 Selected abstract 2
- 11:40 Q&A - discussion
- 12:10 Lunch

## **Session 5 - Case studies: consequences of NGS signal detection in industry**

|       |                           |
|-------|---------------------------|
| 13:00 | Speaker from Industry     |
| 13:25 | Speaker from an institute |
| 13:50 | Selected abstract 3       |
| 14:05 | Q&A - discussion          |
| 14:35 | Coffee Break              |

## **Session 6 - Panel discussion/Conclusions and way forward**