DRAFT AGENDA- Feb. 2022

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

Sept 27 - 28, 2022

IBBR / University of Maryland, Rockville, U.S.A.

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 (FDA) – Co-Chair
Pieter Neels	International Alliance for Biological Standardization (IABS)
Johannes Blümel	Paul-Ehrlich Institut (PEI)
Carmen Jungbäck	International Alliance for Biological Standardization (IABS)
Ivana Knezevic	World Health Organization (WHO)
Laurent Mallet	EDQM – Co-Chair
Siemon Ng	Notch Therapeutics
Carine Logvinoff	Sanofi
Jean-Pol Cassart	GlaxoSmithKline Vaccines
Mia Jakava-Viljanen	FIMEMA
Egbert Mundt	Boehringer-Ingelheim
Michael Wall	Health Canada
Jelle Matthijnssens	Rega Institute, KU Leuven

Day 1 -

08:00 Registration & Welcome Coffee

08:30 Welcome Remarks: IABS and Chairs

Session 1. Current thinking on using NGS for adventitious virus testing

- Regulatory and Health Authorities perspectives – FDA, EMA, PMDA Japan, HC, EDQM, WHO…
- Industry and CRO perspectives including experiences with regulators
- Q & A and panel discussion

Session 2. NGS applications for adventitious virus testing

- Currently available platforms and NGS strategies
- Different biological material types (virus seeds, cell banks, …)
- Human and veterinary biological products (vaccines, biotherapeutics)
- Q & A and panel discussion

Day 2 -

08:00 Registration & Welcome Coffee

Session 3. Standards, NGS qualification and validation

- Reference reagents
- Reference databases
- Case studies (*e.g.* LOD, breadth of virus detection)
- Q&A and Discussion

Session 4. Strategies for optimization of NGS virus detection and follow up of NGS signal

- Strategies to optimize NGS workflow including bioinformatics pipelines
- Specific case studies (follow up for distinguishing true/false hits)
- Q&A and Discussion

Session 5. Panel discussion – Expectations for NGS implementation

– Advancing NGS into broader regulatory applications

- Limitations and opportunities

Closing remarks