Next Generation Sequencing for Adventitious Virus Detection in Biologics

October 26-27, 2017
USP Headquarters, Rockville

The 2017 NGS conference will discuss current perspectives on NGS for adventitious virus detection in biologics with focus on applications for human vaccines and lessons learnt from veterinary vaccines. The meeting will include data presentations and discussions on the current status and future potential of using NGS for virus detection in selected applications of biologics. The meeting will bring together representatives from industry, academia, service providers, and regulatory bodies.

Scientific Committee

Arifa S. Khan	U.S. Food and Drug Administration
Luca Benetti	Merck & Co.
Hansi Dean	Takeda Vaccines, Inc.
Johannes Blümel	Paul-Ehrlich-Institut
Dieter Deforce	Ghent University
William Egan	GlaxoSmithKline
Carmen Jungbäck	International Alliance for Biological Standardization
Ivana Knezevic	World Health Organization
Alan Fauconnier	European Medicines Agency
Robin Levis	U.S. Food and Drug Administration
Laurent Mallet	Sanofi Pasteur
Dietmar Mayer	IDT Biologika
Philip Minor	National Institute for Biological Standards and Control
Pieter Neels	International Alliance for Biological Standardization
Gayle Pulle	Health Canada

AGENDA

Day 1 – Thursday Oct 26, 2017

7:30am Registration & Welcome Coffee
8:00am Introduction
Arifa Khan, co-Chair; U.S. Food and Drug Administration
Pieter Neels, co-Chair; IABS, Chair, IABS Human Vaccine Committee

Session 1 – Current Perspectives on NGS

Chairpersons: **Philip Minor**, National Institute for Biological Standards and Control, United Kingdom
Ivana Knezevic, World Health Organization, Switzerland

8:15am Regulatory perspective on high-throughput sequencing for virus detection
Arifa Khan, CBER / U.S. Food and Drug Administration

8:45am Detection of adventitious agents: WHO approach
Ivana Knezevic, World Health Organization, Switzerland

9:15am Adventitious agents: evolution of the European pharmacopoeia regulations and an industry perspective
Laurent Mallet, Sanofi Pasteur, France

9:45am Coffee Break

10.15am Using NGS to find novel pathogens in clinical samples
Richard Ellis, Animal and Plant Health Agency, United Kingdom

10:45am NGS incidence from an EU regulatory perspective: revisiting the myth of Pandora's box
Alan Fauconnier, European Medicines Agency, Belgium

11:15am Q&A and Discussion

12:00 noon Lunch

Session 2 –Efforts on NGS Standardization for Virus Detection

Chairpersons: **Laurent Mallet**, Sanofi Pasteur, France
Guanhua Wang, Health Canada

1:00pm Reference materials for adventitious virus detection by metagenomics
Ed Mee, National Institute for Biological Standards and Control, United Kingdom

1:30pm A multi-center study to evaluate the performance of high-throughput sequencing for virus detection
Jean-Pol Cassart, GlaxoSmithKline, Belgium

2:00pm Biopharmaceutical manufacturing requires high technology for quality assurance
Fabio La Neve, Merck Group, Italy

2:30pm Coffee Break

3:00pm NIST viral reference materials
Megan Cleveland, National Institute of Standards and Technology, U.S.A.

3:30pm Follow-up investigation strategies for viral nucleic acid signals detected by high-throughput sequencing
Robert Charlebois, Sanofi Pasteur, Canada

4:00pm Current development in bioinformatics tools for characterisation of the virome
Oskar Karlsson Lindsjö, Swedish University of Agriculture and Science

4:30pm Q&A and Discussion

5:30pm End of Day 1

Day 2 – Friday, October 27, 2017

Session 3 – NGS Applications for Biologics

Chairpersons: **Dieter Deforce**, University of Ghent, Belgium
Dietmar Mayer, IDT Biologika, Germany

8:00am Registration & Welcome Coffee

8:15am Koch's postulates in the age of viral metagenomics
Eric Delwart, University of California, San Francisco, U.S.A.

8:45am Purity testing of rabies vaccine by NGS against other species as approach for adventitious agent testing
Dietmar Mayer, IDT Biologika, Germany

9:15am Purity testing of veterinary master seeds by NGS: Schmallenberg MSV analysis
Blandine de Saint-Vis, Merial (now part of Boehringer-Ingelheim Animal Health), France

9:45am Coffee Break

10.15am The role of Next Generation Sequencing for the development and testing of veterinary biologics
David Suarez, U.S. Department of Agriculture

10:45am Application of next generation sequencing to a candidate vaccine-producing cell line for adventitious virus detection
Olivier Vandeputte, GlaxoSmithKline, Belgium

11:15am Q&A and Discussion

12:00 noon Lunch

Session 4 – Current virus detection assays and NGS

Chairpersons: **Johannes Blumel**, Paul-Ehrlich-Institut
Luca Benetti, Merck & Co., U.S.A.

1:00pm Performance of transcriptomic analysis by NGS for the detection of virus infection in cells and differentiation from carryover of viral nucleic acids
Marc Eloit, Institut Pasteur, France

1:30pm Dynamic monitoring of cell cultures using high throughput sequencing
Philip Krause, CBER / U.S. Food and Drug Administration

2:00pm Adventitious agents testing – a GMP-compliant way to high sensitive detection of extraneous viruses in vaccines – first data
Stefan Haase, IDT Biologika, Germany

2:30pm Towards the validation of a high-throughput sequencing assay for viral adventitious agent detection
Siemon Ng, Sanofi Pasteur, Canada

3:00pm Q&A and Discussion

3:30pm Coffee Break

Session 5 – Panel Discussion

Chairperson: **Philip Krause**, CBER / U.S. Food and Drug Administration
William Egan, GlaxoSmithKline; U.S.A.

4:00pm **Panelist**

Cassandra Braxton, Biogen, U.S.A.
Jean-Pol Cassart, GlaxoSmithKline, Belgium
Arifa Khan, U.S. Food and Drug Administration
Ivana Knezevic, World Health Organization, Switzerland
Shyh-Ching Lo, CBER / U.S. Food and Drug Administration
Laurent Mallet, Sanofi Pasteur, France
Philip Minor, National Institute for Biological Standards and Control, United Kingdom
David Suarez, U.S. Department of Agriculture
Dominick Vacante, Janssen

5:20pm **Closing remarks**
Arifa Khan U.S. Food and Drug Administration
Pieter Neels, International Alliance for Biological Standardization

5:30pm End of Meeting