International Alliance for Biological Standardization

4th Conference on Next Generation Sequencing for Adventitious Virus Detection in Biologics for Humans and Animal

Frankfurt, Germany
December 3-5, 2024

WHO perspectives on the use of HTS for detection of adventitious agents in biologicals

HTS technologies have the ability to detect both known and novel adventitious viruses in biological products. As an alternative to conventional adventitious virus detection, which relies on in vivo animal testing and in vitro cell culture assays or on polymerase chain reaction (PCR) assays, HTS has the potential to expand the breadth of virus detection while also significantly shortening the time required for the quality control testing of biological products. Importantly, the increasing implementation of HTS for this purpose aligns with, and provides support for, the shift towards reducing the use of animals in such testing. Encouraged by regulatory guidance worldwide, the need for international viral standards for HTS process qualification and validation to support the application of HTS to biological product virus safety testing has long been recognized.

The First WHO International Reference Panel for adventitious virus detection in biological products using high-throughput sequencing technologies established by WHO Expert Committee on Biological Standardization (ECBS) at its 79th meeting in March 2024 supports the wider use of such highly advanced and sensitive non-animal methods, with considerable benefits envisaged in accelerating testing timelines and thus expediting access to safe and affordable biological products. This reference panel supersedes WHO international reference reagents established by the ECBS in 2020.

WHO has initiated review of the current use of HTS in the regulatory evaluation of biological products with the aim to identify needs for technical support for its implementation into regulatory and manufacturing practices. Feedback from 16 participants who responded to the questions regarding the current practice in their countries will be presented at the IABS conference as a basis for discussion on the way forward.