International Alliance for Biological Standardization

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

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EFPIA's Perspective on the Use of Next Generation Sequencing for Virus Safety Testing

Viral safety testing of biotechnology products relies on extensive testing of the materials used in manufacturing, with a focus on cell banks of animal origin as a critical starting material. The ICH Q5A guideline, used worldwide as a reference for viral safety, has been recently revised to integrate the most up-to-date scientific knowledge and approaches developed over the last decades. Among them, Next Generation Sequencing (NGS) has emerged as a promising technology to detect a broad spectrum of viruses. Also known as high-throughput sequencing, NGS allows massive parallel generation of nucleic acid sequence data without prior sequence information, offering the potential to detect unknown or unexpected viruses.

In parallel with the development of Revision 2 of ICH Q5A, the EFPIA Working Subgroup for Clonality, Characterisation and Viral Safety of Cell Lines has been elaborating a position paper on the use of NGS for virus detection during manufacturing of biotechnology products, focusing mainly on recombinant proteins and vaccines. Envisaged as a practical guide, the paper aims at complementing ICH Q5A with more technical details and at providing a position from Industry for dialogue with Regulatory Authorities. Starting with an overview of the various types of tests used for virus safety testing, including molecular methods (PCR, NGS), the paper provides a detailed discussion on the technical and regulatory challenges that need to be addressed to successfully implement NGS for virus safety testing. The discussion is focused on three topics: recommended approaches for validation of the NGS-based analytical procedure; considerations related to the comparability of NGS-based methods with traditional virus safety tests in view of a replacement; and elements to elaborate a regulatory strategy for successful Health Authority approval of NGS for virus safety. The presentation will provide an overview of the key messages covered by the position paper.