International Alliance for Biological Standardization

Maintaining the Quality of Vaccines through the Use of Standards: Current Challenges and Future Opportunities
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Abstract

Case study: Human vaccine *in vitro* relative potency reference standard qualification in ELISA

Background

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together and is a major actor in the human vaccine supply world.

Challenges

Qualification of in-house biological reference standards used in *in vitro* relative potency ELISA test for release of new human vaccine material is complex to manage:

- No international reference standards are yet available.
- The limited initial reference standard stock leads to the need of managing multiple changes prior to identifying the primary/gold reference standard.
- The stability data package of the initial representative material is often limited (less than 5 years) at the time of regulatory submission.
- Changes of reference material during method lifecycle require an agreement from multiple different authorities which leads to a complex implementation strategy.
- Challenge for transferring Quality Control materials to National Control Laboratories or to other sites with relevant and complex importation requirements.

Proposed approach being taken

We propose to share a practical case-study of in-house biological reference standard qualifications and managements.

- Two approaches will be presented to define how an antigen content value can be determined: using either an absolute orthogonal method or using an antigen specific content method. In addition to the antigen content, the potency value of the primary/gold reference standard, representative of Phase III and supporting the efficacy of the vaccine, is assigned to 100%.
- To support the change of working reference standard lot, instead of using a two-tiered approach to bridge each reference standard to the primary reference standard, we propose the use of a one-tiered approach considering the successive comparability of the new reference standard versus the current one. Based on the product and process knowledge, the difference between new and in-use reference standards is expected to fall within a pre-defined interval depending on the method performance and therefore a 100% potency will be assigned to the new reference standard. This approach circumvents the impact of some potential stability evolutions and error propagation inherent to the application of corrective factor.
- Finally, to facilitate the lifecycle management and anticipate the change of reference standards, pre-approved qualification protocols are shared with authorities allowing to smooth and accelerate the new reference standard implementation.
- With a continued growth of vaccines in the coming years, we propose to improve the robustness of the transfer process to cope on the specific demands of National agencies and the importation process.