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

Challenges when assessing multi-component vaccine formulations

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Background – In vivo Potency assays are used for routine batch release testing for many vaccines. The variability that is inherent in many bioassays can be significantly reduced by the inclusion of a reference standard in the assay, with measurement of the biological response expressed in relative terms. Well characterised, stable reference materials are established as WHO International Standards based on evidence that they improve agreement between laboratories in one or more assay models. For some vaccines, this has facilitated the development of internationally agreed minimum criteria for potency that is applied during routine control testing.

Challenges – Biological standardisation is underpinned by the concept of comparing like vs. like, since valid relative potency estimates are dependent upon achieving an acceptable degree of parallelism between the reference vaccine and the test vaccine. The complexity of many vaccine products – in terms of the number and type of components and adjuvant used – means that there may be significant qualitative differences between the International Standard and the test vaccine. This can pose challenges either in routine testing or when transferring the unit of activity to a local standard in a calibration exercise, making it difficult to manage a local reference standard programme that is traceable to the International Standard. Qualitative differences between the reference standard and the test vaccine can also lead to discrepancy in results obtained for the same sample tested in different laboratories (or assay models). This case study will present some examples of these challenges and the implications for using common acceptance criteria for potency across different product types.