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

Regulatory expectations on the use of vaccine reference standards for maintaining product quality.

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Introduction – The manufacture of vaccines often involves complex processes requiring a strict control strategy at all steps. The Final Drug product should meet all requirements regarding safety and efficacy before its release to the market. The use of (international) reference standards or reference preparations plays a key role in assay validation and product qualification.

Challenges – Manufactures are sometimes faced with the challenge to select, produce and qualify suitable standards for their intended use. Ideally, international reference standards are developed that can be used worldwide independently of the brand of the vaccine and this both by manufactures as well as by National Control Labs. In case international standards are not (or in limited quantities) available, the use of suitable and properly qualified in-house standards is a valid alternative, but additional qualification requirements might apply.

Relevant Guidance – The requirements for reference standards are greatly determined by their intended use. Different requirements are applicable for a reference standard used for assay validity versus a reference standard used for final lot qualification, especially if it is an assay to determine the potency or activity of the vaccine. In the latter case, it is important that the candidate standard has a clear link with clinical batches that were shown to be safe and efficacious. In any case, when standards are being qualified, the set of release tests should be accompanied by a set of additional characterization assays. Special requirements should be taken into account when in-house reference standards are qualified against internal reference standards and when newly proposed primary or secondary standards are bridged against existing standards.

Conclusions – It is obvious that reference standards play a very important role in the control strategy of vaccines. The requirements for selection and qualification of standards depend on their intended use. The more international reference standards become available and are used, the more harmonization in quality control by companies and authorities can become a reality.