



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**

An overview of the contribution of reference standards to the quality control of vaccines

The quality of medicines, including vaccines, is of critical importance to their safety and efficacy for the end user. The ability to produce consistent batches of the appropriate quality, in line with batches found acceptable in the clinic, should be an integral part of production and control strategies for medicines. Reference standards have long played a key role in these control strategies. The control of biologicals, like vaccines, has historically faced challenges linked to the inherent variability in starting materials, the products themselves and the test methods used to control them. The very definition of biologicals reflects this i.e. *'substances which cannot be fully characterised by physico-chemical means alone, and which therefore require the use of some form of bioassay'*¹. Without the ability to use a defined metrological unit, content/potency/activity in a biological assay has traditionally been compared to a reference standard with some defined unit, the first of which is usually assigned arbitrarily. The advent of International Standards (IS) from the World Health Organisation and use of the International Unit (IU), a common basis for the 'arbitrary' unit, was a great step forward. Use of these standards and units has been an essential part of ensuring vaccine quality in the past decades. The IU allows calibration of secondary standards, like common regional standards, established by organisations such as the European Directorate for the Quality of Medicines and HealthCare, US FDA and others, or in-house standards, by providing a common, externally verified basis of comparison. The presentation will include a look back at the history of reference standards and their use and their contribution to maintaining the quality of biological medicines like vaccines.

1 WHO/IVB/11.03: WHO manual for the establishment of national and other secondary standards for vaccines