Table 1: Vaccines – Analytical Platform Technology

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Scope:

There are many different vaccines in development and on the market. Vaccines are based on the administration of either live, attenuated or inactivated organisms or other molecular entities to induce immunity against infectious diseases. For example, subunit vaccines (peptides, toxoids, polysaccharides, conjugate vaccines) and genetic vaccines such as viral vectors and, more recently, nucleic acid vaccines, are used. Vaccines can be monovalent (targeting one disease) or multivalent (targeting different diseases or different variants of a disease). Therefore, this diversity of biomolecules and formulations leads to a diversity of analytical techniques to analyse vaccines for characterization, release and stability testing.

In the race of pandemic, of different variants of a disease (like for seasonal flu or for new SARS-CoV-2 variants) or of multivalent formulation, industrial and regulatory organizations are looking for ways to accelerate the development of new vaccines. In this mindset, an analytical platform technology approach could be a solution, by considering that one analytical method validation could support the analysis of different antigens.

Questions for Discussion:

1. What are the analytical challenges to have validated analytical methods for multivalent and variant vaccines?
2. Are there possibilities for analytical platform validations? Can this be applicable for all kinds of vaccines?
3. Have you ever used an analytical platform approach to validate your analytical methods for vaccines?
4. Do you expect that the new revision of ICH Q2 and the implementation of ICH Q14 will provide more opportunities for analytical platform validations?

Discussion Notes:

- Potential Platform Applications discussed:
    - Adenovirus and Adeno-Associated Virus (AAV) vectors
    - mRNA Lipid NanoParticles (LNP)
    - Multivalent vaccines
    - Variant vaccines (against new serotypes)

- Goal:
    - By applying a platform approach, the “revalidation” of all analytical methods won’t be needed for each new product.
- How
    - Does this new product and its manufacturing has an impact on the validated characteristics of the analytical methods? This impact can be evaluated through a risk assessment.
- No impact:
    - Need to generate data to demonstrate that the method is suitable for its intended use, being the new product
    - No change in the SOPs between the validated method and the one which will be applied for the new product.
- Impact
    - Potency tests these tests are based on the mode of action (biological activity) and so cannot be included in a Analytical Platform approach.
    - For variants, assessment of specificity may be needed
    - Limited validation could be considered