VACCINES HAVE MANY CMC CHALLENGES THROUGH PRECLINICAL DEVELOPMENT

One of the leading causes of delay in a drug or therapeutic candidate achieving IND/CTA is due to CMC deficiencies associated with analytical testing. Consider that the average additional time to obtain approval with this type of delay can be up to a year or longer and the commensurate drop in asset value can be up to 20% or more.\(^1\)

### Characterization
Characterizations of a vaccine, as per ICH Q6B, is expected for both the antigen and any associated adjuvant. This should address purity, chemical/biochemical and physical characteristics. Characterization of the antigen-adjuvant combination should also be evaluated, including binding and interaction parameters.

### Formulation
Vaccine formulation involves ensuring antigen conformational and colloidal stability, as well as optimizing the interaction with any adjuvant(s). Formulations need to be specific for the mode of administration and be tolerable, minimizing adverse reactions, for the recipient.

### Adjuvant Selection
Boosting an antigen immune response often requires a vaccine to contain an adjuvant. Adjuvants can be particulate or immunopotentiators, or both in combination. Careful selection of the adjuvant(s) is essential to elicit the specific B- or T-cell immune response required.

### Release and Stability
Batch release of a vaccine is performed to ensure the safety of the material and to confirm consistency between batches and with the vaccine used in clinical trials. Stability studies utilize these techniques to determine the shelf life under the proposed environmental conditions and any anticipated deviations.

### Potency Assays
The design of the potency assay depends on the mechanism of action and the technology used to manufacture the vaccine. The ability to measure the B-cell and T-cell responses may be required for some vaccines.

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1. Estimate based on (NPV model)
COVANCE VACCINE CMC DEVELOPMENT SOLUTIONS

Trusted Insights

to reduce the risk of CMC analytical testing deficiencies, originate from scientific expertise and experience.

Helping You

to make better choices of how you manage and what you spend to support your vaccine's lifecycle.

- Analytical control strategy and plan to align with product CQAs
- Method development, phase appropriate qualifications and validation (GMP/ICH)
- Potency assays and formulation development
- Analytical testing (including in-process): safety, identity, strength, quality and purity
- Routine global lot release and stability testing under commercial GMP conditions

Vaccine Types Supported

- Live-attenuated
- Inactivated
- Viral vector
- Virus-like particles
- Protein subunit
- Polysaccharide subunit
- DNA
- mRNA
- Polyvalent
- Synthetic
- Liposomes
- Loaded nanoparticles

Learn more about our CMC analytical solutions at: www.covance.com/CMC

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