Roundtable Session 2 – Table 9: Vaccine-Specific Regulatory Considerations

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Abstract:

As the global vaccine landscape continues to rapidly evolve — driven by therapeutic vaccines, global health emergencies and novel platforms, such as mRNA technologies — regulatory agencies and vaccine developers face unprecedented challenges and opportunities. This roundtable will examine the unique regulatory considerations that distinguish vaccines from other biologics and therapeutics. We'll discuss efforts including, harmonization of global regulatory standards, strategies for novel vaccine platforms, accelerated approval pathways, and the integration of real-world evidence. We aim to foster dialogue that supports regulatory agility while maintaining rigorous safety and efficacy standards, ultimately accelerating access to life-saving vaccines worldwide.

Notes:

- Discussion about reliance between different regions such as US and EU.
- Potency assay change: In-vivo vs in-vitro. In major markets e.g. US, EU -preference is to continue to use in-vivo as characterization for early-stage programs
- Run both USP and EP tests where differences exist e.g. guinea pig challenge vs serological test
- Reference standard requirement for multicomponent vaccine: typically finished vaccine (containing all components) is used as a reference standard
- Discussion on Platform approach: possible for mRNA-based vaccine in relation to both manufacturing and analytical, at least for some release assays
- An example: Flu vaccine, where the manufacturing process is largely the same except new serotype, sponsors have to make a case for the platform and see how the agency reacts
- Discussion about whether using monoclonal antibodies as a vaccine falls under CDER or CBER. Most of the MAbs fall under CDER, they may consult with CBER depending on the mechanism
- For Comparability of multivalent vaccines-perhaps try matrix approach
- If you know variability across sites, create a range that could justify the next new site
- Testing requirement of final vaccine by Health Canada. The group was unsure whether it was also needed for early-stage/investigational vaccines.
- Develop a structure-function based assay that would be easy to justify as in-vitro potency assay