

Shaken, Stirred, and Stable? Tales from a CMC multivalent Cocktail Party

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CMC challenges associated with multivalent products including co-formulation and co-administration



- 1) Distinctions between “platform” and “prior knowledge”. How are they relevant and used to develop multivalent products?
- 2) What are some unique challenges in formulation development for multivalent products? Potential development scenarios to be discussed include:
 - Combining previously approved separate components together
 - Combining previously approved components with novel components on the same platform
 - Maintaining separate components vs. co-formulation
 - Field-mix scenarios for dose-finding in clinical development
 - Approaches for establishing comparability and clinical consistency

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3) What stability approaches can be used for multivalent products?

- Concepts to predict shelf-life with appropriately designed stability program when clinical doses are initially unknown (Representative Batch concept)
- Considerations for in-use stability for multivalent products (e.g. adjuvants/adsorption) for vaccines, co-formulated products, products for co-administration

4) What are some analytical or control strategy considerations unique to multivalent products?

- Approaches to identify CQAs unique for co-formulations and analytical challenges
- Leveraging advanced analytical technologies to improve quality control in co-formulations