

Vaccines, Clinical Trials & B2B

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Challenges and solutions for maintaining quality and potency of the product in vaccine development

The quality of vaccines is increasingly guaranteed by the use of robust and reproducible production processes. FDA and other regulatory agencies generated recommendations and guidelines to ensure high quality levels. The present talk will be focus on the discussions of the following areas:

- Why need to assess the quality and the potency of vaccine product from early phase through the late phase vaccine development, even after licensure of the product
- Strategy thinking and planning in the assessment of the potency and safety of Human Vaccine: *in vivo* animal assay vs. *in vitro* assays.
- Cases studies to demonstrate the challenges and solutions to timely evaluate the quality and potency of vaccine products.
- Regulatory considerations of the potency evaluation of vaccine products

Biography

Laura Hong has more than 15 year's extensive experience in biologics and vaccine development. She had been support for monoclonal antibody drug development in the area of CV, ID and oncology. In recent years, her major responsibilities have been leading a group in supporting vaccine process and formulation development and release, including stability of manufactured vaccine products. Sha has contributed in more than ten vaccine project development, including Gardasil and Gardasil 9 vaccine.

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