

[P-61]**Point to Consider on the Evaluation of Safety and Efficacy of
Dna Vaccine**

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Plasmid DNA vaccines are currently under development and the use of purified preparations of plasmid DNA constitutes a new approach to vaccine development. Plasmid DNA vaccine are defined as purified preparations of plasmid DNA designed to contain a gene or genes for intended vaccine antigen as well as genes incorporated into the construct to allow for production in a suitable host system. We compared and analyzed the regulatory aspects of DNA vaccines in other countries and prepared point to consider on the nonclinical toxicity, pharmacology and clinical evaluation of DNA vaccine based on our current situation. This point to consider (PTC) provides manufactures with useful information in relation to the manufacture and preclinical toxicity and pharmacology evaluation intended for clinical studies. This PTC will be revised periodically as NRA (National Regulatory Authority) gains more experience in the regulatory review of submission for plasmid DNA vaccines.

Keyword : DNA vaccine, safety evaluation, efficacy evaluation, point to consider