Determining whether adsorption state is a critical attribute in aluminum adjuvanted vaccines

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Aluminum based adjuvants have a long history of safe and effective use in vaccine products. When developing vaccine formulations incorporating aluminum adjuvants it is important to understand whether adsorption state is a critical attribute of the vaccine. Investigations initiate with obtaining an understanding of how the antigen of interest interacts with aluminum adjuvant surfaces. The balance of attractive versus repulsive interaction forces (including electrostatic, ligand exchange, and hydrophobic interactions) determines the resulting adsorption state of the antigen. Once the interaction of aluminum adjuvant and antigen is understood, formulations can be prepared along the spectrum of aluminum adjuvant surfaces to obtain various levels of adsorption. These formulations are evaluated in a relevant animal model to determine the impact of adsorption state on potency of the vaccine. The impact of adsorption state on potency determines whether antigen adsorption state is a critical attribute of the vaccine formulation. Further development can then optimize the formulation to maintain safety, stability, and efficacy over the desired shelf life of the vaccine product.

Assessment of the criticality of adsorption state was evaluated for the development of a vaccine targeting Streptococcus pyogenes (group A strep) to determine that adsorption to an aluminum containing adjuvant was critical to optimize potency of the vaccine. Process and analytical techniques used to determine antigen/adjuvant interactions, produce variable aluminum surfaces, as well as vaccine formulation for in vivo potency determination will be discussed. Understanding how to determine the criticality of antigen adsorption state early in the development process allows for rapid development of a robust vaccine formulation.