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Vaccine formulation: A balancing act of antigen and adjuvant stabilization

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Most of the contemporary vaccines contain either single or multiple sets of antigens and adjuvant(s). To assure safety and efficacy, each of the vaccine components has to be stable during manufacturing, storage and administration. The stabilization of the multi-component Drug Product encompasses challenges of characterization and stabilization of each antigen in the mixture. Additionally, the stability of the adjuvant and interactions of the antigen with adjuvant have to be evaluated. One of the challenges is the instability of aluminum adjuvants during freezing, often resulting in irreversible aggregation/agglomeration that can lead to low reproducibility of otherwise efficacious vaccine dose delivered after drawing into a syringe. One of the possible mechanisms of the aluminum adjuvant aggregation during freezing could be attributed to overly close proximity of the particles due to particles being forced together (into the primary energy minimum) by ice formation. The overview of the factors involved in the stabilization of the vaccine suspensions with aluminum adjuvants will be presented.

Biography

Maya Salnikova currently a Senior Research Scientist at Merck&Co., Inc. Merck is a world leader in human vaccines for the past decades. Dr. Salnikova is an expert in vaccine formulations and characterization. She has developed complex vaccines with different modalities. Dr. Salnikova has contributed in development of vaccine formulations through her in-depth expertise in both traditional aluminum adjuvants and novel adjuvants. Before joining Merck &Co., Inc., she was involved in characterization and development of vaccines at the Macromolecule and Vaccine Stabilization Laboratory at the University of Kansas with Professor Middaugh. She earned her Ph.D. degree at the University of Kansas and has authored more than a dozen peer-reviewed scientific publications.

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