76e Adjuvant-Adsorbed Vaccine Susceptibility to Hydrodynamic Shear

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High shear can damage vaccines adsorbed to adjuvants, leading to decreased potency. A model system to determine the level of shear sensitivity early in vaccine development would be beneficial during scale-up and the transfer of new technology to commercial-scale manufacturing. In this study, a series of experiments were conducted at various multi-dimensional turbulent flow conditions that may be encountered at the commercial scale. Methods including a homogenizer, rheometer and a variety of geometrical pipe flow conditions (T-mixer, 90-degree elbow, wall impingement, etc.) with a low-shear peristaltic pump were developed to study the effect of various shear conditions on a shear-sensitive vaccine. A change in particle size was found to be an indicator of shear damage to the vaccine, and was a function of power input and the energy dissipation rate (EDR) in turbulent high shear zones. The resulting vaccine particle size and potency were measured at various stress rates. The results are being used to predict vaccine shear sensitivity during early phase development, to ensure product quality, and to drive process engineering decisions to improve process design of the commercial-scale manufacturing facility.