Vaccine development and formulation is based upon understanding of the candidate’s target product profile, and leverages knowledge and experience in pharmaceutical products. Developing an optimal formulation takes into account factors such as ensuring route of administration, product stability, and identifying Quality Target Product Profiles that are suitable for the product’s intended use. Based upon such knowledge and experience, multiple excipient formulations may be first identified for initial screening. Achieving the QTPP is a measure of results, and can be achieved with screening formulations by aggressive accelerated stability study conditions to enable the final formulation components to be down-selected. This presentation highlights what has proven to be a successful approach to formulation development of a vaccine product.

Product design and formulation selection criteria focused on attributes associated with lyophilized preparations of a live attenuated vaccine candidate, and included accelerated stability studies. Beginning with an understanding of optimal buffer and formulation parameters in solution, an initial screening of 8 lyophilized formulations were evaluated. A single formulation was selected for further development where the relative concentration of each of the components was tested using a definitive DoE screen. Lyophilized samples were prepared, behavior during processing evaluated, finished product attributes assessed and dried state accelerated stability was monitored by measuring potency. Statistical methods were used to predict the interaction and synergistic effects of each of the formulation components. Results of the evaluations and assessments of the varying concentrations verified the predictive analysis, leading to selection of the most promising formulation that met or exceeded the initial defined QTPP. Use of statistical methods were then used to refine the DoE central composite design, to build on the understanding of the design space for further evaluation of the final formulation.