get population (e.g., pediatric), and the necessity for a potential adjuvant to ensure the vaccine is immunogenic [3, 4]. This information will be captured early in the global target product profile (GTPP) and will be an evolving document as the program moves through product development. During the generation of the GTPP, it is important to ensure not only that the stability profile aligns with the requirements but also that the proper packaging of the product will suffice within the respective markets.

Early in development, different primary images including single- and multidose vials, prefilled syringes, liquid, and lyophilized products will be explored. The decision to move forward with a respective primary image will be based on the necessary stability profile required to meet the specific market demands and be customer driven. Beyond exploring the primary image, the formulation scientist must also consider the secondary package (1x vs. 10x, kits vs. single vials) and the tertiary package to ensure the cold chain can be kept under control (i.e., gel packs, dry ice pack-outs, and nano-cooling technology). Aligning the formulation scientist to this GTPP will ensure the customer is provided with a vaccine that meets the market demands, is safe, efficacious, and has been developed with customer centricity in mind.

Complexity of vaccine formulation development is often further enhanced by combination vaccines. An example currently on the market is the ProQuad® and RotaTeq® vaccines each consisting of four or five different live viruses, respectively [3, 5]. Another example of a multicomponent vaccine is Pnuemonvax®, which consists of 23 different polysaccharides [6]. Selecting a formulation that can stabilize these multicomponent vaccines and achieve the desired GTPP is a significant hurdle for the formulation scientist. The formulation must be compatible with all components within the vaccine as well as the manufacturing process. This may result in some compromises with regard to stability for one entity and is a balancing act for the combined vaccine.

Vaccines serve an important medical need in preventing disease and lessen the overall health care burden. As a result of their health care benefits, there has been increased pressure on vaccine manufacturers to increase their global footprint and reach areas of the world that were not previously covered [7, 8]. As the markets for vaccines continue to expand into the developing world and emerging markets, the need to ensure that vaccine and formulation can withstand increased thermal stress becomes paramount. This is due to the developing and emerging markets not having proper command of the cold chain and thus, the vaccine product being exposed to increased temperature and excursions during routine shipping and administration. By ensuring that the vaccine stability profile can withstand increased thermal stress, the impacts associated with temperature excursions can be minimized and ensure that a safe and efficacious vaccine is delivered to the patient. It is important to not only deliver a robust formulation that can withstand thermal stress but also have a formulation and filling process that can be manufactured robustly. The robust manufacturing process is essential since there are specific regulatory guidances requiring local manufacturing of the vaccines, thus, requiring technology transfer and well defined critical quality attributes (CQAs) [9] to allow manufacturing to be successful.