product. During the assessment to proceed with liquid or lyophilization, the formulation scientist will utilize past experience with similar vaccines and likely complete the risk assessments to help shape the formulation strategy moving forward. Both liquid and lyophilized vaccines are feasible and it is the job of the formulation scientist to ensure a proper image is defined and able to support the product long term commercially.

Vaccine Drug Product Development Stages

In our opinion, prior to any drug product development, it is essential that the GTPP has been defined and aligned across the development team. The GTPP outlines the target population, desired shelf life of the product, dosing schedule, and route of administration. It is expected that as the program advances in development that the GTPP will evolve. However, to ensure that the formulation scientist does have an initial target, the GTPP is utilized. An example of a GTPP is outlined in Table 1 below.

After establishing the GTPP, drug product development can be initiated. It is our opinion that vaccine drug product development can be broken down into three main stages. The first stage of development consists of the early development space where preformulation activities occur. The main goal is to identify the proper antigen to bring forward as a preclinical candidate. Identifying the main degradation pathways for the antigen is critical and using that knowledge will help shape the initial formulation. Early screening of wide ranges of excipients is usually completed here and may involve design of experiment (DOE) approaches to find factors that impact product stability. Once the preclinical candidate has been identified, additional early formulation screening occurs that leads to a formulation that can

Table 1 Global target product profile

Attribute	Minimally acceptable profile
Vaccine serotypes	Vaccine consists of 5 serotypes and covers at least 75 % of invasive disease
Target population	Vaccine to be administered to children < 5 years of age and particularly effective in infants < 2 years of age
Safety, reactogenicity	Safety and reactogenicity should be similar to other marketed vaccines. No significant AEs
Dosing schedule	A two-dose regimen is required
Route of administration	Intramuscular, intradermal, or subcutaneous
Product images	Single-dose vial, syringe, and multidose vials desired
Product formulation	Liquid formulation preferred
Product stability	Refrigerated product desired for minimum of 24 months, desire a minimum of 6 months of RT stability, request vaccine vial monitoring 14 (VVM14)