derived from viral particles, while more general stabilizers may be employed for vaccines of other modalities.

There are other modalities of biologics on the horizon. Although these products are yet to be approved by the FDA, various DNA-based biologics are currently under development. While most gene therapy products are stable enough to be stored in liquid solution, some show instability, e.g., topological change of plasmid products that would require lyophilization for adequate stability. Lyophilization has been also effectively been applied for delivery vehicles without intrinsic stability issues, e.g., liposomes and nanoparticles for nonviral vectors.

Formulation Role in Business Strategy

The choices of drug formulation and delivery are significant in determining the clinical and commercial profile of a product. Choices made early in formulation development may impact the frequency of administration, drug level, safety, and efficacy of a product. Depending on the indication, medical practice, and competition, these development choices can have positive or negative effects on the success of a product.

As a result, the formulation representative should work as part of a larger drug development team to develop a comprehensive strategy for planning and testing potential attributes of the drug as it evolves through drug development. The target product profile, or TPP, is a document used by many companies to manage and communicate these product attributes.

Target Product Profile

The TPP is a management tool used to communicate product attributes throughout the drug development process. Early in development, targets are based on the characteristics of the molecule, clinical needs, and commercial requirements, as many attributes have yet to be fully characterized through experimentation.

The format of the TPP captures elements of a product insert. Some companies use a marketed competitor's product insert as a template.

Major sections of the TPP that involve the entire development team include:

1. Indication
   a. Launch indication
   b. Additional indications
2. Efficacy
3. Safety
   a. Tolerability
   b. Adverse events