

TABLE 2 Cost Considerations for Dual Chamber Vs. Vial Packaging

	Dual chamber cartridge/syringe (DCC/DCS)	Vial	Comments
Drug product in primary package			
Primary package	Barrel, plungers, closure, finger rest, piston	Vial, closure, cap	Additional packaging needed to reconstitute and deliver dose from vial
Overfill	Minimal overfill due to elimination of product transfer step	Increased overfill due to loss in product transfer step	Cost of API must be considered, especially for a biologic drug
Freeze-drying cycle time	Longer due to poorer heat transfer	Shorter due to better heat transfer	Depends on specifics of the formulation, primary package and lyophilization parameters
Batch size	Generally larger due to smaller unit dimension	Generally smaller due to larger unit dimension	Depends on rack and loading configuration for DCC/DCS
Yield	Rejection rate potentially higher	Rejection rate potentially lower	Depends on specifics for the formulation, primary package and lyophilization cycle
Accessories			
Injection needle	1	1	
Reconstitution needle	N/a	1	
Plastic syringes	N/a	2	Syringes needed for reconstitution and delivery
Vial with diluent	N/a	1	
Secondary package	Blister + carton	Carton	Syringe packaged in blister
Disinfection swabs for reconstitution and loading of delivery needle	N/a	2	
Device for delivery	Pen injection device needed for DCC	N/a	
Other			
Competition in marketplace	Needed to compete in certain therapeutic areas, e.g., home administration of chronic therapeutics like insulin or growth hormone		Choice of package, and ability to sell product, is dependent on the standard-of-care for therapy

Abbreviations: DCC, dual chamber cartridge; DCS, dual chamber syringe; API, active pharmaceutical ingredient.