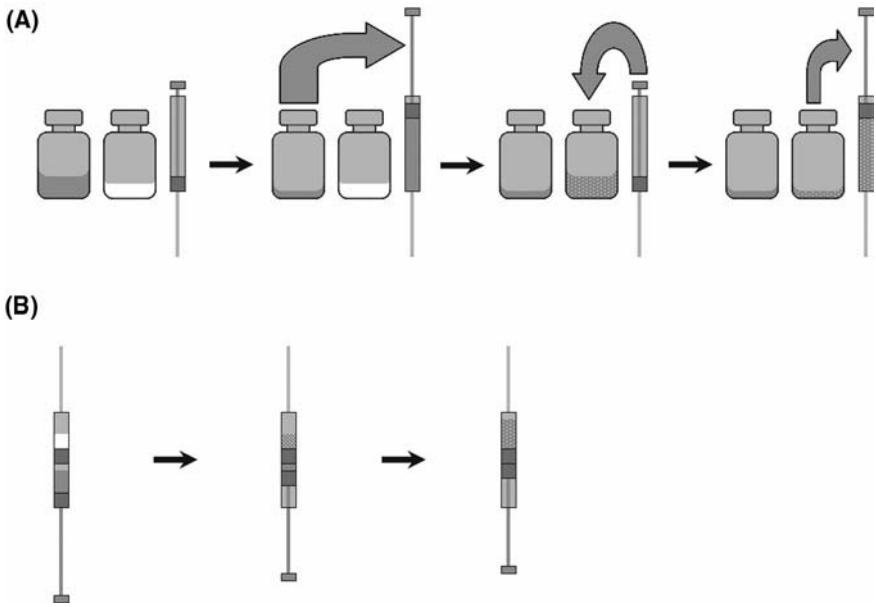

FIGURE 1 Simplified comparison of reconstitution of a lyophile in vial (**A**) versus dual chamber syringe (**B**).

the manual reconstitution step and greatly improves patient convenience and safety. A comparison of the reconstitution steps between traditional vials and a DCS is illustrated in Figure 1. Genotropin® [recombinant human growth hormone (rhGH)] was the first lyophilized protein product that transitioned in 1987 from a standard vial to DCC packaging. Presently, several rhGH products are marketed in lyophilized dual chamber package systems [e.g., three pharmaceutical companies market lyophilized rhGH products in DCC with multidose pen devices (Eli Lilly, Pfizer, and Merck Serono) and one markets it as a single use DCS product (Pfizer)].

However, lyophilizing a drug in a dual chamber system can be challenging compared to lyophilization in a standard vial configuration because of differences in heat transfer during lyophilization and the presence of siliconized glass surfaces. The purpose of this chapter is to review practical considerations for lyophilizing drugs in dual chamber systems and outline strategies to address these challenges.

DUAL CHAMBERED PRIMARY PACKAGING SYSTEMS

There are several dual chamber package systems that contain lyophilized products. These systems include dual chamber vials, dual chamber cartridges, and dual chamber syringes. One of the main benefits of dual chamber packaging is that the reconstitution step is built into the package and thereby improves patient convenience and safety. Each of these dual chamber package systems is briefly discussed below. Examples of marketed lyophilized drug products in dual chamber packages are listed in Table 1.