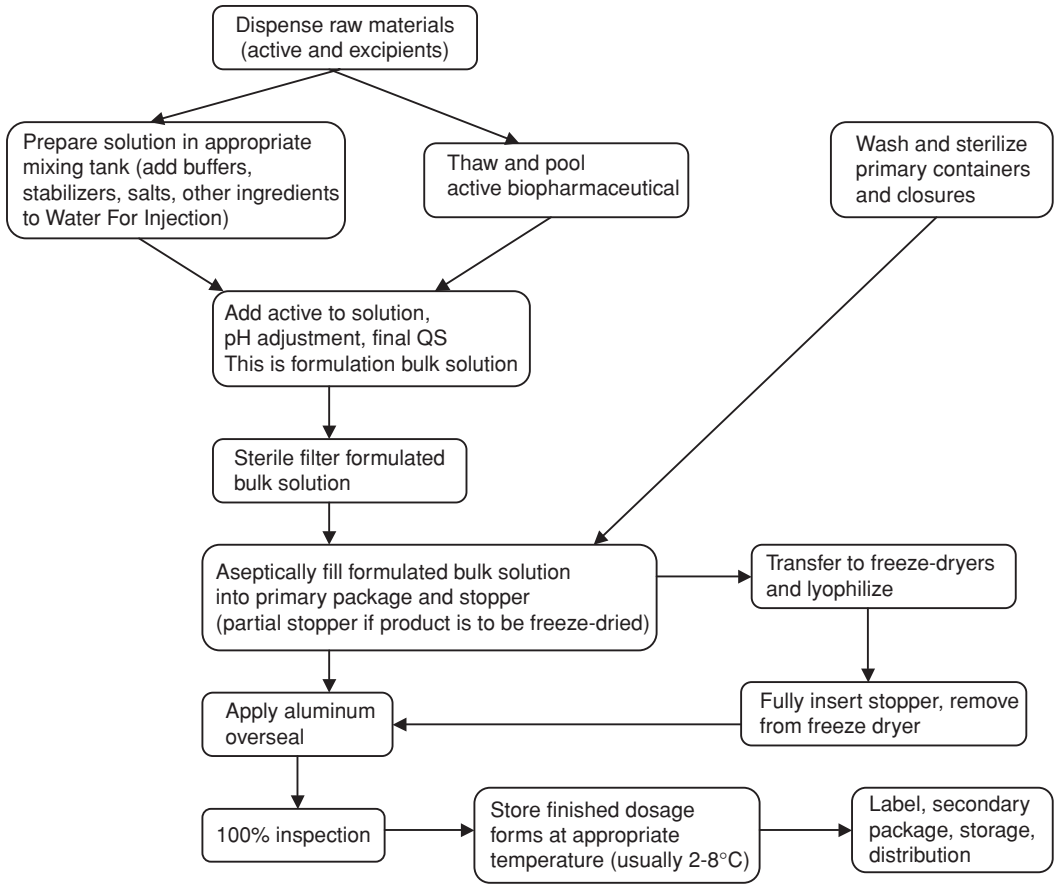

Figure 12-1 Schematic overview of processing solution and freeze-dried biopharmaceutical dosage forms.

overseers of pharmaceutical manufacturing. Therefore, the operations of the pharmaceutical industry are subject to the oversight of the FDA and, with respect to manufacturing practices, to the application of the cGMPs. These regulations are discussed more fully in chapters 25 and 26.

In concert with the pursuit of cGMPs, the pharmaceutical industry has shown initiative and innovation in the extensive technological development and improvement in quality, safety, and effectiveness of parenteral dosage forms in recent years. Examples include developments in the following:

- modular facility design and construction
- container and closure cleaning, siliconization (if applicable) and sterilization
- disposable technologies
- sterilization technologies
- filling technologies
- aseptic processing technology including barrier isolator technology
- aseptic connections and sampling
- freeze-drying technologies including automated loading and unloading
- control of particulate matter
- automation in weight checking, inspection technologies, and labeling and finishing operations.

SCHEDULING

Scheduling functions are the key deliverables of the planning role. Scheduling is the function of coordinating all of the logistical issues required to organize an efficient period of time to