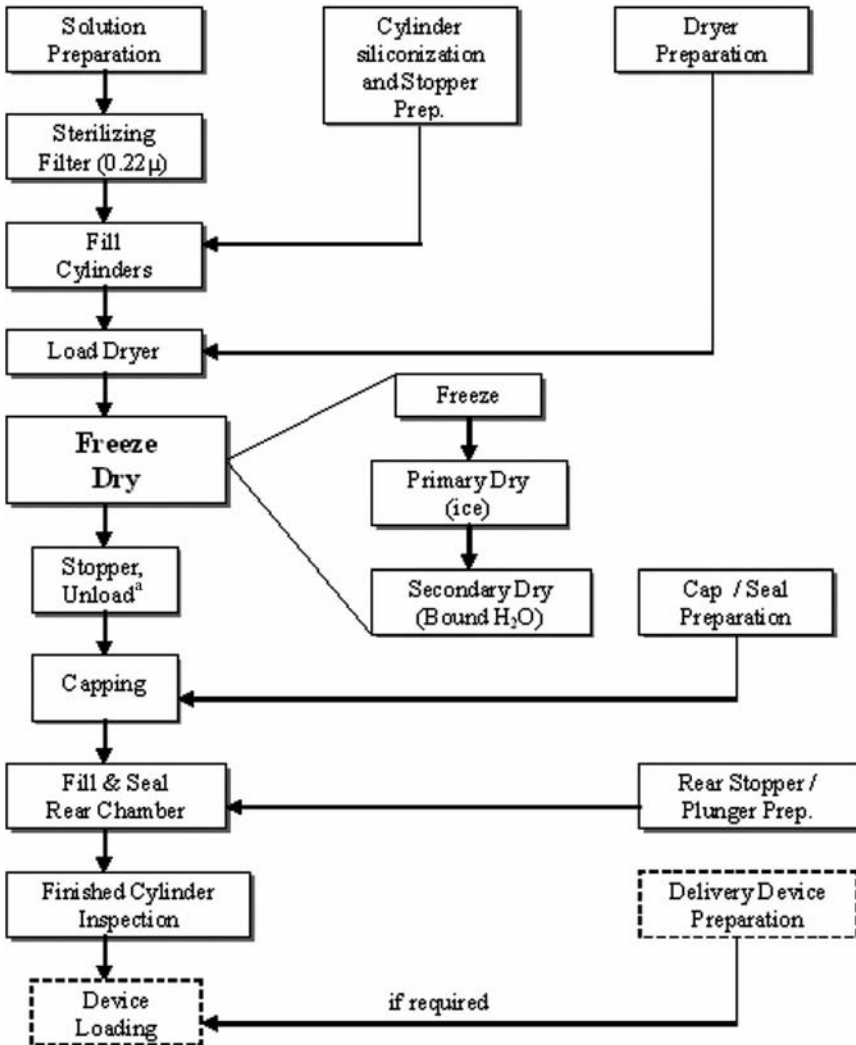


luer tipped needles depending on closure utilized for the selected package system.

FREEZE-DRY CYCLE DEVELOPMENT

This section provides a brief overview of lyophilization cycle development, with particular attention to considerations for lyophilization in dual chamber packaging systems due to salient differences from lyophilization in vial formats. The process flow diagram shown in Figure 9 outlines the various unit operations



^aSome systems require external stoppering (after unloading)

FIGURE 9 Process flow diagram for manufacture of a lyophilized product in a dual chamber package system.