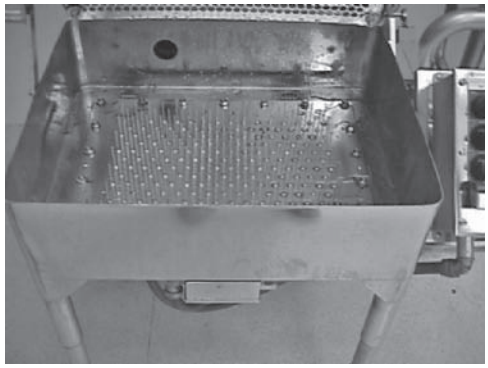
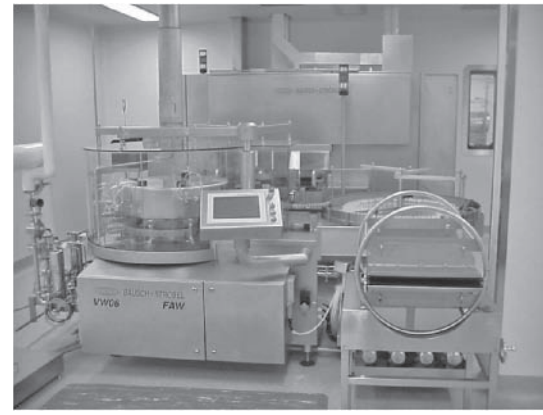
Calumatic



Metromatic



Bosch + Strobel

Figure 13-2 Examples of glass container washers. *Source*: Courtesy of Baxter Healthcare Corporation.

Cleaning of Containers

A variety of container washers of various ranges of sizes and automation are available for cleaning sterile product container (Fig. 13-2). The selection of the particular type will be determined largely by the physical type of containers, the type of contamination, and the number to be processed in a given period of time.

Validation of cleaning procedures for equipment is another "hot topic" with respect to cGMP regulatory inspections. Inadequate cleaning processes have been a frequent citing by FDA and other regulatory inspectors when inspecting both active ingredient and final product manufacturing facilities. It is incumbent upon parenteral manufacturers to establish scientifically justified acceptance criteria for cleaning validation. If specific analytical limits for target residues are arbitrarily set, this will cause concern for quality auditors. Validation of cleaning procedures can be relatively complicated because of issues with sample methods (e.g., swab, final rinse, testing of subsequent batch), sample locations, sensitivity of analytical methods, and calculations used to establish cleaning limits.

Cleaning containers requires adherence to some very basic principles:

1. The liquid or air treatment must be introduced in such a manner that it will strike the bottom of the inside of the inverted container, spread in all directions, and smoothly flow down the walls and out the opening with a sweeping action. The pressure of the jet stream should be such that there is minimal splashing that might affect adequate cleaning and turbulence that might redeposit debris loosened during the process.
2. The container must receive a concurrent outside rinse.
3. Cleaning cycle should alternate hot and cool treatments with the final rinse treatment using water for injection (WFI).