SIP Validation In order to ensure the integrity of the machine for aseptic drying, it is imperative to ensure the effectiveness of steam sterilization cycle, which ensures sterilization of the probable product exposure components such as the condenser, the vacuum/nitrogen inlet, and the chamber. Typically, chemical and biological indicators are used to validate the steam sterilization cycle.

Drying Recipe Validation Freeze-drying recipe validation is an integral part of the overall manufacturing process. At the end of drying cycle, samples are withdrawn from key locations in the freeze-dryer and evaluated for critical quality attributes of the product including moisture content (loss on drying), residual solvents if any, particle size distribution, and other material properties (purity or critical impurity levels, assay, protein impurities with high molecular weight, aggregates). The general sampling methodology involves taking aliquot from a minimum of five locations in each tray, one in each corner and in the center of the tray. The pooled sample from these five locations represents a sample from a particular tray. Samples are taken from each tray in all the shelves. Such an elaborate sampling strategy is relatively easy for material being lyophilized in container closure systems such as vials and relatively complicated for bulk drying; however, such a strategy provides assurance on the uniformity of the product quality. It is a common practice to use several sampling locations and generate extensive processing data as a part of product drying validation.

GORE® LYOGUARD® Freeze-Drying Trays: Biopharmaceutical Application

GORE® LYOGUARD® (W. L. Gore & Associates, Inc., Elkton, MD, USA) freeze-drying trays (Fig. 9) represent a significantly improved methodology addressing some of the inherent limitations of the bulk freeze-drying process. In contrast to the routinely used open stainless steel 316 L trays, the GORE® LYOGUARD® trays

Fig. 9 GORE® LYOGUARD® trays. (Courtesy: W. L. Gore & Associates, Inc., Elkton, MD, USA; GORE, LYOGUARD and designs are trademarks of W.L. Gore & Associates)