LYOGUARD® trays) was suggested to be an integral aspect of the freeze-drying process transfer [34].

While the GORE® LYOGUARD® trays may significantly improve the bulk freeze-drying process depending upon individual product or material properties, some of the definite advantages of GORE® LYOGUARD® trays are product containment post drying, ease of unloading the lyophilizate (which at times may be light and fluffy with significant electrostatic charge built up), and the option to seal the trays in preformed pouches (for shipping to different sites).

Conclusion

Based on the several aspects discussed in this chapter, we can conclude that bulk crystallization followed by freeze-drying of a biopharmaceutical can certainly be a preferred processing strategy. However, the successful implementation of both these processing techniques depends upon several factors including crystallization potential of a protein therapeutic (ability to form crystals), stability of the said protein during such operations, sensitivity to processing conditions, scalability of the processing technique, and overall regulatory compliance of the operations. In a globally expanding biopharmaceutical industry, where logistics and transportation are important considerations, such bulk processing–finishing techniques will certainly find widespread applications. It would be inappropriate to summarize both bulk crystallization and freeze-drying as general biopharmaceutical processing techniques without describing the specific applications of both these techniques by means of relevant case studies or examples. The next chapter discusses specific examples of biotherapeutic modalities wherein both (or either one of) these techniques have been applied as unit processing steps.

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