based on the principles of Food and Drug Administration (FDA)/ International Conference on Harmonization (ICH) Q8, Q9, Q10, Q11 guidelines, involves knowledge transfer, science and risk-based approaches which ensure a comprehensive and systematic transfer of information and documentation between transferring site and receiving site [2–6].

Most of the biopharmaceutical products are delivered through parenteral route and a large number of such products are manufactured utilizing lyophilization process to ensure long-term stability of biologic drug substance and drug product [7–9]. The lyophilization process as such is complex, time-consuming, expensive, and requires a robust and reproducible process transfer from development laboratory to commercial manufacturing site, or from one manufacturing site to other manufacturing site within same company or to a CMO.

In this chapter, focus is on the TT of the lyophilized products wherein an overview of general TT activities of sterile lyophilized product including specific case studies is discussed.

Technology Transfer

As described in the FDA ICH Q10, the goal of TT activities is to transfer product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realization [4]. This knowledge forms the basis for the manufacturing process, control strategy, process validation approach, and ongoing continual improvement [2–5].

An overview of different types of TT of lyophilized product is shown in Fig. 1. In general, TTs can be categorized in two types:

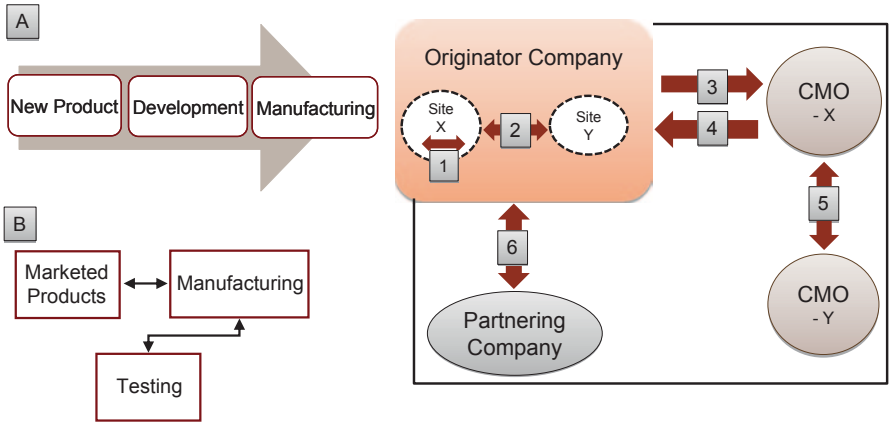

Fig. 1 Types of technology transfer. **a** New product transfer; **b** Marketed product transfer. *1*: Intra-site; *2*: Inter-site; *3*: Outsourcing—CMO; *4*: Insourcing—CMO; *5*: Inter-CMO; *6*: Intercompany (licensing). *CMO* contract manufacturing organization