Lyophilization Process Technology Transfer Towards Product Launch

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Introduction

In the past two decades, there has been a rapid increase in the number of biological (e.g., therapeutic proteins, biosimilars, biobetters) and novel vaccine (e.g., multivalent) products developed by many small and large biotech companies. Development of such biologics is quite expensive and many companies lack in-house setup and capability to develop biologics from discovery to commercialization. In contrast, large multinational biopharmaceutical companies, engaged in core or noncore business, have realized cost saving by utilizing contract manufacturing organizations (CMOs) and improved productivity trends, as compared to investing in setting up and maintaining own facilities with required expert staff and regular updates [1]. In this diverse and changing industry, technology transfer (TT) of active pharmaceutical ingredients, analytical methods, and drug products from development to market phase is becoming increasingly common and important to deliver safe and quality products in the most cost-efficient way.

A successful TT ensures the quality of product during the entire life cycle of manufacture and validation, in accordance with current good manufacturing practices (cGMPs), providing predictable and consistent operation of the processes. It is

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