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Strategies for Vaccine Development and Lifecycle Management

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Table of Contents

FIGURES AND TABLES IN[illegible]EX

1.0 Introduction

Vaccines comprise a very diverse group of products with respect to chemical composition and manufacturing processes. Vaccines can also be very complex as they are frequently composed of multiple entities and administered as a combination vaccine. For instance, six or more different antigens can be included in common pediatric vaccines, and seasonal influenza vaccines are quadrivalent. Adding to that complexity, many vaccines are administered with adjuvants that may involve complex formulations and manufacturing processes. The use of adjuvants increases the challenges of developing a robust control strategy.

Vaccines are characterized by relatively long product lifecycles. Vaccines that were licensed decades ago (e.g., for tetanus and diphtheria toxoids, tuberculosis, measles, mumps, and rubella) are still produced and recommended for global vaccination programs. The manufacturing programs for these vaccines must be updated continually to comply with contemporary regulatory expectations, which requires multiple supplemental submissions around the world. These technical and regulatory challenges lead to an intricate management process for vaccine lifecycle and supply chain.

Managing the development, licensure, and lifecycle of vaccines is an extremely complicated process, especially in cases of multinational products. **Figure 1.0-1** illustrates the complexities of vaccine development and commercialization; many of these are common to other biological products.

For most vaccine platforms, developing and launching vaccines can take several years. After a vaccine becomes commercially available, it can take from 6–36 months to produce, control, and release a batch. The majority of this time may be spent on product testing and release. From bulk antigen production through product release, the entire process must be strictly controlled to ensure sterility and to minimize the variability inherent in a biological system. Up to 1,000 control tests may be performed during the manufacturing cycle for each lot of vaccine, including complex in-vivo tests. Additional testing required by national health authority laboratories adds to the intricacy of releasing a vaccine in local markets, though many health authorities are willing to conduct testing in parallel with the manufacturer to minimize the time-delay associated with official control batch-release testing.

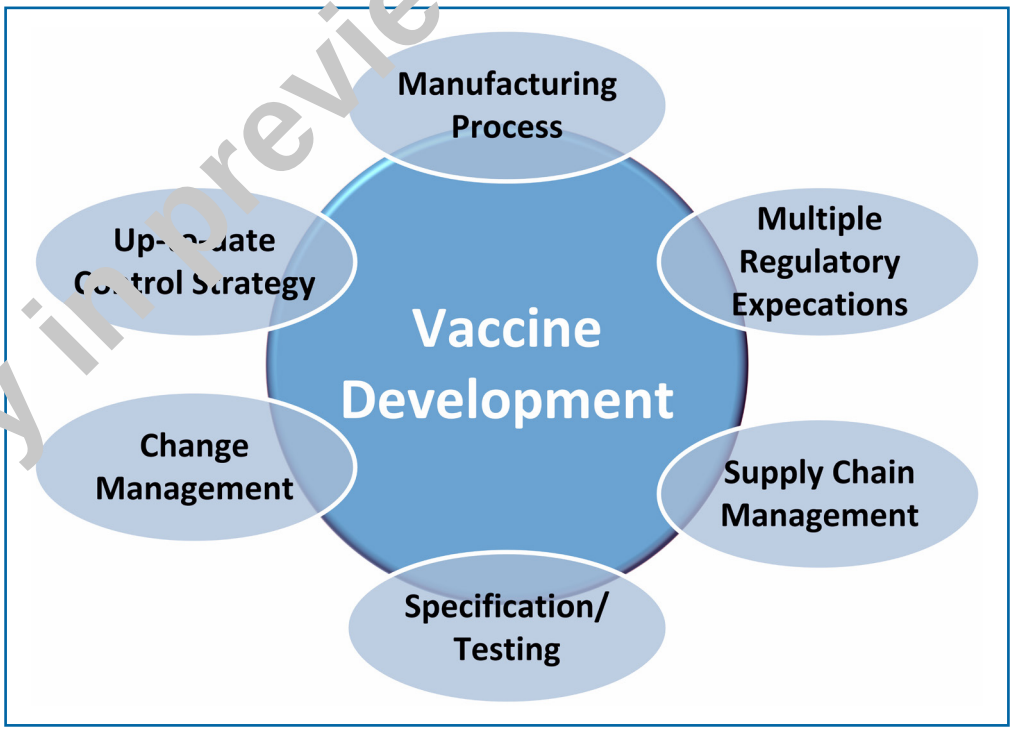

Figure 1.0-1 Complexity of Vaccine Development and Lifecycle Management