

## **MODERNIZING ANALYTICS FOR IMPROVED VACCINE MANUFACTURING EFFICIENCY: REGULATORY CONSIDERATIONS**

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As analytical methods and technologies have advanced and have become more cost-effective, the scope of use has broadened from limited in-process testing to defining the relationship between process parameters and critical quality attributes in an effort to establish “design space” to provide for manufacturing flexibility without affecting the target product profile. However, for complex biologics like vaccines, these analytical-based approaches to defining the manufacturing process have been slow to develop and even slower to adopt since slight variations in the manufacturing process, which might not be detectable by the analytics being used, could have dramatic effects on the quality, safety, or efficacy of the final product. Thus, for most biologics, assurance of product quality remains heavily reliant on testing of product and product intermediates for a myriad of biological attributes. These tests are often labor-intensive, time consuming, and suffer from high variability which greatly impacts production efficiency and uncertainty related to the successful release of product. These older testing methodologies are gradually being replaced with more modern methods which are not only more efficient, but provide a higher level of sensitivity and specificity, better assuring manufacturing consistency and product quality. Examples of newer methodologies used in vaccine testing and associated regulatory considerations are presented.