6-12-2022

Test tubes and turnaround times: An accelerated biosafety testing approach for new vaccines against emerging pathogens

Sarah Sheridan
Merck, United Kingdom

TEST TUBES AND TURNAROUND TIMES; AN ACCELERATED BIOSAFETY TESTING APPROACH FOR NEW VACCINES AGAINST EMERGING PATHOGENS

Sarah Sheridan, Merck, , United Kingdom
sarah.sheridan@merckgroup.com

Key Words: Biosafety testing; rapid test methods; next generation sequencing; regulatory requirements

Recent outbreaks of infectious viral disease such as those caused by SARS-CoV-2 and Ebola have led to the successful development and approval of vaccines at unprecedented speed. These achievements are possible by using an accelerated approach to vaccine development. For example, vaccine development under an accelerated or pandemic approach could take 18-24 months compared to the traditional approach of 5-10 years.

A critical part of vaccine development is clinical trials and a key step in this pathway is Quality Control (QC) biosafety testing of materials used in the manufacture of clinical trial material. The traditional approach for applying and performing such QC tests does not align with the accelerated / pandemic development approach. Take for example, identity and adventitious agent testing of cell banks and vaccine seeds used to produce clinical trial material. Using a traditional approach, these alone can each take up to 8–10 weeks even with the best planning, resulting in a total time of 20 weeks if cell line and virus seed stock are characterised sequentially.

Here we describe accelerated biosafety testing strategies used in industry to expedite pre-clinical and first in human clinical studies for a variety of SARS-CoV-2 candidate vaccine modalities without compromising patient safety. We will present examples and data from actual scenarios on approaches and watch-outs for rapidly producing a Chemistry Manufacturing and Control (CMC) data package, that meet regulatory requirements. This will include parallel testing approaches, use of rapid test methods such as next generation sequencing, challenges with neutralising virus seeds and scaling QC testing capacity.