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DEVELOPMENT OF ANALYTICAL CHARACTERISATION TOOLS FOR PROCESS MONITORING OF ADENOVIRUS-BASED VACCINES (ChAdOx AND Ad5)

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Product quality understanding is a critical part of viral vector vaccine manufacturing and regulation. Mass spectrometry is a technique that has widely been applied to protein-based therapeutics and could be used as a characterisation tool to monitor viral vector vaccine product quality. The ultimate objective of this Bill and Melinda Gates Foundation funded project is to enable vaccine manufacturing in Low and Middle-income countries (LMIC) through increased scientific understanding of viral vector vaccine manufacturing bottlenecks and therefore de-risking of vaccine development and manufacturing.

In this study, mass spectrometry was used to identify key adenovirus (AdV) viral proteins that are involved in virus maturation and infectivity as measured in different preparations of two different AdV vectors. This may enable the analytical differentiation between relative proportions of empty, non-infectious, and infectious viral particles as part of process monitoring. Two viral vectors used as the basis for commercial vaccines, Chimpanzee adenovirus (ChAdOx) and Human adenovirus Type 5 (Ad5), were processed at lab scale, analysed and differences in key viral proteins were observed that could potentially be used as critical quality attributes (CQA) to monitor or optimise manufacturing processes. In addition, by using electron microscopy different morphologies were characterised that are observed in different AdV particle preparations and demonstrate that these can also be used as an indication of product quality.

In summary, these analytical characterisation techniques can potentially be applied to characterise and improve AdV manufacturing processes. For example, these CQAs can be monitored throughout the process in order to distinguish the quality of each manufacturing step on the adenovirus-based vaccine. Such analytical techniques could enhance process understanding and product quality and be implemented for commercial AdV vaccine production.