ENABLEMENT BY SINGLE-USE TECHNOLOGY OF PRODUCTION OF TWO BILLION VACCINE DOSES OF ADENOVIRUS-VECTORED VACCINE IN UNDER A YEAR

Carina C. D. Joe, Nuffield Department of Medicine, Jenner Institute, University of Oxford, Oxford, UK
carina.joe@ndm.ox.ac.uk
Jinlin Jiang, Biopharmaceuticals Development, R&D, AstraZeneca, Gaithersburg, Maryland, USA
Thomas Linke, Biopharmaceuticals Development, R&D, AstraZeneca, Gaithersburg, Maryland, USA
Richard Turner, Biopharmaceuticals Development, R&D, AstraZeneca, Gaithersburg, Maryland, USA
Alexander D. Douglas, Nuffield Department of Medicine, Jenner Institute, University of Oxford, Oxford, UK

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Manufacturing of the simian adenovirus-vectored vaccine ChAdOx1 nCoV-19 (AZD1222, Vaxzevria) has played an important role in control of the COVID-19 pandemic. More than two billion doses have been produced, with the majority both made and used in low and middle income countries. This has been enabled by a programme of early technology transfer to multiple drug substance production sites, occurring in parallel with process development. The University of Oxford was transferring technology to five sites by March 2020, and AstraZeneca subsequently extended the drug substance manufacturing network to 12 countries.

This innovative approach was possible only as a result of single-use technology (SUT), and the presentation will provide a case study of the application of such technology to pandemic response. Pre-pandemic research in the Jenner Institute had developed a potentially scalable adenovirus manufacturing process, prioritising simplicity and end-to-end single-use product contact materials to facilitate future technology transfer. From February 2020, this was aggressively scaled up, reaching 200L by April and 1000L by June. In most respects the process scaled linearly, with small-scale work largely predictive of parameters which were successful at large scale. In parallel, process optimisations targeted further simplification.

This simple SUT-based process has been the critical factor enabling distributed manufacturing of a novel product type in existing facilities. Several of the facilities contributing to the production (including those in LMICs and the one which has contributed most to global output) had no previous experience of viral vector manufacture, yet were able to rapidly and effectively on-board the process and. Use of shared SUT has also assisted product comparability across the network.

SUT has thus played a pivotal role in both scale-up and scale-out, allowing manufacturing to reach a scale we believe to be unprecedented for any viral vector, and making a major contribution to equity of access to COVID-19 vaccines.