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TACKLING A CAPACITY BOTTLENECK TO PERMIT LARGE-SCALE DOWNSTREAM PROCESSING OF AN ADENOVIRUS-VECTORED VACCINE

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We recently described the strategy by which the University of Oxford and AstraZeneca collaboratively scaled up production of our adenovirus-vectored COVID-19 vaccine, using a productive fed batch process and distributed manufacturing approach in twelve countries around the world.

Here we will focus on the development of the downstream process used to make this vaccine. In early development, the first tangential flow filtration step in our previously developed process was noted to be a potential obstacle for scale-up beyond 200L. By removing this first tangential flow filtration step, we established a simple purification process capable of handling the increasing quantities and concentrations of viral titers which are becoming a bottleneck for many adenoviral vector manufacturing processes. Product quality was in line with regulatory expectations. This strategy has enabled 2 billion doses of the Oxford/AstraZeneca vaccine to be produced by November 2021, with the majority made and used in low- and middle-income countries.