Road to Manufacturing a COVID-19 Vaccine

A BC D E F G H I J K L

| WK1 | WK2 | WK3 | WK4 | WK5 | WK6 | WK7 | WK8 | WK9 | WK10 | WK11 | WK12 |

AstraZeneca provides CSL **'starter material'** which forms basis of vaccine (***adenovirus*** *and* ***host cells***)

A

B

Vials of **host cells** are thawed

Small batches of **host cells** are grown and transferred into increasingly larger size containers to expand and multiply

C

These cells are transferred to large scale **bioreactors** (2000L) for further growth

D

Once cells are at their critical volume - the **adenovirus** is introduced to the bioreactor

E

The vaccine is then **harvested** - a process of separation from the cells, then further filtration and purification

F

G

Bulk concentrated vaccine is frozen and stored in bulk CryoVaults, this is called **drug substance.** Samples are taken and undergo extensive testing – there are checks at **every step of manufacture,** not only at the end

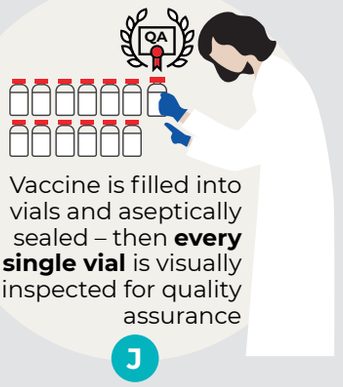
H

CryoVaults are transferred from **CSL Broadmeadows** to **Seqirus Parkville**, and are thawed out ready for formulation

Vaccine is formulated by diluting with buffer to the correct concentration and to ensure it is stable. This product is now called **'formulated vaccine bulk'**

I

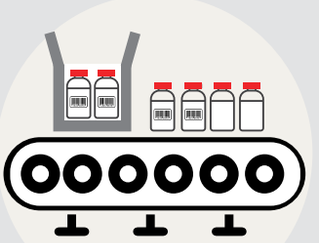
J



Vaccine is filled into vials and aseptically sealed – then **every single vial** is visually inspected for quality assurance

K

Samples taken for extensive **quality**, **sterility** and **stability** testing

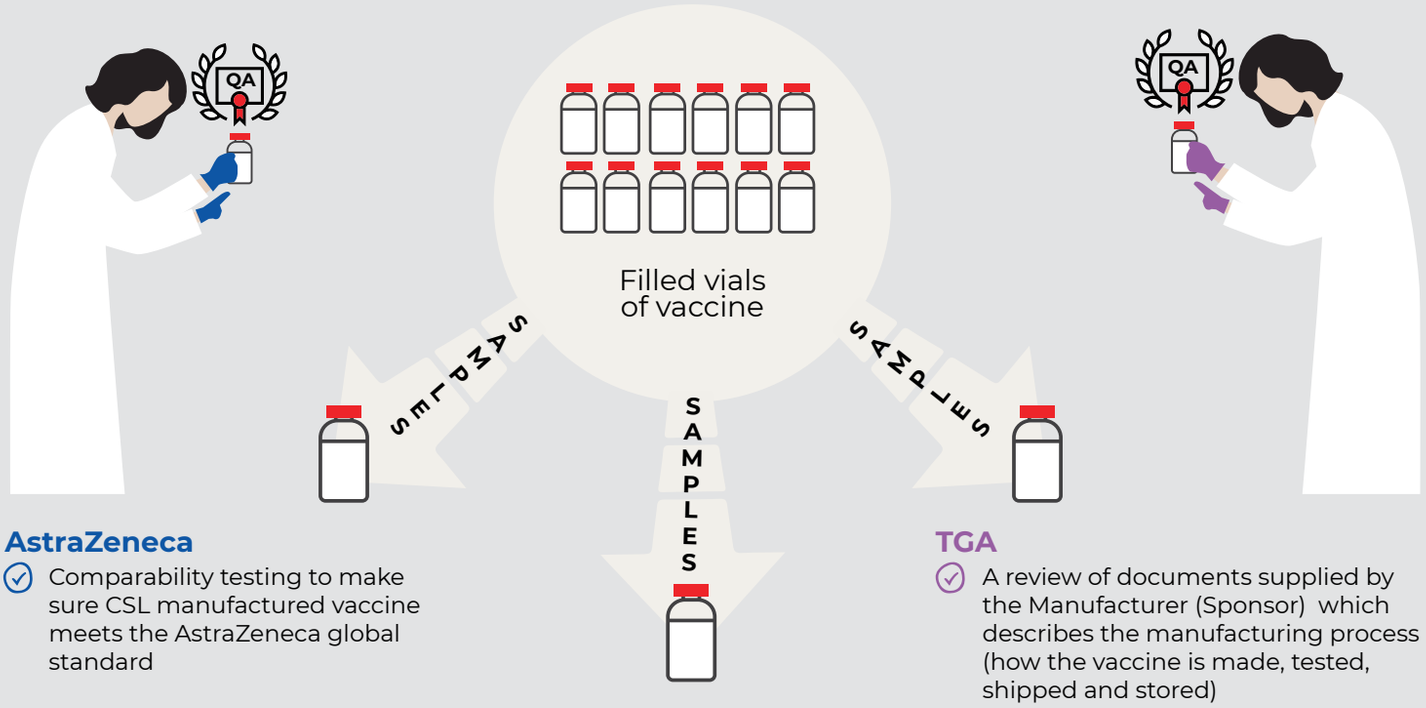


L

Products labelled and packed, ready for distribution

Road to a Vaccine

Quality testing process after vials are filled



AstraZeneca

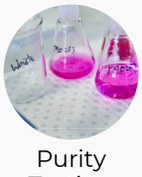
- Comparability testing to make sure CSL manufactured vaccine meets the AstraZeneca global standard

TGA

- A review of documents supplied by the Manufacturer (Sponsor) which describes the manufacturing process (how the vaccine is made, tested, shipped and stored)
- TGA laboratory testing (and/or review of testing results from an overseas regulatory laboratory that has been recognised by the TGA) to ensure the vaccine has been manufactured according to the required standards
- The TGA's laboratory may carry out a range of tests, including assessments for composition, identity, potency, purity and adventitious agents (contamination with microorganisms)

CSL

- CSL's Seqirus team undertakes weeks of critical quality testing which provides additional data for the TGA to assess each batch. Each batch is tested to confirm its stability and sterility - as well as confirming the vaccine contains the right level of antigen (potency testing)


Purity Testing


Potency Testing


Stability Testing

CONCURRENT TESTING PROCEDURES


CSL


TGA


AZ

DID YOU KNOW...

- Each pallet is temperature monitored to track the storage conditions as vaccines are transported
- Every single vial is visually inspected for quality assurance prior to labelling and packing
- The AstraZeneca COVID-19 vaccine is stored between 2-8 degrees celsius – the same temperature as a household refrigerator


Vaccine Release