

FILL AND FINISH

The initial Fill and Finish plant in Shanghai is expected to produce its first BioNTech batch next month. CEPI has modular fillers that can be installed in developing countries in three months. The manufacturer, MedInstill can assemble one in warehouse space in 3 days (see video). BioNTech's CEO believes it will take 12 months to establish a Fill and Finish plant in Africa. Could we establish contact with CEPI, MedInstill, Imperial College VaxHub, Moderna, BioNTech, AstraZeneca and CSL to help install one here and one in South Africa very rapidly and organize clinical trials for TGA/EMA/FDA to accept 200 dose pouches as alternative presentations for the Final Dose Form of all three vaccines?

See:

1. https://www.dcvmn.org/IMG/pdf/dcvmn_webinar_the_multidose_prefilled_bags_for_pandemics_08apr21.pdf
2. <https://www.youtube.com/watch?v=ZjyB0Hh6dRU&feature=youtu.be&t=1859>
3. <https://www.ft.com/content/2db9e21f-881d-4da2-8394-3ec732024581>
4. Why aren't covid-19 vaccines being manufactured in standard prefilled syringes? BMJ 2021; 372 doi: <https://doi.org/10.1136/bmj.n263> (Published 03 February 2021)
5. Resources, Production Scales and Time Required for Producing RNA Vaccines for the Global Pandemic Demand, 23 December 2020 Vaccines 2021, 9, 3 <https://dx.doi.org/10.3390/vaccines9010003>
6. www.medinstill.com/intact_modular_filler_imf.php (with links to 4 interesting videos)
7. https://www.medinstill.com/press_release_3.php
8. <http://www.aseptictech.com/compliance#modal6m2> (click "Read more" link for "Validation Master Plan")

Starting with Fill and Finish leaves things open for both Moderna and BioNTech/Pfizer, establishes contact with both of them and involves CSL in something they are actually doing.

Enables next step of an LNP formulation plant attached to the Filler instead of just tanks for excipients.

Actually makes a difference in current catastrophe while also being a necessary step in preparing for future ones.

Unable to include videos as DISER upload service was not provided successfully despite request 48 hours before deadline as required.

Out of time to include lots of other stuff and fill in pointless forms.