Introduction to vaccine R&D, manufacturing, and technology transfer to ramp up capacity

WTO – C19 Vaccines R&D, Manufacturing & Distribution workshop
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Organisation,
Coordination,
Collaboration,
Synchronisation,
Timing...
## Categories of vaccine platform technologies

<table>
<thead>
<tr>
<th>Category</th>
<th>Technology</th>
<th>Antigen(^1) used</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Pathogen Vaccines</td>
<td>Live Attenuated</td>
<td>Weakened pathogen</td>
<td>Rotavirus, MMR, Chickenpox, yellow fever</td>
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<tr>
<td></td>
<td>Inactivated</td>
<td>Killed/Altered Pathogen</td>
<td>Polio, whooping cough, Hep-A, rabies</td>
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<tr>
<td>Subunit Vaccines</td>
<td>Recombinant Protein</td>
<td>Yeast cells containing pathogen DNA</td>
<td>HPV, Hep-B, Men-B</td>
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<td></td>
<td>Toxoid</td>
<td>Toxins produced by pathogen</td>
<td>Diphtheria, tetanus</td>
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<tr>
<td></td>
<td>Conjugate</td>
<td>Sugars found on surface of pathogen</td>
<td>Hib, typhoid conjugate</td>
</tr>
<tr>
<td>Viral vector vaccines</td>
<td>Virus like particles</td>
<td>Molecules resembling virus</td>
<td>Hep-B, HPV</td>
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<tr>
<td></td>
<td>Replicating</td>
<td>Harmless viruses deliver antigen producing code to cells</td>
<td>Ervebo (Ebola)</td>
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<tr>
<td></td>
<td>Non replicating</td>
<td>Same as replicating but viruses cannot reproduce</td>
<td>Oxford-AstraZeneca COVID-19, J&amp;J COVID-19</td>
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<tr>
<td>Nucleic acid Vaccines</td>
<td>RNA</td>
<td>mRNA which causes cells to produce antigen</td>
<td>Pfizer, Moderna COVID-19</td>
</tr>
<tr>
<td></td>
<td>DNA</td>
<td>DNA which causes cells to produce antigen</td>
<td>None approved(^2)</td>
</tr>
</tbody>
</table>

Notes: 1. Antigen: a toxin or other foreign substance which induces an immune response in the body, especially the production of antibodies. 2. Melanoma, West Nile vaccines approved for veterinary use.

Source: University of Oxford, Vaccines Europe
Core stages of vaccine manufacture: CEPI’21 survey*

- Research (i.e. Identification, Investigation, and/or Characterization of novel vaccine candidates)
- Development (i.e. up/downstream processing and analytical development of novel vaccine candidates to support GMP processes and/or clinical trial material supply)
- Drug Substance (i.e. provision of starting seed/initial drug product for bulk manufacture)
- Drug Product (i.e. bulk drug product manufacture)
- Formulation & Filling (i.e. final formula preparation and filling of bulk drug product)
- Packaging & Labelling (i.e. package & label vials of final drug product and/or clinical trial material)
- Storage & Distribution (i.e. storage and supply of vaccine final drug product and/or clinical trial material)

*CEPI web: Survey launched by CEPI to track multinational vaccine manufacturing capacity for use in future epidemics and pandemics (19May’21) & Vaccine production efforts across key regions mapped in first-of-its-kind study to prepare for future pandemics (27Oct’21)
EoI (Q1/22)* - vaccine development and MfG facilities

Identified against a quorum of eligibility criteria to improve preparedness and response to future epidemics or pandemics

(i) Develop and supply vaccine candidates for use in GMP manufacture (of drug substance/product), QC, formulation & fill, distribution supporting commercial or clinical trial use

(ii) Rapidly provide vaccine emergency counter measures e.g., drug substance/product to LMICs for processing to address epidemic and pandemic threats

(iii) Ability to support transferring vaccine manufacture technologies/processes, analytical methods, innovations, and equipment to LMIC developers, manufacturers &/or CDMOs.

(iv) Be a training provider either at or virtually from the “Facility” and on site at LMIC developer/manufacturer to support strengthening workforce capability and expertise

(v) Evaluate and develop innovative equipment, processes, vaccine presentations to support rapid response to epi-/pandemic outbreaks

(vi) Where applicable, appropriate IP and associated license rights to under-take the required core criteria activities and where mutually agreed, support a technology transfer process to/from other entities in support of CEPI’s Equitable Access goals

(vii) Proven or clear plans to have appropriate quality systems, authority certified GMP readiness (incl. import/export experience) and recorded regulatory experience aligned to the activities described

*Calls-for-Proposal of interest:
1. Central Lab Network expansion (Q4/21) to more diseases than SARS-CoV2 vaccine analysis & onboard SH organizations
2. Innovative technologies to improve vaccine thermostability (Q1/22)