Manufacture of Covid-19 Vaccine
Overview and Challenges

Dr. Umesh Shaligram
Director, R&D

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SIIPL Introduction

- SIIPL was founded over 50 years ago in 1966
- World’s largest vaccine manufacturer by number of doses produced and sold globally (more than 1.6 billion doses)
- “It is our endeavor to make quality vaccines more affordable around the world because we firmly believe health should be the right of every child”
- SIIPL has successfully scaled-up various path breaking technologies/products over last five decades achieving huge economies of scale and resulting in optimisation of costs.
- SIIPL vaccines are used in more than 170 countries
- 65% of the children receive at least one SIIPL manufactured vaccine
# Covid-19 Vaccine Candidates with Collaborations

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<table>
<thead>
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<tbody>
<tr>
<td>1</td>
<td>Codagenix (COVI VAC)</td>
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<td>2</td>
<td>AstraZeneca-Oxford University - COVISHIELD</td>
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<td>3</td>
<td>Novavax - COVOVAX (NVX-CoV2373)</td>
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<td>4</td>
<td>SpyBiotech COVIVAXX (RBD HBsAg VLP)</td>
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**Note:** Due to confidentiality reasons it is not possible to disclose more information about these products at this stage.
## Covid-19 Vaccine Manufacturing

<table>
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<tr>
<th>Vaccine manufacturing Technology</th>
<th>Challenges in method of manufacturing</th>
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<td>messenger RNA (mRNA) vaccine</td>
<td>mRNA’s extremely large size, charge, intrinsic instability, and high susceptibility to enzymatic degradation</td>
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<td>Live attenuated viral vaccine</td>
<td>sensitivity towards adverse conditions such as extreme temperature</td>
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<tr>
<td>Inactivated viral vaccine</td>
<td>- improper virus inactivation&lt;br&gt;- possibility of destruction of viral-neutralizing epitopes at the time of inactivation process</td>
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<td>Recombinant vaccine</td>
<td>- selection of correct vector&lt;br&gt;- efficacy of recombinent vector&lt;br&gt;- stability of the insert</td>
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Covid-19 Vaccine Manufacturing and Scale up

- Single dose vials
- Multi dose vials - with preservative and without preservatives
- Prefilled syringes

Challenges:

- Selection of right cell line and vector
- Selection of precise methodology for purification
- Quick turn around for scale-up to achieve global demand
- Proper allignment of upstream and downstream processing units to handle large volumes
- Establishing analytical methods, specifications, method qualification and validation
- Hurdles in supply chain of essential raw materials and equipments
- Shortage of manpower
- Support from Regulatory Authorities
Challenges:

• Establishing large scale cold storage facilities for stock pilling
• Labelling - each country has its own labelling requirements
• Set up supply chain network and contract with airlines within shorter time span
• Tracking of vaccine supply and post vaccination monitoring
• Mass Immunization - how to handle? single dose vaccine vs. multi-dose vaccine
Thank you