Unlocking vaccine manufacturing potential with novel bioprocessing technology

Dr. Tulip Nuwal
Who we are and what we do?

- India's first bioprocess engineering company engaged in development and manufacturing of “Single-use bioreactors” for adherent and suspension cell cultures.

- We also offer off-shore contract development services for various applications ranging from
  - Vaccine manufacturing
  - Viral Vector production,
  - Cell and Gene Therapies
  - Biotherapeutics.

- **Clientele:** >70 successful installations around the globe

- **Patented DYNAMIC-BED REACTOR technology**
DBR technology ensures sufficient mixing and homogeneity while accommodating large surface area for high density growth of adherent cells. It provides superior scalability, process efficiency and up to 90% upstream cost reduction at larger scale.
## Available technologies v/s OmniBRx

<table>
<thead>
<tr>
<th>Performance criteria</th>
<th>Roller Bottles</th>
<th>Cell factories</th>
<th>Packed bed</th>
<th>Microcarriers</th>
<th>CellBRx® SUBs (200L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scalability</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Mixing</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Facility footprint (in sq. ft)</td>
<td>2378</td>
<td>1259</td>
<td>65</td>
<td>258</td>
<td>18</td>
</tr>
<tr>
<td>Ease of handling</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Equivalent no's of units to CellBRx</td>
<td>17647</td>
<td>2344</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

- Scalability ✓
- Efficiency ✓
- Affordability ✓
### Integrated Seed-train for 50L CellBRx:

#### Surface area (m²)  
- 0.5L SUB: 0.2
- 1L SUB: 1
- 5L SUB: 6.5
- 10L SUB: 40

#### Media Volume (L)  
- 0.5L SUB: 0.5
- 1L SUB: 2.5
- 5L SUB: 16
- 10L SUB: 75

#### Cells Seeded (mvc)  
- 0.5L SUB: 60
- 1L SUB: 300
- 5L SUB: 1,950
- 10L SUB: 12,000

#### Cells Grown (mvc)  
- 0.5L SUB: 2500
- 1L SUB: 16,250
- 5L SUB: 16,250
- 10L SUB: 1,00,000

### Conventional Seed train:

#### Surface area (m²)  
- T-175x: 0.0175 x 2
- CS-2: 0.127
- 2X CS-4: 0.509
- 3X CS-10: 2.04
- 4X CS-40: 10.2
- 20X CS-40: 51

#### Media Volume (L)  
- T-175x: 0.070
- CS-2: 0.4
- 2X CS-4: 1.6
- 3X CS-10: 6.4
- 4X CS-40: 32
- 20X CS-40: 160

#### Cells Seeded (mvc)  
- T-175x: 11
- CS-2: 38
- 2X CS-4: 153
- 3X CS-10: 611
- 4X CS-40: 3,053
- 20X CS-40: 15,264

#### Cells Grown (mvc)  
- T-175x: 191
- CS-2: 763
- 2X CS-4: 3,053
- 3X CS-10: 15,264
- 4X CS-40: 76,320

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50L SUB

+ Satellite batch (0.5L SUB)

Production vessel
From R&D to Manufacturing scale: OmniBRx has you covered

**Regulatory Compliances:**

For Controller unit:
- Fully Integrated process control system with integrated perfusion process module.
- 21CFR part 11 & GAMP-5 compliance for SCADA based process control system.

For Single-use Bioreactors:
- Biocompatibility, USP class VI, <88> <87> ISO 10993
- Extractables profiling
- TSE/BSE Free
- Sterilization certificate

<table>
<thead>
<tr>
<th>Bioreactor Volume</th>
<th>CellBRx 0.5 L</th>
<th>CellBRx 5 L</th>
<th>CellBRx 50 L</th>
<th>CellBRx 200 L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surface area</td>
<td>1 m² /2.5 m²</td>
<td>10 m² /25 m²</td>
<td>100 m² /250 m²</td>
<td>1000 m² /1500 m²</td>
</tr>
<tr>
<td>Bioreactor Volume</td>
<td>0.5 L</td>
<td>5 L</td>
<td>50 L</td>
<td>200 L</td>
</tr>
</tbody>
</table>
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