Global mRNA Hub

Manufacturers overview: Biovac
Biovac was founded in 2003 in South Africa to improve vaccine access across the continent

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<th>Foundation</th>
<th>The Biovac Institute (Biovac) was founded in 2003. Based in Cape Town, South Africa, it is a Public-Private Partnership between the South African government and the Biovac Consortium</th>
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<td>Vision</td>
<td>Biovac was launched to revitalise local human vaccine manufacture. Biovac’s vision is to be a Centre of Excellence rooted in Africa for the development and manufacture of affordable quality vaccines for Africa and the developing world’s needs</td>
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<td>Mission</td>
<td>Two main missions. Domestic capacity to respond to local, regional and continental needs for the provision of basic Extended Programme for Immunisation vaccines. Secondly, providing capacity for the development and introduction of novel vaccines, relevant to Africa’s particular needs</td>
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<td>Partnerships</td>
<td>Through partnerships, Biovac have set up modern manufacturing capabilities, developed their own manufacturing technologies and out-licensed these to international partners</td>
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Science of Protecting Life

End to end Vaccine Development and Manufacturing Capacity

- Product Development
- Drug Substance
- Drug Product

Mix of technologies – scientific know-how
Built capabilities in formulation, fill and finish as well as product development

... reverse integration approach

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<td>Pe-clinical</td>
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<td>Formulation (and F&amp;F) for 1 product:</td>
<td>F&amp;F technology transfer for 2 products:</td>
<td>Packaging of 3 other vaccines under cold chain conditions</td>
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<td>PCV13 (Prevenar13)</td>
<td>Covid-19 Vx vials per year – to be launched this year</td>
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Building globally recognized product development capability

- The Haemophilus Influenzae type b vaccine project introduced conjugate vaccine capability at Biovac.

Hib Conjugate Vaccine

- The Pneumococcal conjugate vaccine project allowed Biovac to entrench its conjugate vaccine technology platform.

Pneumo Conjugate Vaccine

- Biovac participated in 2 recombinant vaccine technology projects with international partners.

Recombinant Vaccines

- Development of a novel Group B Streptococcus conjugate vaccine.

GBS Conjugate Vaccine

- PATH Partnership
- Chengdu Institute for Biological Products
- Transferred Tech Packages
- Training

HIV/AIDS Vaccine Candidate – Italian partner
IDRI ID93

BMGF
PATH
Inventprise

Oral Cholera Vaccine

IVI, BMGF & Wellcome Trust
Infrastructure: over two decades
Global mRNA Hub: Biovac immediate focus

### Global partners
- Coordinate & lead project, monitor implementation
- Draft IP / Gov. agreements, monitor implementation

### Hub
- Receive tech and transfer to recipients
- Receive tech and produce vaccines

### Recipient

### Local / Regional partners
- Provide regional expertise
- Provide academic / clinical dev. support

### Biovac deliverables:
1. TT from Afrigen at Phase 1 scale of production
2. Establish process for pDNA, mRNA and LNP in-house through reproducibility and robustness testing;
3. Responsible for scale up and developing CPP’s;
4. Industrialisation and optimization of the process (Process and analytical validation);
5. Manufacture of the Ph III CTM.
6. Transfer of Industrial manufacturing process to Afrigen for transfer to other spokes
Forward looking

DS Facility **feasibility and concept design completed**, and suitable for both mRNA/OCV production (multi-product DS facility)

**Procurement: Analytical equipment and scale up manufacturing equipment** in progress

**Future intended applications:** plan to develop a readiness of the technology at scale to manufacture vaccines (if and when developed) **with specific relevance to Africa and other global markets e.g. TB, HIV/AIDS etc**

**Important and necessary project,** delivers much needed capacity for generation of Phase III CTM. Together with mRNA and OCV (& other partners) we are on route to establishing end-to-end manufacturing capacity.
Thank You