Establishing human vaccine manufacturing in Southern Africa

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Setting up the only vaccine manufacturing facility in Southern Africa
# History of human vaccine manufacture in SA

<table>
<thead>
<tr>
<th>State Vaccine Institute</th>
<th>SAIMR</th>
<th>National Institute of Virology</th>
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</thead>
<tbody>
<tr>
<td>Est. 1965</td>
<td>Est. 1935</td>
<td>Est. 1950s</td>
</tr>
<tr>
<td>• BCG</td>
<td>• DPT</td>
<td>• OPV</td>
</tr>
<tr>
<td>• Rabies</td>
<td>• Polio</td>
<td>• Yellow Fever</td>
</tr>
<tr>
<td>• Smallpox</td>
<td>• Cholera /Typhoid</td>
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</table>

All three facilities terminated production of vaccines between 1995-2001

**Due to:**
- Lack of relevant skills
- Lack of capital
- Increasing regulation
- Lack of adaptation with new technologies
- Lack of GMP culture/ lack of willingness to adopt GMP
- SA was in a transition period
Developing Country Manufacturers

Source: World vaccines, 2007
The need for human vaccines in Southern Africa continued to exist

- HIV
- Cholera
- Malaria
- Neonatal Tetanus
- Tuberculosis
- Measles
Options at the time......

1. Shut down completely or
2. Privatise or

THE BIOVAC INSTITUTE
A Public Private Partnership

Partner with the private sector
Vision and Objectives

To be a Centre of Excellence routed in Africa for the development and manufacture of affordable vaccines for Africa and the developing world’s needs

- Establish domestic vaccine production capacity
- Ensure economic viability
- Develop and retain local vaccine production skills
- Establish strong R&D capability
- Create a competitive platform for export
- Enable BBBEE
Mandate

1. Source & Supply EPI vaccines
2. Re-establish Manufacturing capacity
Growth and Development

Phase I
- Basic R&D
- Establish basic Quality Control infrastructure
- Establish Labelling & Packaging & Cold Chain capacity
- Recruit expertise

Phase II
- New manufacturing facility
- Invest in QA, QC, Production Logistics expertise & training
- Attract Technology Transfers

Phase III
- Commence Vaccine manufacture
- Implement Technology Transfers
- Invest in new Technology platforms
- Expansion of the site
- New Warehouse and Cold rooms

2003-08
2008-13
2013-
Biovac Headcount Projection
Perm Staff Only

2008 – 2011: 27% increase on headcount
2011 – 2012: 26% proposed increase
2013: 8% increase predominantly at specialist, technician, operator level
Staff requirements

- Vaccine (biological) production regulation standards are increasing globally.
- This requires more skills and higher level skills to maintain global standards.
- Presence of practical versus theoretical experience.
- Experienced skills are expensive and difficult to attract.
- Largest pool of global vaccine skills are located in Europe and Asia.
- Innovation is needed to attract skills.
Status Biovac Institute

Status 2012

- R&D
- Clinical Development
- Antigen Manufacture
- Formulation
- Filling
- Packaging & Labeling
- Cold chain and Distribution

- Existing GMP pilot scale lab
- Facility built in 2005
- New Manufacturing facility 2012
- Expansion of Warehouse & Cold rooms and Packaging 2013
Site in Pinelands, Cape Town
From 2013

Egypt
Senegal
South Africa
Technological Capability
R&D Capacity

Technology PLATFORMS
- Fermentation
- Purification
- Conjugation
- AMD
- Formulation

Supporting PLATFORMS
- Biosafety
- Documentation
- Pre-Clinical
- Clinical
- Project Management

Infrastructure
- Building D: Development Labs
  - BSL3 – Fermentation
  - DSP / Conjugation /AMD
- Building B: Pilot GMP – Clinical Material

7 Senior Scientists
5 Scientists
2 technologists
2 PhD students
4 Technicians
Conjugate Platform

**Hib**
- Hib development process commenced in 2006/7 aimed at developing a Hib conjugate suitable for use in fully liquid combination vaccines.
- Conjugate chemistry – based on NIH technology. Conjugate chemistry chosen for it’s stability and relative higher yields to previous conjugate processes.
- Stability good as liquid. Data up to 24 months real time.
- Immunogenicity in animals is good - compared very well to commercial conjugate.
- Transferred to two international vaccine companies.

**Pneumo**
- Project funded by PATH.
- Development of processes for tech transfer to CDIBP.
- Fermentation and purification of 3 serotype.
- Conjugation of 3 serotypes.
- Test different protein carriers.
Influenza Project
WHO Technology Transfer Initiative

Objectives:

• Help developing countries to develop influenza vaccine manufacturing capabilities and capacity for pandemic readiness

• Help achieve sustainable influenza vaccine production capacity
Flu vaccine capacity lacking in Sub-Saharan African
## Flu Project

<table>
<thead>
<tr>
<th>Immediate Objective</th>
<th>Longer term Objective</th>
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<tbody>
<tr>
<td>• Source a technology transfer partner and supplier of formulated bulk</td>
<td>• Identify a relevant modern technology compatible with our capacity in order to allow antigen manufacture.</td>
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<tr>
<td>• Establish local capability for filling of both seasonal and pandemic influenza vaccine.</td>
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Capabilities

SA Capability
• Regulatory - MCC (a PIC/S member)
• Universities: Internationally recognised
• Clinical trial Infrastructure: well established
• A clear biotechnology mandate

Biovac capability
• GMP facilities for production ready in 2013
• GMP facilities for pilot scale manufacture
• Established cold chain capability
• Know-how in fermentation, conjugation platforms
In Summary: capability exists in Southern Africa!
Thank you