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# EVOLUTION OF BVI AND FUTURE PROSPECTS

PROVIDING SUSTAINABLE ANIMAL HEALTH SOLUTIONS



## OUTLINE

- **About BVI**
- **Vaccine production**
- **OIE Reference laboratory Activities**
- **Challenges to the industry**
- **Future Production Process**

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## Introduction to BVI 1/2

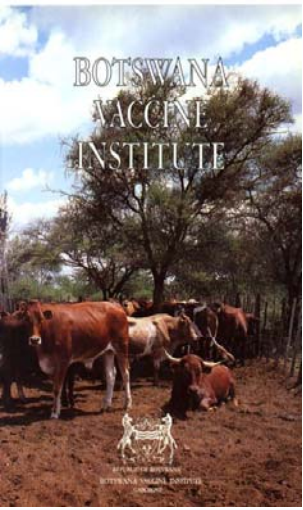






- Established following the return of SAT viruses in N/Botswana
- Technical partnership with Merial signed May 1978 (10 year renewal)
- Objective to research on viruses circulating in the region to make appropriate vaccines to safeguard beef trade
- Operations fully commercial driven by vaccine sales
- 100% Shareholding to GoB
- OIE RRL for Sub-Saharan Africa for FMD since 1985

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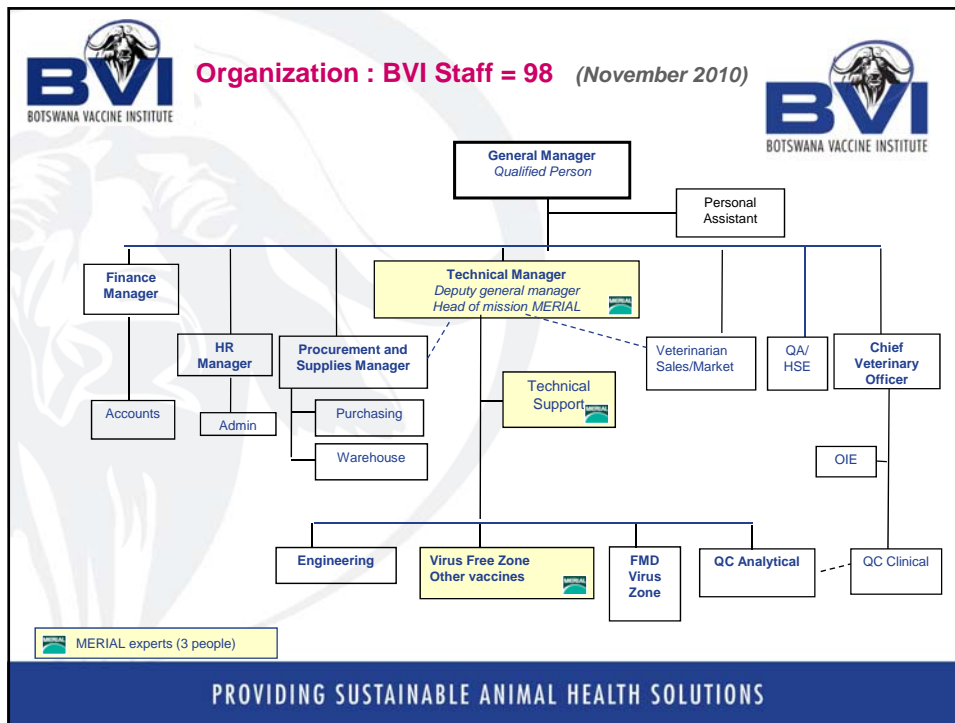
## Introduction 2/2





- Aim to contribute to the livestock Industry in Botswana,SADC Region & Sub Saharan Africa
- Focus on herd health through prevention of trans-boundary animal diseases (TAD's) &
- Promote Animal Health to:
- increased animal production
  - Wealth creation through beef trade
  - Employment creation & prevention of urban migrations
  - Poverty reduction & food security
- Achieve objectives of the UN "MDG" for African continent though livestock

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**BVI** BOTSWANA VACCINE INSTITUTE

## Our Guiding Principles

- **Vision-** *BVI is committed to be the leader in the production of quality livestock vaccines*
- **Mission-**
- *To support the livestock industry by manufacturing relevant vaccines and providing services of the highest quality through utilization of the best technology, skilled and dedicated employees to combat economically devastating livestock diseases.*
- *Through a network of partnerships, enhance adherence to sound manufacturing and environmentally friendly processes and remain sustainable.*

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## Diversification in Manufacturing and Sales



**1978** ⇒ FMD vaccine (AFTOVAX)

**1985** ⇒ Rinderpest vaccine (PESTOBOV 100) \*

**1992** ⇒ Anthrax (CARBOVAX)  
⇒ Blackleg (ASYMPTOL)

**1993** ⇒ CBPP (PERIBOV)

**1994** ⇒ **Thermostable Rinderpest (PESTOBOV-50T) \***

**1998** ⇒ "Peste des Petits Ruminants" PPR-VAC

**2010** ⇒ Purified FMD Vaccine (Aftovaxpur) and Antigen Banks

\*Product discontinued 2005 due to GREP recommendation



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## Quality Control Tests (1/2)



- vaccination requires high quality, safe & potent vaccines
- In process controls:
  - Sterility tests
  - Purity test (typing etc)
  - virus concentration (sucrose density gradient)
  - Inactivation slope
  - Safety on cells

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## Quality Control Tests (2/2)



- Safety = laboratory & clinical methods
- Potency/efficacy
- Vaccines routinely sent to PANVAC for testing
  
- **Other Assurance Steps**
  1. Institution of QMS since 2007
  2. BVI ISO 90001:2008 accredited until 2013
  3. Currently undertaking steps for ISO 17025 accreditation for QC and OIE (documentation complete awaiting assessment)

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## BVI contribution to FMD diagnosis in Africa



• 1985 : Recognition by the O.I.E., the World Animal Health Organisation, as "Regional Reference Laboratory for the Sub-Saharan Africa"



- Provides free laboratory diagnosis to SADC & SSA
- Provides free technical assistance during field investigation and sample collection
- Facilities used for training of officials of FMD Diagnosis
- Plans for capacitating of lab in both mechanical and human aspects

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## Epidemiological Surveillance



- The use of the most appropriate vaccine as an integrated control program relies on the in depth knowledge of the virus strains circulating in the area or regions.
- OIE Regional Reference Lab at BVI (in collaboration with others) therefore plays a significant role in collecting, and characterisation of field isolates, then publishing the epidemiological characteristics of the isolates and thereafter making them available to manufactures.
- Continuous monitoring of the field virus against the vaccine strains (r1 values) must be maintained. (Priorities vary between MS)



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## Challenges to industry (1/2)



- **Product Quality**
  - Counterfeit products vs. fit for purpose
  - Strain variations (no epidemiological surveillance)
  - Un harmonised techniques for vaccine selection
- **Product availability**
  - Limited know how (no technology transfer)
  - Lack of capacity (limited supply base)
  - Unavailability of emergency stocks
  - Business model and pricing

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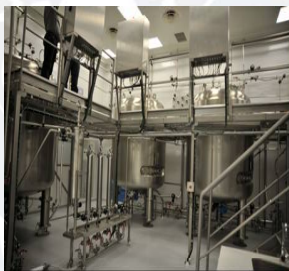
## Challenges to industry(2/2)



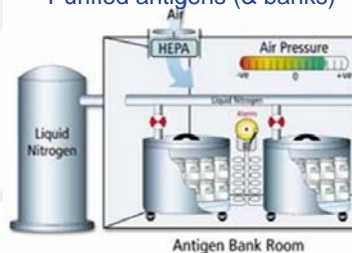
- **Regulatory & legislative controls**
  - Un harmonised registration requirements
  - Lack of use of AU/PANVAC by continental vaccine manufacturers
  - Variability between regional markets
  - Lack of regulation of vaccines/medicines imported into Africa
- **Regional Collaboration**
  - Lack of harmonised regional disease control programs
  - Lack of sample submission to OIE Lab for disease characterisation most of the BVI- OIE has to initiate
  - Lack of transparency in disease reporting on the continent

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## BVI FMD Project 2010



- Improve GMP compliance
- Double production Capacity
- Purified antigens (& banks)



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