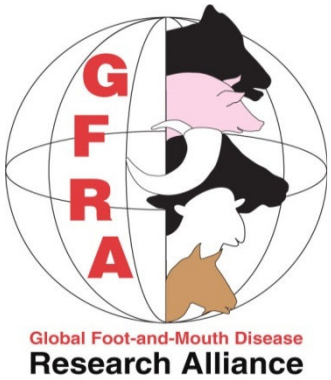
Research and Development Centre
Indian Immunologicals Limited, Hyderabad



Quality Assurance of FMD Vaccines in India

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2012 GFRA Scientific Workshop
Surveillance, Epidemiology, Vaccination and Control of Foot-and-Mouth Disease.
Hazyview, South Africa
17 to 19 April 2012

Outline …

- FMD vaccine production in India
- Quality control
- Regulatory requirements
- Summary and recommendations

FMD vaccine production in India

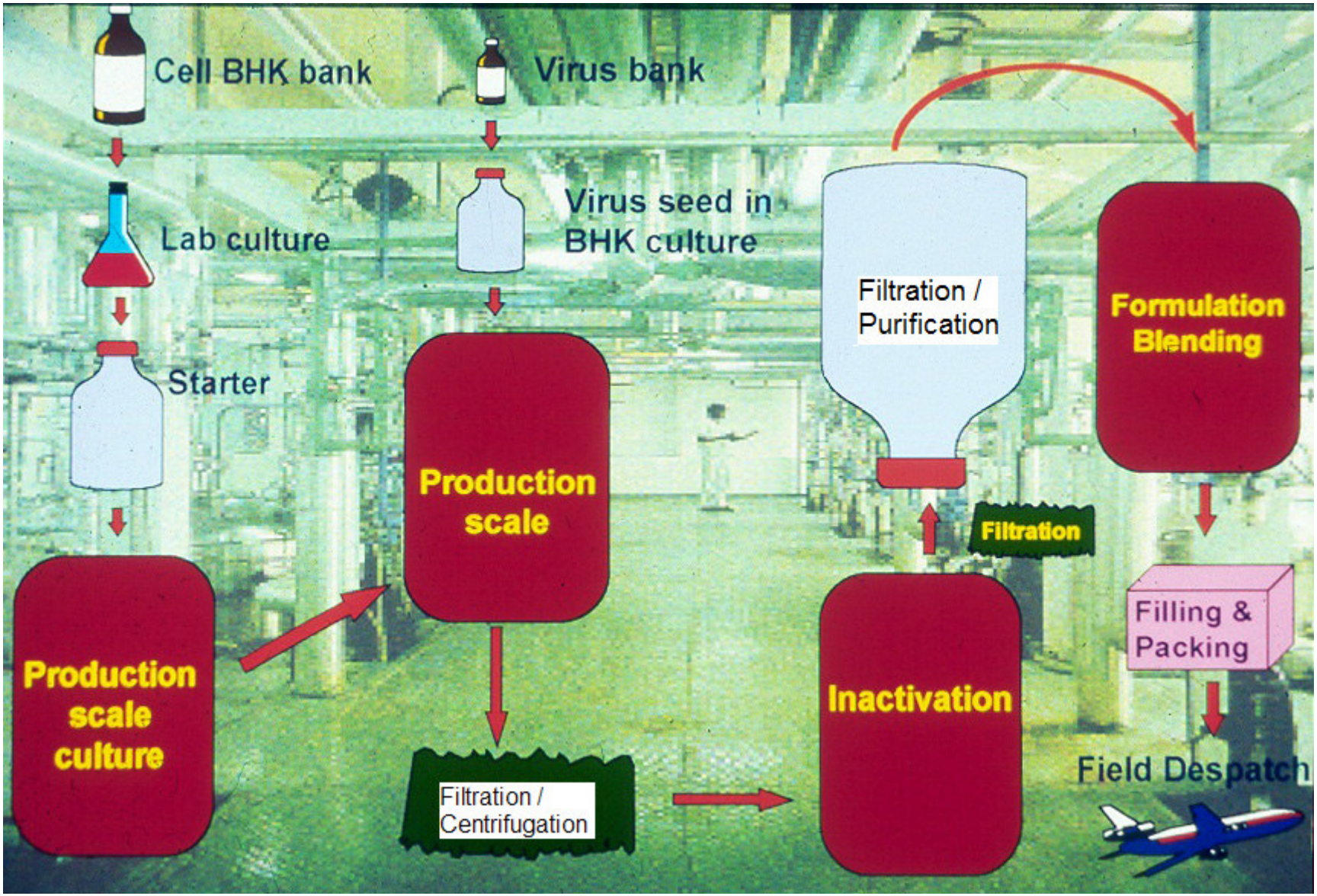
1. FMD vaccine manufacturers
2. Vaccine production technology
3. Vaccine strain selection

Vaccine production technology

- All manufacturers use BHK suspension culture technique for manufacture of vaccine.
- Bioreactors/fermentors ranging from 50 L to 10000 L are being used for production of vaccine
- Binaryethyleneimine (BEI) is used as an inactivant.
- Aluminium hydroxide and oil adjuvant vaccines are manufactured.

Serotype	Vaccine strain	
Type O	O TNN 24/84 or O IND R2/75 until October 2003	O IND R2/75 from October 2003 onwards
Type A	A IND 17/82 or A IND 7/77 Till 2003	A IND 17/82 till September, 2008 A IND 40/00 from September 2008 onwards
Type Asia1	Asia1 WBN 117/85 or Asia1 IND 63/72 until October 2003	Asia1 IND 63/72 from October 2003 onwards
Type C	C IND 51/79 or C BOM 64 until October 2003	Discontinued since October 2003

Vaccine production flow diagram



Quality Control

1. Raw material testing
2. In-process control
    - 2.1. Cell line characterization
    - 2.2. Virus characterization
    - 2.3. Cell culture cycle
    - 2.4. Seed virus testing
    - 2.5. Virus production
    - 2.6. Inactivation
    - 2.7. Purification and concentration

Quality control

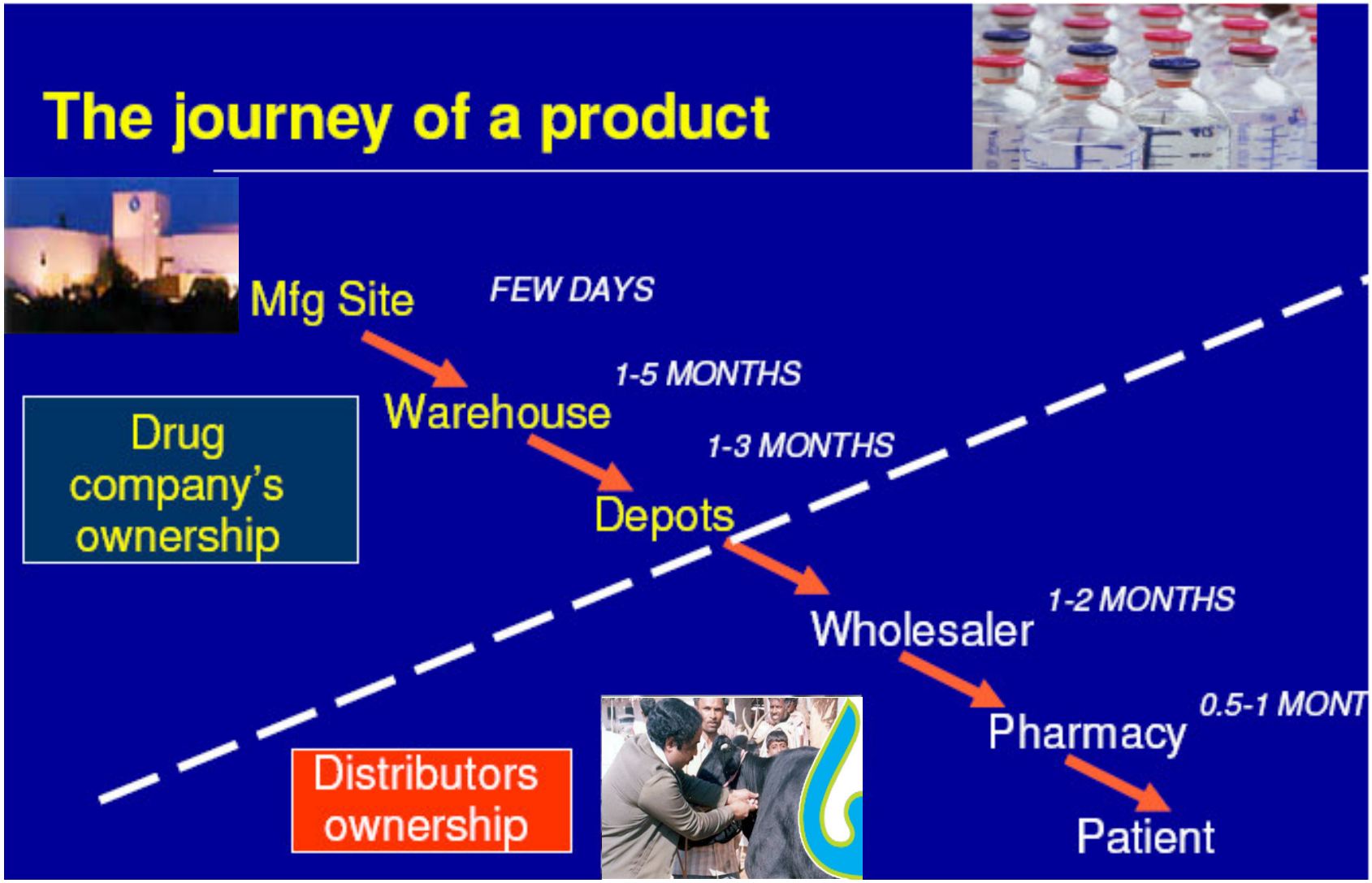
- FMD vaccine monograph – IP 2010

↓ Identification

↓ Tests
- Safety
- Sterility
- Potency
  - Alternate Potency Test
  - Serological Assay

↓ Labeling

FMD vaccine – Cold chain



Post-marketing surveillance

Phase	Type O		Type A		Type Asia 1	
	Pre-Vaccination	Post-Vaccination	Pre-Vaccination	Post-Vaccination	Pre-Vaccination	Post-Vaccination
IX	63.7	85.6	52	73.3	52.6	73
X	63.4	87.4	50.6	74.1	48.9	76.7

Percentage of animals showing antibody titers of ≥1.8 log10 against FMD virus – 30 DPV Source: PD FMD Annual report 2010-11

Regulatory requirements

1. Regulatory authorities

1.1 Drug Control authorities

1.2 Animal Ethics Committee

Conclusion

- Installed capacity of five Indian FMD manufacturers are 440 M trivalent doses.
- Several improvements in production have been made.
- cGMP and QA procedures adopted by Indian manufacturers help in production of quality FMD vaccine.
- Harmonization of vaccine strain and post marketing surveillance will add value to the satisfaction of customers.

Recommendations for consideration

1. An independent agency to carry out FMD vaccine batch testing and provide the manufacturers with the batch release certificate.
2. Post-marketing surveillance should be made mandatory.

Acknowledgements

GFRA
Global Foot-and-Mouth Disease
Research Alliance

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Excellence in Research and Development

Thanks for your attention