



# **AU-PANVAC'S VIEW AND EXPERIENCES ON AUTOGENOUS VACCINES**

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# OUTLINE OF THE PRESENTATION

- ❖ **Introduction**
- ❖ **Criteria for Autogenous Vaccines**
- ❖ **Benefits/Effective Autogenous Vaccines**
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- ❖ **Autogenous Vaccine in Africa**
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- ❖ **Conclusion**



# INTRODUCTION

- ❖ Autogenous vaccines are farm specific vaccines produced with farm specific bacteria/virus
- ❖ Autogenous vaccine may be approved to meet a specific and immediate need when :
  - ❑ Disease(s) associated with **new pathogen(s)**,
  - ❑ **Rapid response** is required prior to the approval of a commercial vaccine (approval process for commercial vaccines can be three to five years)
  - ❑ A commercial vaccine is **ineffective or not available**.



# CRITERIA FOR AUTOGENOUS VACCINES (AV)

- ❖ AV are prepared by Authorized Manufacturers for Emergency use.
- ❖ Veterinarian-Client-Patient Relationship (VCP): *Preparation and the use of AV are under the direction of a Vet. Practitioner (or Approved Non-Vet. Specialist).*
- ❖ AV are custom vaccines that consist of herd/Farm specific (homologous) antigens.
- ❖ AV are **killed vaccines** prepared from the culture(s) of microorganism(s) isolated from the Herd/Farm
- ❖ AV **must be safe** for the target and non-target animals, humans, and the environment



# BENEFITS OF AUTOGENOUS VACCINES

- ❖ Provide an **individual solution** where:
  - ❑ Commercial vaccines are **ineffective** due to **antigenic diversity**
  - ❑ Licensed commercial vaccines are not available
- ❖ Fight against multi-drug resistant bacteria
- ❖ Limit the use of antibiotics



## PUBLICATIONS ON EFFECTIVE AUTOGENOUS VACCINES

❖ **Papilloma vaccine:** *Efficacy of Autogenous Vaccine and Auto-hemotherapy in Bovine Cutaneous Papillomatosis, [Intas Polivet \(2013\) Vol. 14 \(II\): 411-414](#)*

❖ **Infectious coryza (*Avibacterium paragallinarum*) in chicken:** *Development of autogenous vaccine for effective control of Infectious coryza in chicken, <https://doi.org/10.1016/j.ijid.2018.04.4220>*

Comparison Commercial and Autogenous Vaccine

- ❑ Indigenous coryza vaccine is the best preventive measure against both homologous and heterologous challenges.
- ❑ Commercial vaccines provided good protection against homologous challenge but showed poor performance against heterologous challenge



# REGULATIONS OF AUTOGENOUS VACCINE

	USA	EU	Canada	AU MS
Regulation	9 CFR 113.113	Under National specific regulation (Harmonized in process)	CFIA-CCVB	Specific country Regul. ???
Registration	Not required	Not required	Not required	???
Production	Vet. Order	Vet. Order	Vet. Order	???

- ❖ Use of autogenous vaccine limited generally to 6-12 months.
- ❖ Repeat the production of autogenous vaccines is based on the success of vaccination and the disease agents isolated from the herd.

# PRODUCTION OF AUTOGENOUS VACCINES

## ❖ Roles and responsibilities of Vet. Practitioner (s)



- Proper veterinarian-client-patient relationship
- Coordination of disease diagnosis, isolation/identification of causative organism
- Deliver a prescription for production of an AV
- Administration of the AV under the directions of the Vet.





# PRODUCTION OF AUTOGENOUS VACCINE...

## ❖ Roles and Responsibilities of the Manufacturer

- ❑ Characterization and Preparation of Microbial Seeds
- ❑ Ensuring the purity and identity of Seed Materials
- ❑ Production, testing, packaging, labelling, storage and distribution of AV (*Rules & Regulations in the country*).
- ❑ Ensuring the purity/sterility and safety prior the use of AV
- ❑ Maintaining appropriate records
- ❑ Reporting any suspected adverse reaction due to the AV

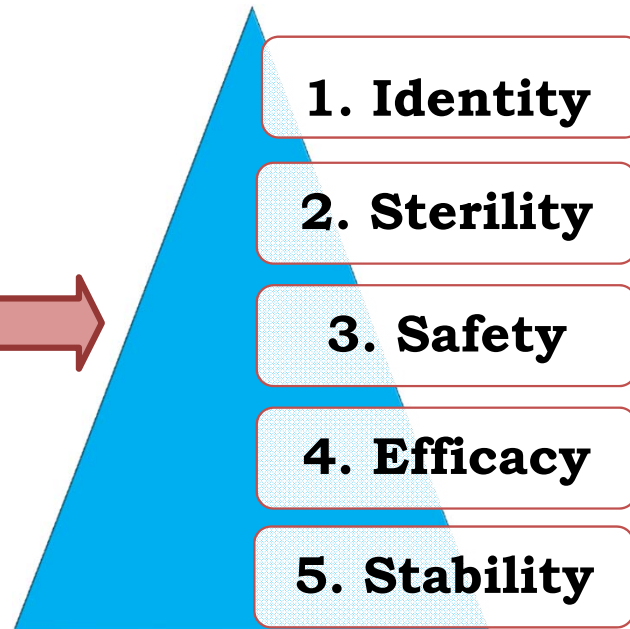
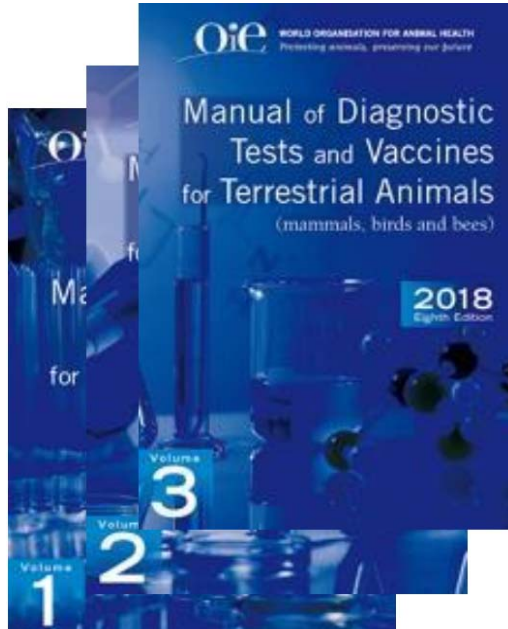


# AUTOGENOUS VACCINES IN AFRICA

- ❖ In Africa Vaccines classified as autogenous, do not strictly fit the definition of AV
- ❖ Several manufacturers produce killed vaccines with local specific isolates from regions/areas of countries.
  - ❑ Pasteurella Vaccines
  - ❑ Clostridia Vaccines for Black quarter/Black leg (*Clostridium chauvoei*):
    - *Madagascar and Sudan: Very good vaccines with local isolates*
  - ❑ East Coast Fever vaccine (Parasitic vaccine): based on local isolates (Malawi, Zambia, Kenya and Zimbabwe)

# BRIEF RECALL ON AU-PANVAC ACTIVITIES

- ❖ **Mission:** “To promote the use of **Good Quality Vaccines** and **Diagnostic Reagents** for the control and eradication of animal diseases in Africa.”
- ❖ **Quality Control of Veterinary Vaccines**





# BRIEF RECALL ON AU-PANVAC ACTIVITIES

## ❖ International Recognition in Quality Control of Veterinary Vaccines



**OIE Collaborating Center for Quality  
Control Of Veterinary vaccine** (OIE  
Gen. Ass. Resolution 32, May 2013)



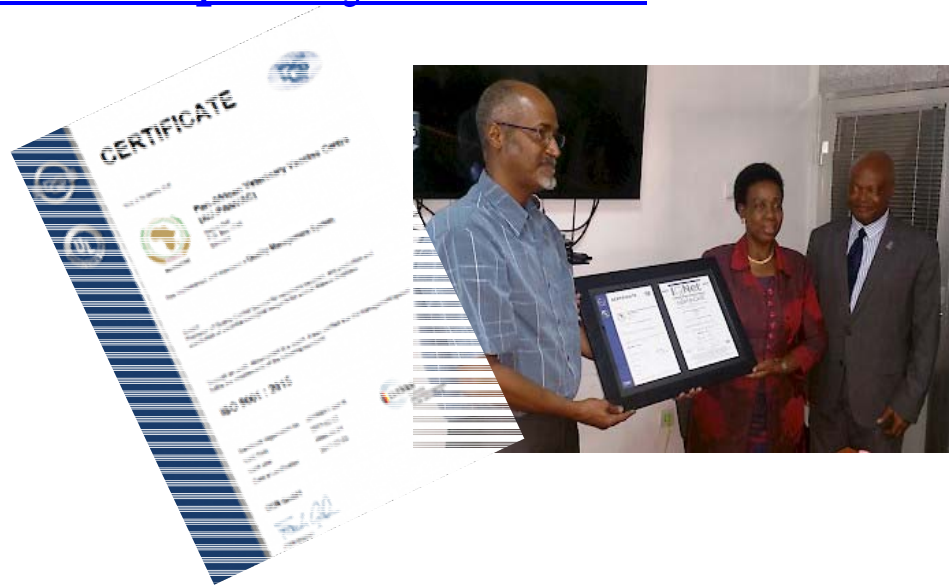
**FAO Reference Centre for Technical  
Assistance in Quality Control of  
Veterinary Vaccines** (11<sup>th</sup> May 2015)



# AU-PANVAC: ISO Certification and Accreditation

## ❖ ISO 9001:2015 Certified by DQS Holding (Germany)

<https://www.dqs-holding.com/en/news/iso-9001-2015-and-dqs-in-support-of-quality-vaccines>



## ❖ ISO 17025 accredited by Ethiopian National Accreditation Office (ENNO)





# AU-PANVAC ACTIVITIES: SUPPORT TO VACCINE MANUFACTURERS

## ❖ Project PANVAC & MIPROLAB.COM in German (Prof. Bohnel):

- ❑ To build capacity in AU-PANVAC to train National laboratories & Manufacturers on the **characterization of local isolates**
  - Bacterial isolates: genus and species level.
  - Viral isolates: identified to at least the family level
- ❑ The **use of local isolates as vaccine candidates**



## **AU-PANVAC ACTIVITIES: SUPPORT TO VACCINE MANUFACTURERS...**

- ❖ Ensure the purity and identity of seed materials (microbial seeds) used for the production
- ❖ Testing of the final product: Evaluation of the purity, sterility and safety
- ❖ Ensure all necessary validation processes are implemented for the vaccine to be considered as commercial vaccine



## CONCLUSION

- ❖ In Africa, AU-PANVAC is working to promote the use of vaccines produced from local isolates by Vaccines Manufacturers
- ❖ This is necessary in view of the increasing importance of diseases such as Pasteurellosis (*Pasteurella multocida*) and Clostridiosis (*Clostridium chauvoei*)...
- ❖ Promoting the use of Indigenous Vaccines will contribute greatly towards reducing the use of antibiotics/antimicrobial resistance
- ❖ PANVAC will continue to work with partners to build capacity for the production of autogenous vaccines in Africa.





**THANK YOU**

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