○○○ **Chair: Dr Jamil Gomes De Souza**

ASSURING THE POTENCY, PURITY AND QUALITY OF FOOT AND MOUTH DISEASE VACCINES

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Foot-and-mouth disease (FMD) vaccines are used in many countries where the disease is endemic and in countries/zones recognised as free of FMD where vaccination is applied. Free FMD countries keep reserves of vaccines or concentrated antigens as Vaccine Banks in case of an emergency.

The quality of FMD vaccines used is critical to assure the efficacy of control and eradication programs.

FMD vaccines currently used contain chemically inactivated antigens. The inactivant used is BEI (binary ethyleneimine) added in two stages to assure complete inactivation of antigens. After inactivation the antigens are usually concentrated by different processes. Regarding quality control, safety (innocuity) of the final product regarding absence of residual live virus is of utmost importance. Additionally manufacturers should perform the kinetics of each inactivation process.

Potency of FMD vaccines is evaluated in the target animals. Direct methods are based on virus challenge with the homologous strain in a group of vaccinated cattle. The approved methods are the 50% Protective Dose (PD_{50}) and the PGP test (percentage of protection against generalised foot infection). Direct methods are used as requirement for licensing of the product.

For batch control, post license, and in order to reduce the virus challenge trials and animal welfare consideration, indirect methods that evaluate the level of antibodies post vaccination are used, being the Liquid-Phase ELISA the preferred test. These assays should have a statistical validated correlation with direct methods PD_{50} or PGP. Other tests could be used for assessment of vaccine potency in the future.

Amongst others, its is critical the characterisation and purity, regarding absence of adventitious agents, of master seed virus used in the FMD production. Sera, and other raw materials of animal origin used for cell culture or media, should be originated in countries with negligible risk of BSE.

The term vaccine purity is related to the lack of immunogenicity against non structural proteins induced by FMD vaccines. During the manufacturing process a purification step is needed to remove the majority of NSP. Non purified vaccines should not be approved for use in vaccination programs because they can interfere with the serosurveillance tests applied for demonstrating absence of viral circulation as part of control programs, and recognition of free areas.

Vaccine production laboratories shall comply with general framework of Good Manufacturing Practice (GMP) and the facility should meet the requirements of Biosafety Level 4 (OIE containment group 4)