Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

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Use of platform technologies in regulatory applications for veterinary vaccines in the European Union – Perspective from the pharmaceutical industry.:

This presentation will provide the perspective (benefits and challenges) from the veterinary pharmaceutical industry on 3 types of platform technologies that can be used in regulatory applications for veterinary vaccines in the European Union: the vaccine platform technology master file [vPTMF], the vaccine antigen master file [VAMF] and the multi-strain [MS] dossier. Since the actual implementation of the Regulation 2019/6 that introduced or modified those concepts and came into force in 2022, the veterinary industry has quickly gained experience with those, since several vPTMFs and VAMFs have already been certified by the EMA, and several MS dossiers have been approved. A vPTMF is a file containing comprehensive data on a vaccine platform's manufacturing, quality control, stability, safety, and efficacy. Once a vPTMF is certified, the data already approved in the vPTMF do not need to be re-assessed for subsequent products using the same vPTMF. A VAMF is a comprehensive dossier that contains all the detailed quality-related information about a specific antigen used in vaccine production. Once a VAMF is certified and the corresponding antigen is used in a new vaccine, the data already certified do not need to be re-assessed by the regulatory authorities. A MS dossier means a single dossier containing the relevant data for a unique and thorough scientific assessment of the different options of strains/combinations of strains permitting the authorisation of inactivated vaccines against antigenically variable viruses or bacteria for which rapid or frequent change in the composition of vaccine formulations is needed to ensure efficacy with regard to the epidemiological situation in the field. A MS dossier covers a number of different strains of a single virus species, bacteria genus or vector produced according to the seed lot system. The formulation of the final product includes a specification for the maximum antigen content per strain and the maximum number of strains in accordance with the safety data submitted with the application.