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Quality and consistency of cell culture media with a highlight on FMDV

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The GMP requirements for veterinary vaccine processes are very similar to GMP requirements for human vaccine manufacturing. All materials should be subjected to a risk assessment and testing when necessary, in particular, raw materials derived from humans and animals, which can be a primary source for the introduction of adventitious agents. One of the challenges related to the production of FMDV is the ability to produce a highly potent vaccine at low cost, while improving process efficiency and maintaining regulatory compliant production environment. Complex cell culture media is used for propagation of BHK21 cells for FMDV production. The typical media is a GMEM base formulated with TPB and Lactalbumin. Most of the media contains also adult bovine serum (as high as 10%) but during virus incubation stage, the serum containing media is removed and the virus propagation happens in fresh serum free media. The use of more defined media composition without serum becomes a must, mainly due to the high variability of serum, the risk of introducing adventitious agent in the process, the fact that serum may contain antibodies against FMD and the associated cost of supply and serum treatment before it enters into the process. This presentation will describe how advancements in raw material procurement, characterization and processing has led to new high quality cell culture media standard that enables FMDV Vaccine manufacturers to resolve a long standing paradigm - the elimination of serum from their cell culture process

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