

PCV-1 detection in Rotavirus vaccine: a case study in the risk assessment for adventitious agent testing

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GlaxoSmithKline has been made aware of research data indicating the presence of Porcine circovirus type 1 DNA (PCV-1) in *Rotarix*TM. Subsequent testing of *Rotarix*TM has confirmed that material of PCV-1 has been present in *Rotarix*TM since the initial stages of the vaccine's development. In-depth investigation combined with retrospective analysis of any potential impact of the presence of material from PCV-1 on the safety of the vaccine led to the conclusion that the benefit/risk profile of *Rotarix*TM remained unchanged and positive. This presentation will focus on the learning's from this case study in terms of adventitious agents testing and risk assessment, and on the actions taken by the Company in order to guarantee continuous quality and safety of vaccines within the context of limited downstream purification process.