Manufacturers of vaccines and other biological products must ensure that final products derived from continuous mammalian cell lines contain low levels of residual host cell DNA (HCD). The presence of HCD in the final product is of significant concern due to:

- Potential transfer of activated cellular and/or viral onco-genes, particularly if the cell substrate is tumourogenic
- Production of infectious viruses from viral DNA
- Aberrant gene expression by insertion of sequences into sensitive control regions of genes

Stringent guidelines stipulate the maximum amount of DNA that should be present in the clinical lot. For example, a vaccine production using a continuous non-tumourogenic cell line such as low passage Vero should be limited to a maximum level of 10ng of cellular DNA per dose. There may be instances where continuous cell line DNA is considered to pose a great risk; for example, if the cell contains retroviral proviral sequences and limits of 100pg per dose can be recommended. Therefore in many cases the maximum amount of residual DNA per dose should be set on a case-by-case basis dependant on the product and its application.

SGS uses the Applied Biosystems 7900HT and Quantitative TaqMan PCR (qPCR) technology to quantify residual DNA in the drug substance. Various other methods exist to detect Residual HCD, namely Threshold assay (ELISA-based Anti-DNA antibody) and DNA Hybridization (slot-blot assay). SGS offers qPCR because it is the most robust, reliable, reproducible and sensitive method for this purpose and is approved by worldwide regulatory authorities.

Because SGS has extensive experience in sample preparation and qPCR, and is able to analyze samples from various matrix compositions with high quality results and rapid turn-around-time.
ABOUT SGS

Part of the SGS Group, SGS Life Science Services is a leading contract service organization providing analytical development, biologics characterization, biosafety, quality control testing and clinical research. Operating 25 facilities in 13 countries across Europe, the Americas and Asia, with 1,600 employees, SGS represents the world’s largest, state-of-the-art network of GMP compliant laboratories.

SGS provides a comprehensive range of biosafety services such as: virology, cell and molecular biology as well as microbiology and electron microscopy. Health Authorities, including the US FDA and the EMA, require companies to undergo safety testing to demonstrate that all cell banks, viral banks, raw materials of animal origin, bulk harvests, and batches of clinical drug are free of bacteria, fungi, mycoplasma, viruses and other potential contaminants. SGS helps clients by ensuring product safety in satisfying these regulatory requirements through a large range of validated assays and develops new services in the following areas:

- Cell bank and virus seeds characterization per the major compendia, regulatory and ICH guidelines
- Raw material and bulk harvest testing (sterility, mycoplasma, viruses and other potential biological contaminants)
- Final product testing for residual DNA and other process related impurities
- Regulatory and safety consultancy services
- Custom development of assays

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WHEN YOU NEED TO BE SURE

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