Question #1

Based on currently available data, what range of cellular DNA derived from cells in which there is no evidence of viral elements should be considered essentially risk-free (i.e., less than 1 in 10^6) for an oncogenic event?

Question #2

Should cellular DNA derived from cells in which there is no evidence of viral elements be considered an impurity rather than a risk factor when it is reduced to acceptable levels?

Question #3

Is DNA at any level from any cell type of any concern when an inactivating agent such as BPL is used in the manufacturing process and data are available to demonstrate the inactivation of DNA as well as the vaccine virus (e.g., rabies)?

Question #4

Should distinctions be made between the amount of cellular DNA that should be allowed as an impurity in parenteral vs oral products?

Question #5

Are there different levels of risk associated with DNA from autologous, homologous, or heterologous sources?

Question #6

Are positive control(s) appropriate or feasible in any future risk assessment studies on cellular DNA in view of the absence of data to demonstrate that cellular DNA is oncogenic?

Question #7

What sensitive and validated methods can be applied in cell substrate characterization studies to evaluate the potential of cellular DNA to be oncogenic?

Question #8

Can an alternative approach to laboratory testing, such as risk assessment, be used to address the risk of cellular DNA in biological products?