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## CASE STUDY: IDENTIFICATION, CHARACTERIZATION AND MITIGATION OF GROWTH INHIBITARY LEACHABLE COMPOUND FROM DISPOSABLE PLASTIC VESSELS

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The inhibition of CHO cell growth was observed in culture medium incubated in disposable plastic vessel, but not in a control glass vessel. Gamma irradiation of vessels during terminal sterilization step was required to produce the growth inhibitory leachable, as unsterilized vessels showed no inhibition of cell growth. Also, the growth inhibition was cell line specific in that some CHO cells were more sensitive than others, and some were not sensitive at all.

Using chromatographic and spectroscopic methods we were able to identify and characterize a single leachable responsible for this growth inhibition in some CHO cells. By understanding the nature of this leachable and the effect of gamma sterilization on its generation, we were able to eliminate this leachable and completely restore cell growth.

Having the internal expertise in analytical chemistry, cell biology, materials science and process engineering was critical for quick identification and mitigation of this leachable.