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Flow cytometry: An efficient method for antigenicity measurement and particle characterization on an adjuvanted vaccine candidate H4-IC31 for Tuberculosis

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Abstract

We have developed an accurate, precise and stability-indicating flow cytometry (FC) based assay to directly measure antigenicity of H4 protein in a vaccine formulation of H4-IC31, without desorbing the H4 protein from the IC31 adjuvant. This method involves immuno-staining of H4-IC31 complex with anti-H4 monoclonal antibodies (mAbs) followed by FC analysis. The assay is not only able to consistently measure H4 antigenicity levels

in H4-IC31 stored under normal condition at 2-8°C, but also able to detect changes in H4 antigenicity after H4-IC31 undergoes heat stress or freeze-thawing. In addition, the FC method is able to characterize particle morphology while measuring antigenicity. The biological relevance of the changes in H4 antigenicity detected by the FC assay was supported by an in vitro cell based functional assay using human PBMCs to measure IFN-gamma (IFN-γ) secretion upon re-stimulation with H4-IC31. Our results show that the FC based antigenicity assay can efficiently monitor the biological and physicochemical properties of H4-IC31 and is an indicator for adjuvanted vaccine product stability.

Biography:

Liwei He has over 25 years of experience in academia and pharmaceutical industry. Currently he is working as a Scientist in the Analytical Research and

Development Department at Sanofi Pasteur in Toronto. He has contributed to several vaccine projects and developed analytical test methods for characterization of vaccine products. He has also led several new multiplex based approaches for characterization and quantification of antigens and has contributed to the validation of these methods in accordance with the regulatory guidelines. To date, he has contributed to several scientific publications and co-authored a few patents related to vaccine technologies