Biomarker development for allergic risk assessment

There is an increase in the incidence of allergy/immunotoxicity-related post-market adverse events associated with medical devices. Biomarkers are commonly used in toxicology for risk assessment and clinically as diagnostic and monitoring tests. We developed a new *in vitro* model where human peripheral blood mononuclear cells (PBMC) serve as immunomodulators for biomarker development specifically for metal related allergenicity. The cell surface proteins were determined quantitatively. One of the purposes is to know whether the biomodulator system is transferable from the dendritic cell (DC) to the PBMC. Out of 12 surface proteins selected from the first tier selection that were screened, we found consistency of BM1 performance between DC and PBMC, and other 3 proteins (BM2, BM3 and BM4) showed promise. The expression of BM1 was down-regulated significantly following exposure to three well-known metallic allergens (Cobalt (II) chloride, nickel (II) sulfate, potassium dichromate (VI)), while the expression remained unchanged when exposed to two metallic nonallergens (lead (IV) acetate, magnesium (II) chloride) compared to untreated cells. Data from four healthy donors showed the same pattern. These results indicate that BM1 shows promise for use as a pre-clinical biomarker in screening potential allergic risks to metal-containing devices. Further validation is planned.

**Biography**

Mu has completed his PhD from Gunma University/Japan and postdoctoral studies at Kyoto University, Carnegie Mellon University and University of Pittsburgh. He is the board certified toxicologist (D.A.B.T.) and a principal investigator at the FDA. He has published more than 25 papers in reputed journals and is interested in the development of biomarkers for allergic risk assessment.

Ying.Mu@fda.hhs.gov

Notes: