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Affinity and beyond: Comparison of a biacore affinity assay with a cell-based potency assay for an anti-bacterial fab fragment

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The affinity and potency of candidate therapeutic monoclonal antibodies are important parameters to monitor during product development. A biacore-based assay was developed to measure the binding affinity of a Fab' fragment developed for targeted antibacterial therapy. The assay demonstrated precision and robustness, and was able to detect changes in Fab' binding affinity due to various stressors including heat, oxidation, and photo stress. Moreover, the affinity assay correlated well with an *in vitro* cell-based potency assay developed for the Fab' molecule. Specifically, a decrease in Fab' binding affinity to its bacterial protein target was correlated with a drop in relative potency measured by the cell-based assay. Noticeable effects of stress conditions on the Fab' fragment were observed at earlier stages using the Biacore affinity assay compared to the cell-based assay, suggesting the former method was more sensitive at detecting these changes. Overall, these results show that specific antibody-based *in vitro* potency assays can be complemented, or possibly replaced, by biosensor-based affinity assays. Advantages of biosensor assays include the reduction of the inherent variability and biological hazards associated with cell-based potency assays which rely on culturing cell lines and pathogenic bacteria.

Biography

Jason Szeto completed his PhD in the Department of Biochemistry, Microbiology and Immunology, University of Ottawa and conducted Post-doctoral studies at the Hospital for Sick Children in Toronto, prior to joining Sanofi Pasteur. He is currently a Scientist in the Immunology Platform of the Analytical Research and Development Division of Sanofi Pasteur (Toronto) where he helps to develop various assays that monitor the quantity, purity and potency of vaccine and antibody products.

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