



***Speaker Interview with Vibha Jawa, Ph.D., Principal Scientist, Clinical Immunology, Amgen, Inc. on “What are the greatest challenges in immunogenicity today?” Dr. Jawa is speaking at CHI’s Immunogenicity Summit 2012, October 10-12, 2012, DoubleTree by Hilton Hotel, Bethesda, MD – Interviewed by Nicole Lyscom, Ph.D., Conference Director, CHI .***

**Q1: What do you regard as the greatest challenges in Immunogenicity today?**

- A lack of consistency in reporting types of ADA responses; thus, characteristics of the ADA that have an impact on PK/PD are reported in diverse ways (e.g., titers, concentrations, isotypes, etc.) and are difficult to compare among compounds.
- The inability to accurately measure the concentrations of antibodies, especially during the course of the study, hampers the ability to model the time course of an immune response to therapeutic proteins.
- The mechanism of action of ADA-induced impact on PK of therapeutic proteins has not been extensively investigated and remains unclear.
- There is a lack of a database of product- and patient-related factors that influence the impact of immunogenicity on PK/PD and efficacy.
- Do all antibodies (binding as well as neutralizing) affect exposure?
- Polyclonal nature of ADA with diverse epitope specificity and variable impact on drug exposure and inability to predict such a response in preclinical models
- Variability of immune response due to genetic makeup of individuals in the clinical studies

**Q2: Will these be covered by you or someone else at the event?**

A2: YES

**Q3: By whom**

- Maureen Deehan, Ph.D., Head of Pharmacology in Experimental Science & Translational Medicine at NovImmune, Robert J. Kubiak, Ph.D., Research, Translational Sciences at MedImmune and others.

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