

## 2<sup>nd</sup> International Conference on **Genomics & Pharmacogenomics**

September 08-10, 2014 DoubleTree by Hilton Hotel Raleigh-Brownstone-University, USA



**Zuben E Sauna**

Food and Drug Administration, USA

### **Personal factors: Pharmacogenetic determinants in the treatment of bleeding disorders**

The development of anti-drug antibodies to therapeutic proteins is a significant impediment to development and licensure of these products and limits their clinical utility. There is increasing evidence that patient related genetic factors can play an important role in why some individuals develop inhibitory anti-drug antibodies while others do not. Moreover, as most native proteins do not make for good drugs a new generation of therapeutic-proteins, which have been engineered to improve product attributes or to enhance process characteristics, are rapidly entering the drug development pipeline. Engineered proteins inevitably require the generation of so-called neo-epitopes which do not exist naturally and are thus potentially immunogenic. Here we demonstrate how emerging computational and experimental techniques can potentially be used to assess the immunogenicity risk posed by neo-epitopes to the patient population as well as to specific patients and ethnic groups. We also provide examples of replacements therapeutic proteins that present different risks to patients based on their genotype. Finally we discuss patient specific genetic risk factors for immunogenicity in the context of a recent controversy with respect to a marketed engineered Factor VIII drug product and the discontinuation of the development of a Factor VIIa analog in Phase III clinical trials.

### **Biography**

Zuben E Sauna has been a research reviewer with the US Food and Drug Administration since 2009. He is associated with the Department of Hematology where he is involved with the review of plasma-derived and recombinant coagulation proteins that are used as therapeutics. He also leads an active research laboratory. His research interests lie in the next generation of therapeutic proteins and in pharmacogenetics. A key focus of his research activities has been to understand the pharmacogenetic basis of the immune response to protein therapeutics, which can significantly affect the efficacy and safety of these drugs. His laboratory uses the coagulation Factor VIII as a model and exploits a combination of computational, *in vitro* and *ex vivo* approaches to understand why some individuals and/or sub-populations develop inhibitory antibodies while others do not. He has over 50 research papers to his credit; his work has been published in high impact publications too. He received his PhD from Poona University, India with subsequent training at the National Cancer Institute, Bethesda, USA.

[Zuben.Sauna@fda.hhs.gov](mailto:Zuben.Sauna@fda.hhs.gov)