Biosimilars-2013
OMICS Group Conferences
Accelerating Scientific Discovery
2nd International Conference and Exhibition on
Biowaivers & Biosimilars
September 23-25, 2013 Raleigh, North Carolina, USA

The Relevance of Immunogenicity in Preclinical Development

Ciriaco Maraschiello
Harlan Laboratories Inc, Taiwan

Abstract

The relevance of immunogenicity in preclinical trials will be discussed as a hot topic in the development of biopharmaceuticals and biosimilars. The preclinical and non clinical development of Biopharmaceuticals and related regulatory issues will be reviewed and discussed. Two preclinical cases involving parenteral administration will be presented and discussed in terms of immunogenicity and relevant species for the preclinical safety assessment. Study designs and results will be presented. The prediction of immunogenicity and the Cytokine Release Syndrome as part of anaphylactoid reactions will be also discussed.

Biography

Currently employed by Harlan Laboratories Inc. where he started to work in 1998. Harlan Laboratories CRS offers preclinical and non clinical services including drug discovery and translational medicines to the Pharmaceutical, Chemical and Agrochemical Business segment.

Ciriaco Maraschiello held various positions in Harlan Laboratories CRS from Study Director to manage larger teams over the years and acquired a solid background especially in the preclinical Pharmaceutical arena. He managed the whole Harlan Toxicology platform in the CRS (Contract Research Services) branch and is currently in charge of the Drug Discovery & Translational Medicines operational platform, manage the strategic portfolio of CRS and responsible to open new business streams for the company.