

3rd International Conference and Exhibition on **Biowaivers, Biologics & Biosimilars**

October 27-29, 2014 Hyderabad International Convention Centre, Hyderabad, India

Host cell protein and other impurity clearance assays for biosimilar development

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This presentation will cover approaches needed for successful characterization of impurities and development of standardized assays for host cell protein and other impurity clearance assays for biosimilars and biologics expressed in CHO, Pichia and E. coli.

Topic will also cover the following:

- Overcoming challenges around development of host cell protein and other impurity Clearance assays needed for biologics developed in CHO, Pichia/Yeast and E. coli hosts
- Do's and Don'ts during in-house HCP and other clearance assay kit development
- Assessing the impact of immunogenicity due to HCP during Clinical trial
- Technical advancement in developing anti-HCP immunoassays
- Simple immunoprofiling methods for biosimilar drug development

Biography

Arumugam Muruganandam is MD and CSO at Affigenix Biosolutions Pvt. Ltd., Bangalore, India. He is a protein biochemist & cell biologist with more than 23 years' experience in academic (USA & Canada), government (Canada) and corporate (Dyax, USA & Biocon, India) research environments, with proven track record of successfully leading & managing development of biotherapeutics for treating or diagnosing different diseases. He is experienced in bioanalytical and biomarker assay development, preclinical and clinical PKPD, immunogenicity, and CMC assays applied to drug development with excellent understanding of large molecules/biologics/biosimilar drug development. He is a Global Bioanalysis Consortium Member in two of the large molecule harmonization teams focusing on ligand binding (PK) assays and have co-authored in white papers on Ligand Binding assays. To his credit he has filed >20 patents and published more than 20 papers in refereed journals.

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