

4<sup>th</sup> International Summit on

# GMP, GCP & Quality Control

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## Shivraj Dasari

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### Developments in analytical methods (QC) to meet US-FDA & EU requirements for rDNA therapeutic proteins (MAB's) with special emphasis on the companies & their problems from Asia (India)

The old paradigm of process defines the product is being replaced by analytical methods defining the product. With more and more IND products losing their patents in the coming years, the biosimilar war is only going to hot up more. As more countries put in place a regulatory system to regulate the biosimilars, the requirements for biosimilars for entry into the regulated markets will be very keenly fought by the biosimilar players. The expectations of the regulators namely US, EU and the Asian regulations would be discussed in detail. The expectations of the analytical methods and some of the industrial benchmarks for release benchmarks, etc., will be discussed. Though, the expectations of structural evidence for the active substance (including comparison with reference or natural product), post-translational modifications, conformational data for macromolecules with special reference to recombinant antibodies, immunological characterization, expression of purity, strength, etc., would be discussed in detail.

#### Biography

Shivraj Dasari has completed his PhD in Microbiology from Osmania University, Hyderabad, India and has worked in the biotech industry for more than two and a half decades in various Senior Management Positions. He is the Managing Director of SLS Cell Cure Technologies Pvt. Ltd., a start-up organization. It is a rare combination of two rapidly evolving biotech disciplines of *in vitro* Molecular Diagnostics and Stem Cell & Tissue based technologies. Both these fields have been making rapid strides in terms of technology development and have a special relevance in today's world besieged with life style diseases. He has published more than 10 papers in reputed journals and has been serving as a Technical Consultant for more than 4 international biotech companies.

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