Closing the gap- Addressing similarity challenges of a biotherapeutic with the innovator product

Gargi Seth, Biopharma Division, Intas Pharmaceuticals

Biosimilar development holds the promise of increasing access of low cost medicines to patients in emerging markets and the world at large. At the core of a biosimilar program is the ability to ensure that the physico-chemical, pre-clinical and clinical data generated for the biotherapeutic is similar to the innovator product with respect to the structural