Challenges in developing biosimilars

Biopharmaceuticals are the new growth driver of the pharma industry. They are usually more difficult to develop via R&D, more expensive to produce and more challenging to navigate for regulatory approval and commercialize. The key challenges are finding the right talent, technology and investors who believe in the long-term vision of this field. The technology for biotechnology and biosimilar keeps changing and so do the regulations. It has often been the case when the company starts with technology X to develop products for the local market and some exports. Thereafter, the strategy changes to work on different markets. What are the implications of such changes? What role does government regulatory or policy place in biosimilars development? How does the regulatory strategy impact the effectiveness to develop the right products in a high quality and yet cost-effective manner? This requires huge upfront investment which can be challenging for small and mid-size companies to commit. Sometimes with small commitments, there are unrealistic expectations in terms of R&D or product quality. How much money does a company need for its biopharma strategy? Finding the right talent is difficult in emerging markets since the talent concentration is very high in developed markets and the ecosystem is well developed. Few emerging markets are breaking this barrier.

Biography

Subir K Basak is currently working in the International Finance Corporation, private arm of the World Bank Group. He completed his MS and PhD in Biochemical Engineering from Purdue University, USA and MBA from Northwestern University, USA and also BE in Chemical Engineering from the Indian Institute of Technology, India.