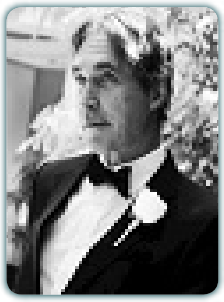
DOI: 10.4172/1948-593X-C3-043

13th International Conference on
BIOLOGICS AND BIOSIMILARS
&
BIOPHARMA & BIOTHERAPEUTICS
October 24-25, 2018 | Boston, USA



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Development of biologics and biosimilars in emerging markets – Challenges example Brazil

Rising health care costs are not only haunting Europe and the USA, but they are also especially challenging for third world countries and emerging markets. Many highly effective treatments are simply not available due to the high cost. There are governments that have put in place measures to make "high tech" biologicals more available to their populations. One important example is Brazil. Brazil is the largest country in Latin America and has a population of 200 million. It is actually the largest economy required by its constitution to provide free healthcare to all of its citizens. While this is a great set up, it is also a huge budgetary burden. Especially the highly efficacious biologics are taking their toll. Around 40% of Brazils total drug costs are due to 5 or 6 Biologic compounds such as Herceptin or Humira. In a clever move, the government put in place a system designed to both reduce the cost of biopharmaceuticals and also to establish high-tech know-how and facilities in the country. The name is PDP or development partnerships. In short, the government provides contracts to Brazilian drug companies that partner with foreign manufacturers of biologics or biosimilars in order to establish the full technological and manufacturing capabilities in Brazil. The incentive being that the Brazilian government assigns large market shares of the public market to these partnerships. Timelines and prices are contractually fixed at the start of the collaboration. However, there are significant challenges associated with the establishment of such Technologies in countries such as Brazil. These span from the availability of highly trained staff and support personnel all the way to the acceptance of biosimilars by the prescribers. In my talk, I will discuss some of these challenges and look at ways and means around them and analyze the actual probability of success of this approach.

Biography

Peter H Kalinka is Chairman and Principal Consultant at Longmore 60 Biotech Inc. He possesses in-depth knowledge of drug development and directed numerous development projects including Therapeutic Proteins, Monoclonal Antibodies and Fusion Proteins. His experience in overall development spans cloning, process development, scale-up, (e-coli, CHO, Hybridoma etc.) analytical development, bioassays, pre-clinical, clinical Phases, to manufacturing and regulatory affairs. Working with more than 20 companies worldwide, he has directed all or spearheaded parts of development programs for Biosimilars, Biobetters and Biologics.

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