BioSpectrum the business of Bio & Health Sciences

Next gen innovation strategy

04 February 2011 | News

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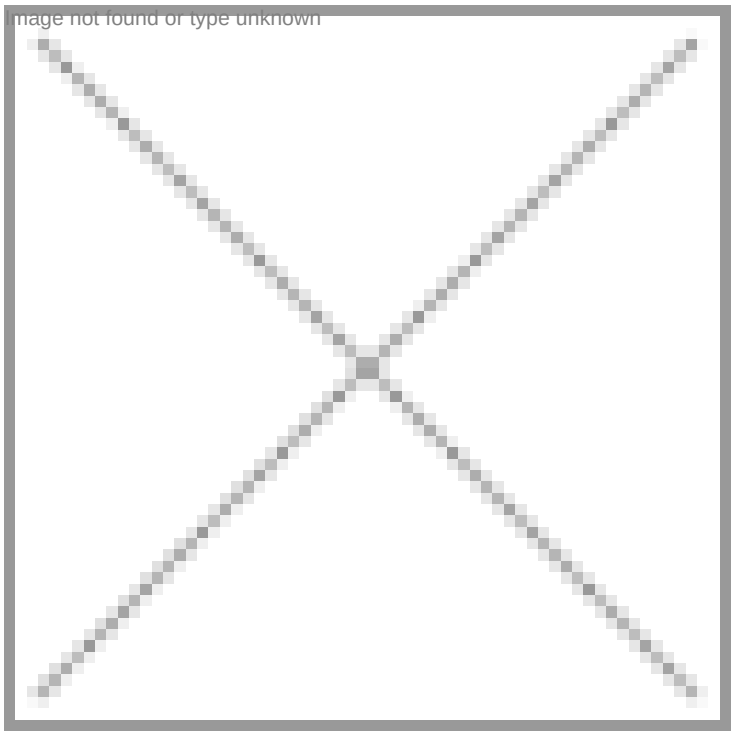

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s an experienced executive who has led multiple successful enterprises. His previous assignments ad of the R&D team at Neurex Corporation, Menlo Park, CA that developed an innovative treatment He has also served as R&D head of AstraZeneca, Bangalore, establishing the state-of-the art R&D ering and developing novel therapies for the treatment of tuberculosis and antibiotic resistant infection. faculty of the University of California, San Francisco for 16 years and is a member of the Indian s.

Dr Janakiraman Ramachandran
Chairman & CEO
Gangagen Inc

Despite the high expectations generated by the genomics-based drug target discovery strategies in the late 90s, pharmaceutical R&D productivity has declined in the last decade. There are many influences that have contributed to this decline even while R&D investment has continued to rise. Only one out of 5,000 compounds from the discovery stage makes it to the market. Only one out of five products in phase I is successful and there is a 50 percent failure even for compounds in phase III. The main reason for this low conversion of discovery to approved products is the neglect of the science of development. There is clearly a need to appreciate that drug development requires as much innovation as discovery, and improvement in pharmaceutical productivity can come only through strong integration of discovery and development. Pharmaceutical development requires good problem-solving skills for overcoming the numerous hurdles a potential drug candidate encounters in the preclinical development pathway. These skills are not taught in any academic programs and those who acquire these competencies on the job are often not sufficiently appreciated and rewarded.

This imbalance in the recognition and appreciation accorded to discovery compared to development needs to be addressedif the biopharma industry wants to increase productivity.

In terms of innovation, novel products can also be discovered and developed by addressing the limitations and side effectsof existing older drugs through the application of modern technologies that were not available when those drugs were originally developed. GangaGen has employed this strategy successfully to develop novel therapeutics for the control of antibiotic-resistant bacterial infection.

The global resurgence of antibiotic-resistant pathogens and the significant decline in the development of novel anti-infectives has led to renewed interest in bacteriophage-based therapies in view of the successful use of phages prior to the discovery of Penicillin. Phages were shown to be highly effective in controlling epidemics of Shigella dysentery in France by Felix d'Herelle and the Cholera Phage Enquiry in the Assam province in India from 1928â€“1935 demonstrated that mortality from cholera could be drastically reduced through judicious use of phage. Although phages had proved efficacious, their development was abandoned due to perceived and real limitations, namely, the immune response to phages, rapid release of toxins due to the lytic actions of phages (e.g., endotoxins), the potential for transfer of toxin genes from pathogens to avirulent organisms, difficulty in dose determination in clinical situations due to the exponential propagation of phages, and the lack of broad patent protection. These deficiencies have recently been rectified by the use of genetic engineering of phages to generate novel recombinant phages, incapacitated whole cell vaccines and phage components that are highly effective against antibiotic-resistant pathogens.

Starting from products containing natural phages that are useful for controlling Methicillin Resistant Staphylococcus Aureus (MRSA) which are therapeutic products with low intellectual property rights (IPR), GangaGen has developed proprietary Lysis-deficient phages, incapacitated whole cell vaccines produced by the use of Lysis-deficient phages, phage entities without DNA (phage tails) and recombinant phage proteins that retain the exquisite specificity of the phage without the attendant limitations referred to above.

A key feature that was essential for the successful development of these products was the close integration of R&D teams into a cohesive unit that focused on solving problems efficiently and rapidly.