

## **Recombinant vaccine against anthrax: From Clone to clinical trials**

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The nature of bio-terrorism resulting from anthrax attack is such that an aggressor is likely to strike at a time and place calculated to induce maximum terror through mass casualties. In the absence of specific intelligence in terms of medical surveillance and integrated real-time detection systems, the unpredictable nature of such events compels the development of medical countermeasures, which will enable the authorities to treat the exposed individuals. Early treatment is essential, when the disease reaches a point at which antibiotics are no longer effective owing to the accumulation of a lethal level of toxin, even though the organism is sensitive to the agent. The currently recommended post exposure treatment is a combination of an antibiotic (ciprofloxacin) and a licensed human vaccine AVA (Highly toxic with side effects).

We have PCR-cloned and over expressed the anthrax protective antigen gene. Bioprocess optimization was done to improve the yields of the genetically engineered protective antigen. The total yield of genetically engineered vaccine obtained was 25 g from a 5-liter bioreactor, which is equivalent to 1 million shots. The genetically engineered protein was found to be functionally and biologically identical to its *B. anthracis* antigen. Toxicity studies conducted on this protein indicated that the protein is devoid of any toxicity and can be safely used for the development of a safe and effective genetically engineered vaccine against anthrax. Phase II clinical trials are being done as per guidelines of Drug Controller of India and US FDA. Technology for making genetically engineered vaccine against anthrax has already been transferred to Panacea Biotech Ltd., New Delhi, a pharmaceutical company already in the business of making polio and Hepatitis B vaccine.

Attempts have also been made for developing, DNA Vaccine, B cell epitope vaccine, edible vaccine and therapeutic antibodies against anthrax.