Industrial process development and licensing of vaccines

Rodney Carbis
International Vaccine Institute, Australia

Abstract

The progression from discovery to introduction of a new drug is a long, difficult and costly process. It has been estimated that in the USA it takes 10 to 15 years from discovery to introduction and the average development costs for a new drug are currently estimated at USD 802 million.

Failure is more common than success, of 5000 screened products only 250 reach preclinical testing and only one in five drugs that enter clinical trials are licensed. Even with those products that are licensed only three of ten produce enough revenue to cover the R&D expenditure. As a result,many large pharmaceutical companies rely on a limited number of highly successful products to finance their operating costs and to finance continuing R&D.

This lecture will briefly discuss the process of development and introduction of new vaccines. Laboratory development and the implications of selecting methods and equipment consistent with large scale manufacture will be discussed with the view of later manufacturing a product. After development of a suitable manufacturing method, assays for the testing of vaccine quality must be developed. The next step is to test the vaccine candidate in laboratory animals, and therefore appropriate animal models must be developed to assess the safety, immunogenicity and protection from experimental challenge.

Once the preclinical testing is complete it is then necessary to test the vaccine candidate in humans. This is done in stages using progressively larger numbers of volunteers.

Phase I is primarily testing of safety in small numbers of volunteers.

Phase II testing is in larger numbers of volunteers generally has the main purpose of examining the immunogenicity of the vaccine, and finally.
Phase III examines efficacy or protection from infection in an area where the disease is prevalent.

The lecture will conclude with a discussion of the introduction of Cholera vaccine into India. The vaccine is currently being produced inVietnam; IVI is involved in transferring the technology to a manufacturer in India. Before the technology could be transferred the vaccine had to be modified to meet international standards for it's quality and safety. Once the production issues had been finalized a very successful clinical trial was conducted in Vietnam and now a second clinical trial will be conducted in India to show that the vaccine works equally well in India. The final phase of introduction will be conducted early next year and this will be followed up with introduction of the vaccine for regular usage in selected target populations in India.