

## **Manufacturing Vaccines for the Developing World: Advance Planning for Large Volume Production of Vaccines**

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A massive worldwide effort is underway to discover, develop and manufacture vaccines for diseases predominantly found in the Developing World. TB, HIV, Malaria and Influenza kill millions of people every year, debilitating social systems and curtailing economic development. Curative treatments for these diseases are either unavailable or too expensive; the only practical approach to the problem of infectious diseases is immunization. Half a century ago, diseases like Tetanus, Diphtheria, Pertussis and measles were causing similar death rates, but the development, introduction and continued distribution of vaccines for these diseases has reduced their impact dramatically. Currently, concerns for Influenza vaccine manufacturing and distribution are also raising issues related to the worldwide supply of effective, low-cost vaccines.

New vaccine development consists of 2 major activities: the discovery of a safe and effective vaccine at the laboratory and clinical scale, and the development of a manufacturing process for the full industrialization of the product, leading to distribution at low cost to billions of persons throughout the world.

The pathway through the development program from discovery to clinical trials and industrialization requires the resolution of biological, engineering, financial and social problems of significant magnitude.

A large political and educational process is also required to develop social acceptance of the vaccine in advance of its availability. At all stages and in all respects, it is critical to "Think to the Endpoint" to achieve overall success. Planning

final manufacturing facilities at a very early stage of product and process development, in order to have an adequate level of detail to guide the process development planning is also critical to success.

Vaccine industrialization for the developing world presents an extreme situation of high volume, high quality government regulated manufacturing, with low expectations of financial profit, but high expectations of social benefit. Optimizing this situation is essential to worldwide public health.