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Development and regulatory strategies to bring vaccines faster to the market

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Vaccines have been the most cost effective public health intervention in controlling deadly infectious diseases. With advances in understanding the immune system and mechanisms of many diseases, significant progress has been made in recent years in developing new vaccines against a number of deadly diseases against which vaccines were not available. Development and licensure of vaccines take years and require commitment, patience and persistence by vaccinologists and the vaccine manufacturers. New biological products, including vaccines, developed using innovative methods require in-depth understanding of regulatory compliance and the law for a smooth and fast licensure of the product. Strong science must be complimented with robust development processes, sustainable compliance and quality by design concepts, leading to consistent and validated manufacturing processes. Strategic planning in licensure and flexible and firm corporate policies are necessary to meet compliance requirements for biological products and changing regulations. Understanding regulations and complexity of biological products, and sound planning are necessary for bringing innovative vaccines faster to the market.

Biography

Rajesh K. Gupta has a Ph.D. in microbiology and is a consultant Vaccinologist and Microbiologist with more than 35 years experience in the development, production, testing and regulation of vaccines, working both at the regulatory agencies and manufacturers. At FDA, CBER, he was a Deputy Director and Lab Chief in the Division of Biological Standards and Quality Control, managing lot release of biological products, regulatory reviews of analytical methods in BLA, generation of reference standards and development of new methods. In his previous jobs, he worked at the Biologics Consulting Group, Wyeth, Chiron, Massachusetts Public Health Labs and NIH, in the USA and at National Institute of Immunology and Central Research Institute in India. His major accomplishments are in adjuvants and delivery systems for vaccines, polysaccharide-protein conjugate vaccines, combination vaccines and development and validation of analytical methods. In these areas, he published more than 100 papers in peer reviewed journals and books and made numerous presentations at scientific and regulatory meetings.

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