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**Manufacturing and quality risk management during the vaccine development and manufacturing process**

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**ABSTRACT**

Successful management of vaccine development, scale up, technology transfer and eventual commercial manufacturing is a complex, yet logical process. Numerous organizations have developed stage gates or milestones required to advance from one level of development to another, for example: Discovery, Preclinical Development, Clinical Development to Commercial Manufacturing. This presentation discusses the tasks necessary in the manufacturing and quality (CMC) areas to advance the project from one development stage to the next with a CMC Readiness Assessment Tool. Included in the presentation will be general concepts illustrated with specific examples for discussions during the talk.

**BIOGRAPHY**

Dr Robertson began his international consulting practice in January 2018 after ten years as the Senior Technical Advisor, Vaccine Development at the global health nonprofit, PATH. His work in this highly matrixed, international environment included projects on ETEC, Shigella, rotavirus, influenza, malaria, pneumococcal and yellow fever vaccines. Additionally, he led a highly successful developing country vaccine manufacturer quality improvement program to advance manufacturers to ICH and WHO prequalification quality standards and made over 80 overseas trips to lead and verify progress. Previously, Dr Robertson had led vaccine quality control operations at major pharmaceutical companies such as Merck and Wyeth and participated actively in development projects for Merck Varicella and Hepatitis A vaccines. His experience and accomplishments also included vice-presidential leadership positions at biotech companies such as DOR BioPharma and professional associations such as Parenteral Drug Association (PDA). He received his PhD in Molecular Biology from the University of Pennsylvania.