

PATH - A GLOBAL HEALTH NONPROFIT ORGANIZATION IN SUPPORT OF INTERNATIONAL VACCINE MANUFACTURING

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PATH is a non-profit global health organization which - among other goals - supports vaccine manufacturers in developing countries by facilitating their entry into international public markets. Some of the most significant challenges for a domestic vaccine manufacturer in a developing country on the path towards expanding to the international public markets are meeting (1) GMP compliance, (2) clinical trial design, and (3) pharmacovigilance standards of international bodies such as WHO. This talk will cover programs to standardize international regulatory practices and examples from several domestic manufacturers working on the transition and the improvements necessary to meet the standards of WHO vaccine prequalification