

1108-00-398

Patrick H Lukulay* (ph1@usp.org), 12601 Twinbrook Parkway, Rockville, MD 20814. *A Risk-Based Approach to Quality Control Testing of Pharmaceuticals in Emerging Markets.*

The quality of medicines is a major issue in developing countries, resulting in increased morbidity and mortality. Regulators seek to address this problem through quality control testing of medicines prior to registration. However, resource constraints create a backlog of medicines to be tested, limiting a lab's ability to conduct full testing and compromising work quality. This results in delayed access to medicines, increased costs, and loss of stakeholder confidence. Currently, most labs treat all medicines with the same assumed level of risk. Labs work hard instead of smart, conducting full testing. Constraints also mean some labs forgo testing altogether while others make testing decisions arbitrarily. PQM and MSU are therefore developing a risk-based quality control model, which uses logistics regression and other data mining methods to determine which products should be prioritized for testing, over time, learning "best practices". It establishes a precedent for identifying products that either need to undergo full testing or may undergo abbreviated testing because of their lower risk. This model is a paradigm shift in the way labs currently function and will conserve resources, improve work quality and ultimately assure the health of the people these labs serve. (Received January 19, 2015)