

“Pharmaceutical Quality Assessment Challenges:
From Drug Discovery to Field Testing in Developing Countries”

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In the various stages of drug development and quality control state-of-the-art analytical technologies to simple Thin Layer Chromatographic procedures may be employed. At the earliest stages of safety-efficacy determination the structures of the materials including detectable impurities must be determined and assessed. In the safety assessments metabolites and blood levels also must be determined. After the Active Pharmaceutical Ingredient (API), dosage levels and forms have been established the product assessments become focused on the API in the product and bioavailability/bioequivalence studies. Some of these technologies evolve from the discovery efforts into manufacturing controls, product release testing and market standards such as those given in pharmacopoeias.

Many of these technologies are not useful in developing countries due to the lack of technical support services, spare parts, required training levels, etc. The use of alternate assessment technologies and strategies to assess product quality and production consistency will be discussed.