Reference Laboratories Can Make Validation More Efficient

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The validation of *in vitro* methods is a lengthy process encompassing multiple phases. It progresses from initial test development, through test optimization and prevalidation, to a formal validation assessment, and eventually to regulatory acceptance. Each of these phases relies heavily on the outcome of laboratory activities - even the regulatory acceptance step involves careful inspection of the data to determine their applicability to the regulatory need under consideration. The competence and experience of laboratories participating in each phase have a significant effect on the efficiency of the entire process. History has shown that the process is never as fast as we would like; however, it can be even slower if technical errors are made along the way. High-quality laboratory work is required to maximize the opportunity for success at each stage. This emphasizes the need for a group of experienced, competent laboratories (reference laboratories) capable of readily participating in any of the phases. Such laboratories should be able to conduct assays under GLP-compliant conditions, and should optimally be independent from the developers. Reference laboratories experienced in each of the phases are particularly valuable to the process since they will be able to help test developers at an early stage to design robust protocols that can withstand the rigors of validation and subsequent routine usage. They will also be able to support the successful implementation of assays to naive laboratories post-validation, and assist the regulatory agencies in training reviewers to correctly interpret data from newly approved in *vitro* assays.