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Risk-based approach in prioritization of site and inspection for GMP

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Quality of drug/pharmaceuticals can neither be tested after the product is manufactured via quality control laboratory nor testing gives assurance of safety, efficacy and quality of products. Although cGMP require testing but alone is not adequate to ensure quality due to its inherent limitations as to date no current knowledge offers non-destructive alternatives for ascertaining the quality and safety attributes of every finished unit in the batch and again it is not a feasible or wise option to extend the testing on unlimited scale. GMP is the only answer for consistent supply of similar quality products in the market. It is a system for ensuring that products are controlled according to quality standards and designed to reduce the possible risks of contamination, cross contamination and mix-up in any pharmaceutical production that cannot be eliminated through testing afterwards. GMP via integrated system of quality management provides traceability and prevents errors that are difficult to catch through testing of the finished products. No mechanisms are in place in any part of the world other than GMP and its inspection, that every batch or unit of batch is of the same quality as the units of medicine tested in the laboratory.

In Pakistan, there are 12 federal inspectors of drugs across the country. Around 700 licensed manufacturing units exist in the country of which about 500 are actively engaged in pharmaceutical manufacturing with a minimal number of units currently involved in biologic manufacturing also. Around 60,000 drug products are registered for local manufacturing in Pakistan. Molecules of a wide range of therapeutic activity from simply analgesics to highly sensitive class of drugs e.g. penicillin, and biologics are registered. In a year, there are about 200 working days. Internationally, at least 5 days are required to inspect a manufacturing facility for one molecule in order to ensure its appropriateness to manufacture that molecule by a team of inspectors. If an inspector in Pakistan inspects a company for a minimum of 5 days, then an inspector can only visit 40 manufacturing units once a year, if a very tight schedule is observed. Moreover, compilation of observations, assigning of violations, report writing and post-inspection follow-up requires additional time and energy. This estimate excludes the distribution channels etc. Hence, it is humanly impossible for an inspector to monitor the compliance and ensure the safety, efficacy and quality of such a huge volume of drugs available in the market. This demands desperately to formulate a risk-based model for prioritization of manufacturing sites for inspections around the country.

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