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# TOWARD A UNIFORM LEVEL OF PERFORMANCE

No one likes to be told how to perform. On the other hand, almost everyone feels that it is perfectly proper to tell others how they should conduct themselves.

For example, we subscribe to the idea of having speed limits posted on our roads and highways. But we feel these restrictions are needed "for the other guy," who often doesn't have sense to drive with care. For ourselves, such restrictions are not necessary even though we may exceed the speed limit and mentally justify doing so by reminding ourselves that our own superior driving skill makes it all right. It is simply human nature to rationalize things in this manner.

The September 29 issue of the *Federal Register* carried a 75-page edict telling an entire industry how to perform in the day-to-day business of manufacturing its products. The product involved is drugs; the industry is the pharmaceutical manufacturers; and the government agency spelling out the rules is the federal Food and Drug Administration.

The rules themselves are formally titled Current Good Manufacturing Practice (CGMP) regulations; they are more commonly known and referred to as "GMPs." Most of our readers are at least casually familiar with the term but have only a vague idea of their impact and bearing on the drug manufacturing operation.

The GMPs first came into being in 1963 as a result of a new provision which was added to the Federal Food, Drug, and Cosmetic Act as part of the 1962 Kefauver–Harris Drug Amendments. Those original 1963 regulations were pretty skimpy by today's standards, and over the years they have undergone the normal process of refinement and expansion to flesh out and to fine tune the original set of rules. In making such changes, the FDA also has tried to consider new technology both in drug product manufacturing and in assessing quality of drug products.

Until this year, the last such revision was completed in 1971, so a thorough overhaul of the GMPs had become timely. However, the result did not come about overnight. The preamble statement in the September 29 document includes a brief historical account of the stepwise adoption of these finalized regulations, beginning with the initial draft version proposed in February 1976. Moreover, some related actions on specific aspects of manufacturing practice—such as how to deal with returned and salvaged drug products—dated back to January 1975.

The general purpose of the GMPs is to establish requirements for such matters as the adequacy of drug processing facilities, the training of personnel working in drug plants, quality assurance procedures, and company procedures for handling consumer complaints.

The big focus of the revised regulations seems to stress the need for companies to adhere strictly to modern quality control practices in drug product manufacture. They mandate the inclusion of a quality assurance unit in each manufacturing plant, with full authority to accept or reject all raw materials as well as finished products. They require special batch-by-batch evaluations at specified time intervals for the purpose of identifying the need for new manufacturing specifications or for changes in manufacturing or quality controls. They require the inclusion of expiration dates on practically all drug products.

So much for the content of the GMPs. What will be their impact or effect?

For the drug industry, they will mean more tests to perform, more records to keep, more analysts to hire, more borderline batches of products to reject. For some companies, the impact will be relatively minor—they have been doing much of this already. For some others, the impact will be much greater. All will be affected to some degree, and all will be forced up to a new standard of performance and acceptability.

Many in the industry probably will feel that—as in the example of the speed laws mentioned above—the requirements are needed for their competitors but not for them. Perhaps so. But whether needed or not, they do need to apply to all manufacturers.

For too long, pharmacists and others have been asked to judge and select drug products on the basis of the ethereal concept of "reputable manufacturers." It is time to separate the sheep and the goats. There is room in the American drug marketplace for only reputable manufacturers, and the new GMPs should go a long way toward creating and assuring that single standard of performance.

—EGF