

The advent of high-potency compounds, new formulation requirements, and more sophisticated medications has dictated change. Particularly during the last ten to twenty years, the research-minded manufacturer has modified his physical plant and updated facilities in order to produce consistently safe and effective products.

The research-oriented innovator type of company generally sets higher quality standards for its products than does the non-innovator. Moreover, a manufacturer of this type will not market a drug product until it has been clinically tested for safety and effectiveness. When one considers that there are many drug products which are classified by the F.D.A. as "old" drugs, for which no proof of safety and effectiveness is required prior to marketing, the extra care taken by the quality-conscious company can be more fully appreciated.

For those drug products which do require F.D.A. approval for safety and effectiveness, the quality company establishes the conditions of manufacture and control which assure that each batch measures up in every respect to the initial batch on which the F.D.A. submission was based. The importance of this procedure cannot be over emphasized.

The former Commissioner of the Food and Drug Administration, George P. Larrick, made some pertinent comments on the importance of manufacturing control before the Senate Subcommittee on Antitrust and Monopoly in 1960. At that time he said:

"* * * It requires a great deal of technical knowledge as well as properly utilized procedures to produce modern drugs that will meet all the requirements of modern medicine and of the law. Our experience has demonstrated the soundness of that position and it is even more true today as the complexity of drugs and their dosage forms increase. Adequate and extensive control from the time the raw materials enter the drug plant to the time the finished drug reaches the patient is essential if both patient and clinicians are to have confidence in the drug prescribed."

Mr. Larrick went on to say: "Our experience has shown that those who do not have proper controls are more like to produce substandard drugs. The point * * * is not whether drug manufacturers are large or small, but whether they have the scientific personnel and laboratory control to produce pure, reliable and safe drugs".

Assurance of quality in the manufacturing of drugs begins with people. For this reason, the quality-minded companies are extremely careful in their selection of the personnel who devise the formulas, test the components and finished preparations, inspect the final product, and perform the many other tasks involved in drug production. These men and women must have a high degree of training, knowledge, motivation and experience.

The research-conscious innovator companies in our business usually are distinguished by stability of employment. Obviously this is a most important factor in attracting good employees who are dedicated to the production of quality drug products. These workers are well-trained people who understand the rules and regulations under which the drug industry operates and who are proud of the part they play in their company's operations.

Laws and regulations are no substitute for the care exercised by men and women of integrity. You simply cannot legislate quality into drug products, any more than you can eliminate traffic fatalities and injuries by making new laws. There are many excellent traffic laws already on the books—local, state, and federal—yet the death toll on our highways continues unabated. In the final analysis, it's the human factor which counts. And so it is with the production of quality drug products—the people a company employs make a big difference.

As an example, in our own manufacturing plant, more than 33 percent of our employees have been with the company longer than fifteen years. They are without a doubt among our most valuable assets. In recognition of this fact, we invest in numerous fringe benefits and special programs designed to demonstrate the high regard we have for our people. In addition, we strongly support safety programs, provide tuition assistance to upgrade the education of employees, and conduct training programs to assure top-level performance.

Because of the importance of employees in the production of top-quality drug products, the more responsible manufacturers go out of their way to provide the best of working conditions. Particular attention is paid to buildings and equipment.