As a matter of fact, many of these firms did not find it necesary to make significant changes as a result of the 1962 amendments to the Food and Drug Act. Because of the high standards they had set for themselves over a period of many years, they were already in compliance with most of these new regulations.

As new medicinal agents have been discovered, our industry has recognized the need for constantly improving manufacturing methods and equipment. The advent of high-potency compounds, new formulation requirements, and more sophisticated medications has dictated change. Particularly during the last 10 to 20 years, the research-minded manufacturer has modified his physical plant and updated facilities in order to produce consistently safe and effective products.

These 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 drugs. 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.

Buildings in which drugs are manufactured must be of suitable size and construction to house the necessary equipment and materials in such a manner that cross-contamination or mixup is avoided. In the better plants, provisions are made for cleaning the air and controlling temperature and humidity. One example of the great care that is taken to assure the most sanitary conditions possible is the sterilization of areas used for the production of hypodermic drugs. Much of the equipment used in these plants is custom-designed, and considerable engineering ingenuity is required.

Of paramount consideration are cleanliness and orderliness. For example, in my own company alone we have spent several hundred thousand dollars to separate operating equipment and functions, to provide a high degree of air filtration and dust control, and to insure the sanitation qualities of floors, ceilings and walls. This is typical of what the research-oriented companies are continuing to do to improve their operating areas.

Now, I should like to point out a few fundamentals about manufacturing methods and procedures of the quality-minded drug manufacturer. Our equipment must fulfill two important requirements:

First, we must be able to produce batches of a drug product with uniform consistency day in and day out.

Second, the equipment must be compatible with the chemicals involved and suitable for thorough cleaning to eliminate the possibility of contamination from product to product.

Clearly, maintenance of equipment is extremely important. For example, in the case of a tablet compression machine, where close tolerances are required, regular examination is essential to insure that each tablet produced meets the dose specified. Such care is part of the standard operating procedure of the quality-conscious, innovator-type of drug manufacturer.

All-important considerations for every capable drug manufacturer are: (1) Quality of raw materials used in the manufacturing process, and (2) in-process controls. I should like to elaborate on both of these points.