To assure the quality of a raw material, the careful company first insists that the supplier guarantee the quality and purity of the material, then makes double sure by conducting its own extensive tests.

This preoccupation with quality of raw materials applies to nontherapeutic as well as therapeutic substances: to nonofficial substances as well as those listed by the U.S. Pharmacopaeia is to assure the user of official medicinal substances of their identity, strength, quality, and purity, it is manifestly impossible to include in each monograph a test for every impurity or adulterant that might be present.

In view of this undisputed fact, the quality-oriented pharmaceutical firm exerts additional efforts through the use of analytical know-how and in-process controls to give greater assurance of the identity. strength, quality, and purity of the ingredients which go into its products.

Throughout the drug manufacturing process, from raw materials through finished product, careful control must be exercised at every step of the way. Every quality-minded manufacturer follows a standing operating procedure which incorporates a system of checks and balances followed by quality audits.

Our standard procedures cover such important considerations as product and container identity, quarantine provisions, and storage conditions. Each product is covered by an appropriate batch record, and throughout the manufacturing operation great care is exercised to assure accuracy of weight, volume, and yield of each batch.

The packaging materials used are subjected to inspection, and particular care is exercised in the issuance of labels, cartons, and package inserts.

The warehousing of the finished product provides for proper storage, segregation, and identification by lot or batch number, as well as systematic rotation and inspection of stocks at regular intervals.

Another key factor in our standard procedures is the maintenance of records covering all manufacturing, packaging, and control operations concerned with a product. These records must be prepared with such care as to provide a history of each batch of every drug product.

The quality-conscious manufacturer continues his testing as long as a product is on the market.

Portions of each lot are retained and checks are made, even after the lot has reached the pharmacist's shelf, to make sure it measures up to the company's high standards.

As an illustration of the importance of checks and balances exercised during pharmaceutical manufacturing by some firms, I think it is interesting to note that in one of our own company's routine manufacturing operations we conduct some 687 inspections and tests during the course of making a finished product. Among these are 215 different inspections and tests on raw materials, 395 checkpoints and tests during the actual manufacturing, and 75 inspections and counts during the packaging operations.

The manufacturing principles I have discussed have been followed by the leading prescription drug companies of this country for many years. It is generally agreed by those who have firsthand knowledge of these research-minded pharmaceutical manufacturers that their plants stand out in their communities as models of modern industrial facilities.