Finally, thousands of individual clinical tests are performed. Patient records obtained from these tests are painstakingly kept and analyzed and a summary of the studies is written. These investigations form the basis for a new drug application.

The final labeling of the product is, of course, based on the results of the clinical trials.

After establishing the safety and efficacy of the product, the design phase of building quality into the product is complete.

Conformance Phase (Please refer to Addendum II)

Now that a product exists, it must be manufactured in a way that duplicates the *design* phase of total quality control. This is called the *conformance* phase.

This is the area in which the production, purchasing and quality control divisions of a pharmaceutical firm are most vitally involved.

There are many systems by which pharmaceutical manufacturers can control their product during the conformance phase.

I would like now to illustrate one of them.

It starts by preparing an elaborate set of specifications for all the components that make up a product.

These specifications include methods for determining the identity, purity, strength, physical characteristics, uniformity, quality, and many other parameters, depending upon the requirements expected of the raw material.

Package specifications and control procedures are also provided for such items as glass containers, bottle closurers, cap liners, filters, and even the glue used for labels.

If the material is to be purchased, the purchasing agent is provided with a set of these specifications.

Suppliers are selected on their ability to produce and deliver quality material.

Quality control personnel often visit the suppliers, firsthand, to verify whether or not confidence can be placed in them.

When the material from the supplier arrives in the plant, it receives an identifiying number. This number is never duplicated.

The incoming raw material is then quarantined until it is sampled, inspected, tested, and approved according to the established specifications.

Labeling the material also undergoes rigid inspection techniques. (Please see Addendum III) Samples of the labeling to be ordered are proofread by at least two qualified people before they are sent for printing.

All labeling material received is 100% inspected for proper identity, lot number, and all regulatory requirements. The labeling material is counted and inspected by both quality control personnel and the label storekeeper. The labeling material is then stored in a secure manner to prevent any label mixups.

All raw material must be approved by the quality control division before it is allowed to enter a product.

The next step is control of the manufacturing process. (Please refer to Addenda IV and V)

Some of these points have already been covered by Mr. Blazey in his submission for the record.

The manufacturing process is very carefully detailed on manfacturing process cards. These cards are precisely controlled by a manufacturing identity number which is assigned to each batch production record.

The entire history of a product, per batch, can be traced through a numbering system.

The particular lot or batch number of every component and manufacturing aid involved in the production of a product must be traceable from the lot number on the final package.

The quality control approved raw materials, clearly labeled, are then accurately weighed and checked for identity and accuracy of measurement by at least two qualified individuals at each dispensing step. The identification numbers of the materials dispensed are recorded on the batch production card.

All materials forwarded to a production department are very carefully labeled and quarantined by a system of control records.

Upon arrival in the manufacturing department, the materials are checked for identity by at least two qualified persons.

All material is then checked again for identity and quantity and verified by a qualified production control checker before it is allowed to be added to the product.