The materials are then combined in the processing operation according to the specific instructions on the batch production card.

During the manufacturing operation, each individual manufacturing process step is checked and endorsed by at least two individuals and their signatures entered on the batch production record.

In-process product and equipment checks and verifications are made and recorded during the processing operation, and production and control procedures are rigidly followed.

Intermediate granulations or mixtures are often tested for homogeneity.

The finished granulation or mixture is sampled, tested, analyzed, inspected, and the yield variation limits determined by the quality control division.

Approval by quality control is given only when all the predetermined specifications and standards are met, and the records are complete.

The approved blended powder mixture is now ready for further processing, such as into a tablet or capsule.

The mixture is now carefully filled into its dosage form. The product is inspected and tested to confirm the uniformity of composition of the active ingredients.

After processing into a final dosage form, chemical analysis and identity tests are performed by the quality control divisions to reaffirm the quantity, quality, and uniformity of the product.

Many firms identify their products by the use of an identity code written or stamped on each tablet or capsule. This aids the physician in identifying the medication being taken by their patients. It is also an aid in identifying the product as it proceeds through the manufacturing process.

The quality control division will approve the *bulk* product (capsules, tablets, etc.) for further processing if the results of the testing, the final yield verification, the documentation, and the control procedures have all been properly carried out according to the established product specifications and standards.

When an approved bulk medicinal product exists, the proper container, the correct labeling, and the packaging materials are joined together to produce a *finished* product. Each of these items, along with their identifying numbers, are recorded on the finishing record. (Please refer to Addendum VII).

Many checks, reconciliations, and identifications are made to control the finishing operations. Included are the following:

(1) A thorough cleaning and checking of the packaging line before the start of the operation.

(2) A check of the identity, quantity and quality of the packaging material and labels.

(3) In-process testing and control procedures on the product.

(4) Complete label reconciliation and a physical evaluation of the final product.

Finally, after all balances and reconciliations are made, product yield variations determined, and all required government approvals are obtained, the product is given final approval by the quality control division.

A reserve sample is removed and stored within the quality control division for reference. All the control documents pertaining to the batch are then filed in the quality control division.

Now the product is ready for distribution. (Please refer to Addendum VII).

Total quality control of a product does not stop here. A system of controlling the storage of the product in the warehouse, and also periodic inspections of the product of the pharmacy shelf, further assure its quality when it is dispensed to the patient.

It is important to remember that the purpose of the conformance phase of total quality control is to duplicate exactly the product produced during the design phase. This does not *just mean* that each batch or lot of product should have the same *physical* and *chemical* characteristics as another batch or lot. It is far more important that each tablet, capsule or pill must perform both *physiologically* and *pharmacologically* in exactly the same manner.

It is inconceivable to assume that merely analyzing a product for potency and purity *will assure* its *quality.*

At this time, I would like to differentiate between the terms "analysis" and "control".

Analysis is predicated on meeting minimum requirements after a product is manufactured. No degree of testing or analysis can change the quality aspects of the product after it is manufactured.