

Quality Control: Encompasses: (1) Employment and cost data on direct quality control activities. Includes all full-time employees responsible for sampling and testing of raw materials as they are produced, or while in storage; investigation of complaints; disposition of returned goods; selection and weighing of components; proper sanitation and storage of raw and finished materials; inspection of labels, contents, packages, etc.; maintenance in the final product of the desired purity, uniformity, potency and stability; and (2) Employment and cost data on indirect quality control activities. Includes the full-time equivalent of production workers and other employees who have inspection or quality control functions incidental to their primary assignments; pro-rated according to hours, facilities, etc., devoted to quality control functions as share of total labor time, and so on.

Research and Development: The term includes basic and applied research as well as development activities carried on or supported in the pharmaceutical, biological, chemical, medical and related sciences, including psychology and psychiatry, if the purpose of such activities is concerned ultimately with the utilization of scientific principles in understanding human diseases or in improving health.

Activity in pursuit of the following objectives is included:

- (1) Planned search for new knowledge, whether or not the search has reference to a specific application.
- (2) Application of existing knowledge to problems involved in the creation of a new product or process, including work required to evaluate possible use.
- (3) Application of existing knowledge to problems involved in the improvement of a present product or process.

For practical purposes, any scientific or technical activity which could result in a new drug, as defined in the Federal law, would certainly be considered research and development. Chemical synthesis of substances which might become drugs would be included in this definition and so would all clinical evaluation of new or old drugs.

The question, "When does development end and production begin?" is often asked. If the primary objective is to make further improvements on the product or process, then the work