

## **Manufacturing Process Control / Quality Assurance**

Manufacturing process control and quality assurance are elements of a quality management system, which is the set of policies, procedures, and processes used to ensure the quality of a product or a service. It is widely acknowledged that quality management systems improve the quality of the products and services produced, thereby improving market share, sales growth, sales margins, and competitive advantage, and helping to avoid litigation.

The International Organization for Standardization has outlined quality principles and the procedures for implementing a quality management system in ISO 9000:2000, ISO 9001:2000 and other documents. These documents have become the gold standards of best practices for ensuring quality and, in many fields, serve as the basis for regulation. that "ISO 9000 guidelines provide a comprehensive model for quality management systems that make any company competitive."

An important element of quality assurance is the collection and analysis of data that measure the quality of the raw materials, components, products, and assembly processes. Exponent statisticians help our company comply with ISO 9001 standards by developing good data collection and analysis techniques during the design, development, and production stages. Specifically, Exponent statisticians are experienced in:

- Acceptance sampling
- Statistical process control (SPC), including Six Sigma techniques
- Troubleshooting studies

Acceptance sampling is conducted to decide whether a batch of product (e.g., supplier components or finished units) is of acceptable quality. Rather than testing 100% of the batch, a random sample of the batch is tested, and a decision about the entire batch is reached from the sample test results. Exponent statisticians are familiar with these standards and can assist clients in evaluating available alternatives—sampling by variables vs. attributes, use of single vs. double or multiple sampling, rectifying vs. non-rectifying with respect to nonconforming items—to determine an appropriate sampling plan.

**Statistical Process Control (SPC)** is an effective method of monitoring a production process through the use of control charts. By collecting in-process data or random samples of the output at various stages of the production process, one can detect variations or trends in the quality of the materials or processes that may affect the quality of the end product. Because data are gathered during the production process, problems can be detected and prevented much earlier than methods that only look at the quality of the end product. Early detection of problems through SPC can reduce wasted time and resources and may detect defects that other methods would not. Additionally, production processes can be streamlined through the identification of bottlenecks, wait times, and other sources of delay by use of SPC.

**Troubleshooting Studies** – If a problem is identified in the end-of-the-line product, a troubleshooting study can be conducted to determine whether changes in certain inputs (e.g., raw materials or process characteristics) are associated with the output variables. Such studies involve the analysis of contemporaneous data recorded on production inputs and outputs. Statistical regression techniques or classification methods can detect associations between raw materials or process attributes and end-of-the-line product outcomes. Although these observational studies cannot definitively prove the existence of a cause-and-effect mechanism, results of troubleshooting analyses may suggest potential targets for corrective actions, as well as off-line experiments or further measurements and analyses to confirm the root cause of the manufacturing problem.