



Quality Managers and Statistical Process Control

By Thomas R. Cutler

SPC tools prevent Over-Packing, Under-Filling and help Quality Managers meet Regulatory Compliance, ISO 22000 and HACCP Requirements.

Over-packing is just giving away product; conversely if packages are under-filled the fines to regulators and damage to a company's reputation are even more costly. According to Evan J. Miller, President and CEO of Hertzler Systems, "Net Contents programs must meet the requirements in governmental regulations for compliance to net content declarations on packaged goods. The NIST 133 standard, for example, does not specify limits for overfilling, which puts food manufacturing Quality Control managers in a difficult spot. Fill weights must be above the Maximum Allowable Variance (MAV), while simultaneously needing the average fill to be over, but as close as possible to the label declaration."

The classic method of meeting the regulation is to shift the curve up, so that the average is at or above label, and the lower tail is just above MAV; this methodology results in giving away product. GainSeeker Suite, Hertzler's SPC (statistical process control) solution, streamlines data collection by connecting directly to all brands and models of scales and balances and can incorporate simple or complex calculations to derive volume, whether immediate or "roaded". As each new measurement is entered into the system QC and QA staff can apply real-time statistical tests to this data immediately alerting staff if a process change is detected.

Automated tools make it easy to discover which fill heads, material suppliers, operators, product lines, and other variables have the greatest impact on process variation – individually or in combination. Armed with this information, the best decisions can be made regarding process improvements that reduce process variation and shift average fill weights closer to the declared label weights.

Lot Genealogy (Farm to Fork)

Lots of raw material significantly impact process variability; if there is a recall all products made with a particular lot of raw material must be identifiable. It is critical that food quality professionals can identify which customers received a production lot being recalled.

Miller suggests, "Lot genealogy makes it easy to search for a specific raw material lot number and identify all the products made with this lot of material. Automated variation analysis can quickly compare the impact of different material lots on process variability, which can then be traced back to various raw material suppliers, or forward to various customers.

FDA 21 CFR Part 11 compliance

Under the US Food and Drug Administration, part 11 of Title 21 of the Code of Federal Regulations (21 CFR Part 11) establishes the criteria under which electronic records and electronic signatures will be considered equivalent to paper records and handwritten signatures. Manufacturers of products that are regulated by the FDA must apply this rule to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted.

In order to comply with 21 CFR Part 11, a number of requirements must be met:

- Any computer system utilizing electronic records and signatures must be validated to ensure its accuracy, reliability, and consistent intended performance.
- These computer systems must maintain an audit trail that is secure, computer-generated, date/time stamped, available for review, and lists the person making the change along with the original and changed data.
- These computer systems must also use authority checks to ensure that only authorized individuals can use the system, alter records, and perform various operations.
- The customer must use the existing security features within the computer systems to limit access.
- The customer must establish and follow written policies that hold its employees accountable for their actions.
- The customer must retain records in a relational database protected by system security. Policies and procedures must be established to ensure that records are retained for the appropriate duration of time.
- The customer must verify the identity of the individual before assigning him or her, an electronic signature. A customer is responsible for certifying, in writing, to the FDA that it intends to use the individual's electronic signature as the legally binding equivalent of his or her handwritten signature.

ISO 22000 / HACCP data acquisition, analysis, and compliance monitoring

ISO 22000 / HACCP (Hazard Analysis Critical Control Point) defines a system for ensuring the safe production and packaging of food.

Miller argues, "A strong SPC solution leverages existing HACCP data by using modern statistical techniques to help you improve process stability over time." Some of the metrics Food QC managers should insist upon when selecting technology solutions that support both HACCP and ISO 22000 include:

- record measurements for variable data in a database for easy analysis and reporting
- immediately identify unstable conditions using statistical alarms (which are much more sensitive than pass/fail data)
- analyze and report results based on product lines, point in process, shift, operator, and other operational variables
- track on-time data collection by department, shift and operator to ensure compliance with safety standards

Statistical Process Control solutions are not a panacea; they do allow for quantifiable, real-time metrics.

When data comes from disparate sources and quality managers need to drill down to find underlying sources of variation in the data (as well as integrate with other information systems) these measurement tools become an extraordinarily valuable lean quality tool.

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