White Paper

Quality by Design

Building Quality into Weighing Processes

Weighing is a critical step in many chemical production processes and significantly contributes to final product quality. Building quality into a weighing process helps to ensure accurate measurements over time and prevent operating mistakes that can lead to out-of-specification materials.

Consistent formulations, accurate batching of components and precise filling and blending of materials are key process steps in chemical production that directly impact final product quality. Here, weighing is usually the measuring method of choice, due to its high level of precision and reliability.

Understanding the factors that contribute to consistent weighing process quality helps to eliminate possible quality risks and prevents out-of-specification batches that will need to be reworked or disposed of, adding extra labor and costs.

This white paper explains how to build quality into your weighing processes to ensure consistent quality of your products, improve productivity and reduce costs.

Content

METTLER TOLEDO

1. Introduction

Quality by Design (QbD)

Quality by Design (QbD) is a concept first outlined by quality expert Joseph M. Juran. Its underlying philosophy is that quality should be built into each process step - not only tested at the end – to ensure consistent final product quality. While initially widely adopted in the automotive and electronics manufacturing, QbD has recently received strong attention in process industries, especially the chemical and pharmaceutical segments.

This development is driven by the need to improve final product quality and manufacturing process stability. On one hand, the chemical industry is experiencing increased outsourcing of process steps and ongoing globalization of the supply chain. On the other hand, manufacturers are required by customers, regulators and the public to meet ever tighter standards in terms of product specifications, process safety and environmental footprint.

Building quality into the production process not only helps to ensure consistent product quality and meet customer specifications, it also contributes to increased process safety and reduces raw material consumption and waste.

Build quality into the process

The Quality by Design concept is a universal, comprehensive approach that consists of three processes:

- Quality Planning
  Developing products and processes required to meet customer needs
- Quality Control
  Evaluating actual performance and correcting deviations from quality goals
- Quality Improvement
  Raising quality performance to unprecedented levels

A key aspect of quality planning is the risk assessment of process parameters that may influence finished product quality. The aim of this white paper is to help understand the potential influences of weighing on product quality and its relevance for QbD concepts. It also provides guidance on what to consider when building a quality critical weighing process.

Figure 1: Quality by Design Concept

Chapters 2 and 3 relate to the quality planning stage. When specifying the weighing process, considerations need to be made for the weighing accuracy required to meet defined process tolerances. Also, the weighing process should be evaluated to identify possible operating errors and implement solutions to eliminate error-prone operation steps.

Chapters 4 and 5 examine weighing related aspects that contribute to the quality control stage. This includes calibration standards and preventative maintenance options that help prevent inaccurate measurements, as well as integration and analysis of weighing data to ensure real-time monitoring and adjustments of critical weighing processes.

Lastly, Chapter 6 introduces the Good Weighing Practice™ (GWP®) methodology, a life-cycle management approach enabling secure selection, calibration and operation of weighing equipment.

2. Ensure Weighing Process Accuracy

Readability (or display resolution) of a scale is often mistaken for accuracy. In fact, readability is just one contributor to measurement uncertainty, which is the scientific expression of an instrument's accuracy. Any measuring device, whether it is a ruler, a speedometer or a scale, is associated with some measurement uncertainty.

Assess measurement uncertainty

Assessing the measurement uncertainty of a weighing device tells you how close to the true value a measurement is, or in other words, how accurately you can weigh.

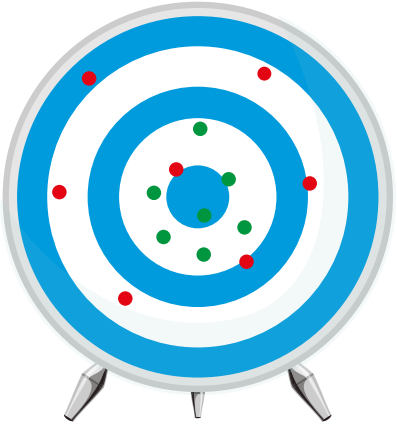
For example, suppose you have a scale that is accurate to plus or minus 1 gram. At 10,000 grams (10 kilograms), this uncertainty represents one hundredth of one percent (0.01%) of the weight. In many situations, that uncertainty is small enough that it won't affect quality. Now suppose you are weighing a 10 gram sample on this scale with an uncertainty ± 1 gram. Now the uncertainty represents a full 10% of the reported weight. Your actual sample may be 10% larger or 10% smaller than what this scale is reporting, just due to the uncertainty!

It is therefore necessary to assess the measurement uncertainty of the weighing process. The performance of weighing devices is influenced by two types of error:

- Systematic errors, including eccentricity (or corner load) and error of indication (or non-linearity), show how far the measurement result is from the true value.

Systematic errors: Eccentricity and Non-linearity

- Random errors influence the repeatability (or precision) of the measurement result. This shows how close together a series of measurements is.



Random errors: Repeatability (or Precision)
Red dots: low precision
Green dots: high precision

To assess the performance of a weighing device, all three parameters (eccentricity, error of indication and repeatability) should be tested.

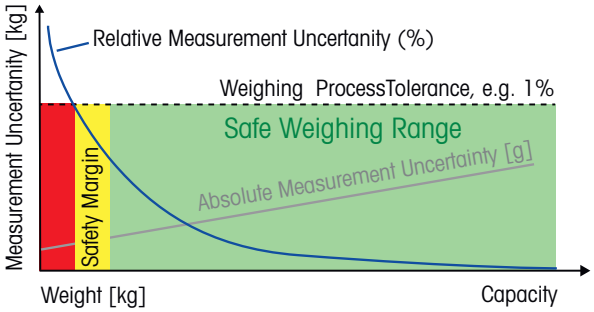


Figure 2: Measurement Uncertainty and Safe Weighing Range

Any weighing device, be it a microbalance or a five-ton floor scale, shows the following behavior of measurement uncertainty (Figure 2):

The absolute uncertainty in milligrams, grams or kilograms increases as you place more weight on a scale. However, the relative uncertainty, which is the absolute divided by the weight, increases with smaller weights. On the lower end of the weighing range, the uncertainty is so high that the weighing results can no longer be trusted.

Define weighing process tolerances

The criteria for assessing whether the scale performs "good enough" depends on the process tolerances set by the quality requirements of the equipment user. Defining a weighing process tolerance eliminates the risk of weighing with uncertainty that is too highand establishes the safe weighing range of the equipment (Figure 2):

- Weighing inside the red area leads to potential out-of-specification results, bad product quality, rework and waste.
- Weighing within the safe weighing range ensures accurate measurements and guarantees excellent product quality.
- The safety margin compensates for external influences such as operators, wind, temperature fluctuations or vibrations from other production equipment.

The indication of the measurement uncertainty is a part of quality systems, such as ISO. The accuracy of measurements can be checked during an inspection and needs to be documented. Good Weighing Practice (GWP) provides guidance on how to assess measurement uncertainty and define a suitable weighing process tolerance. Learn more about GWP in Chapter 6.

Match the weighing technology

Depending on the required weighing accuracy and environmental conditions present, several scales may seem suitable for your measurement process. However, the performance of the scales may differ depending on the technology of the weighing sensor and the construction of the scale. When accurate weighing is quality critical, the actual performance of the scale should be evaluated

This is why METTLER TOLEDO documents the typical specifications of a scale based on actual measurement performance. Comparison of typical specifications allows for the selection of the most appropriate scale for the given weighing process requirements. The scale then needs to be calibrated by an accredited service provider on site to define the specific measurement uncertainty of the given scale.

GWP® Recommendation

- Integrates metrological science with specific process requirements.
- Enables weighing equipment selection with the right accuracy for defined process and quality requirements.
- Environmental and regulatory factors are taken into account before equipment selection.

GWP® Verification

- Based on a calibration service that documents the measurement uncertainty of weighing equipment under real operating conditions.
- Establishes if the measured performance satisfies defined process and quality requirements.
- Contributes to consistently good product quality and efficient equipment management.

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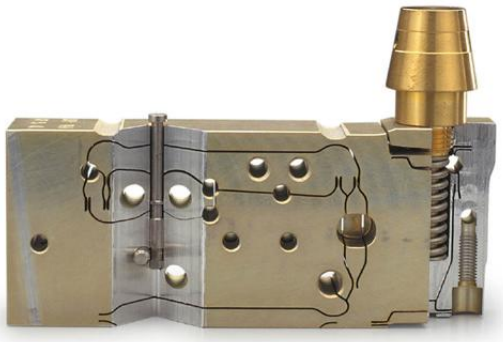


Monoblock® load cells for high precision weighing integrate various mechanical functions into a single high-performance aluminum alloy structure.

3. Prevent Operating Errors

Operating errors are one of the primary reasons for out-of-specification batches and product recalls due to quality issues. Obviously, the risk of human mistakes in a manufacturing process can be significantly reduced by automating the entire process. In line with QbD principles, such an approach would provide a fully monitored and controlled process, ensuring consistent product quality. However, many chemical manufacturing steps, such as the weighing of formulation components, rely on manual tasks that cannot easily be automated.

colorWeight® functionality immediately indicates if the weight is within tolerance.

The challenge in ensuring process safety and product quality is to reduce the risk of operating errors during manual weighing processes as much as possible. Both the usability of the weighing equipment and operator guidance contributes to secure handling of the weighing process by operating personnel.

Operator guidance ensures process consistency

Sophisticated weighing solutions can easily guide the operator step by step through the weighing process, whether in simple filling applications or complex formulations.

In formulation, for example, the application asks the operator to weigh each component of the recipe one after the other with the specified target weight and tolerances on the right scale. The correct raw material is verified via barcode scanning of the material ID attached to the container.

During weighing, the target weight is displayed graphically and numerically and the required tolerances are clearly displayed as limits. Weighing results that exceed or fall below these limits are immediately depicted on the color display, helping the operator to prevent incorrect weighing. The system can even be set up to only document the measurement and allow the next process step if the actual weight is within defined tolerances.

Improved usability reduces mistakes

A number of additional features can help improve the usability of the weighing equipment, including:

- A large and clear display improves the readability of the weighing result, numerically or graphically.
- Self-explanatory and visually appealing icons help the operator make the right selections and avoid errors.
- An integrated user-management system only displays the information to the operator needed to perform the required tasks.
- Country- and language-specific screen layouts further help improve usability.
- Depending on the application and materials used, a touch screen or keys optimized for usage with gloves help prevent operating mistakes.

Finally, it is possible to automatically document all batch-relevant information to prevent potential errors during manual or paper-based documentation. All process steps can be filed in detail in the database and electronic signatures can be given if required.

FormWeigh.Net formulation software securely guides the user through the weighing process

4. Maintain Measurement Quality

Getting the design and operational specifications right and selecting the proper equipment for the specified process are essential steps to achieve quality results. However, quality also depends on precise installation, setup, calibration and maintenance of the weighing equipment.

Regular equipment calibration ensures accurate performance over time.

Implement regular calibration intervals

ISO Quality System 9001 specifies: "Where necessary to ensure valid results, measuring equipment ... shall be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. … Records of the results of calibration and verification shall be maintained."

In essence, this means that evidence that the weighing instrument works correctly needs to be provided and it needs to be demonstrated that the manufacturer understands what is measured. High risk and a narrow process tolerance may call for frequent instrument accuracy verification.

Calibration of the weighing equipment must be conducted according to globally recognized standards, such as OIML and EA 10/18, and needs to account for metrology, as well as equipment construction. As discussed in Chapter 2, eccentricity, non-linearity and repeatability of the device need to be tested during calibration in order to assess measurement uncertainty and evaluate if the device performs within the range of allowable errors. These results must be documented and maintained.

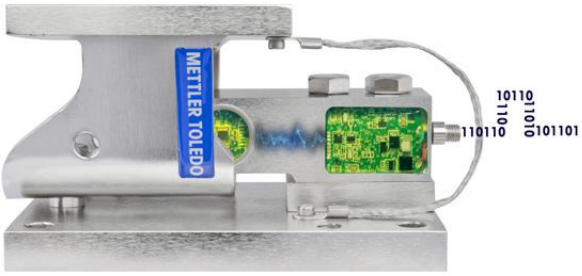
Define adequate maintenance plan

If scales fail or deliver inaccurate measurements, the impact on final product quality can be significant. Regular maintenance of the weighing equipment is required to realize and sustain accurate, dependable, legal and accountable weighing results.

Depending on the installed weighing equipment, a range of maintenance tasks need to be performed, including:

- Cleaning of the scale, terminal and peripherals
- Inspection for proper environmental sealing
- Adjustment of critical scale components when required
- Examination of cabling and wiring
- Testing of human interface and electronics
- Review of scale diagnostics and logs
- Testing and verification of weighing accuracy
- Confirmation of proper operation of software applications

New intelligent load cells enable preventive maintenance solutions to monitor the condition of the weighing system in real time and alert designated individuals of potential failures or maintenance requirements via email, SMS or the operator interface. Built-in diagnostics monitor each individual load cell and control and log various operation parameters for quick diagnostics and immediate action.



Weigh Modules with integrated microprocessors enable real-time diagnostics and fast action.

5. Monitor and Control the Weighing Process

Weighing systems are often central to important production steps, such as formulation, batching or filling. The integration of weighing processes into a manufacturing and management system is therefore an important step in ensuring consistent monitoring and control of quality-critical attributes. As weighing is a quantitative measure, weighing results can be archived, statistically analyzed, tracked and traced, integrated into manufacturing and management systems and used for control-feedback loops.

Collect+ provides real-time visualization of process trends and enables fast corrective actions.

Integrate weighing process data

Seamless integration of weighing process data is a key component of a real-time process monitoring and control setup. Automatic electronic data collection and integration ensures traceability of each step of the production process, from the raw materials to the final product. It also enables direct feedback from sensors to control systems to trigger alarms, allow for process adjustments or even automate process control.

METTLER TOLEDO provides a data collection and visualization software that allows for informed business decisions. The software captures weighing data and related process information and enables real-time graphic visualization of process trends, such as current production status, out-of-specification measurements or material consumption. Quality and productivity deviations can be quickly identified and corrective measures can be taken.

Continuous monitoring of quality data

Continuous monitoring and real-time control of manufacturing processes are important aspects of ensuring consistent product quality. In modern manufacturing, this can be achieved only through comprehensive data integration. When selecting the right weighing equipment for a Quality-by-Design-driven manufacturing process, consider the necessary software, interfaces and controlling capabilities to ensure seamless process integration.

6. GWP® - A Risk-Based Approach to Weighing

METTLER TOLEDO has developed the global Good Weighing Practice™ (GWP®) standard as a unique approach that provides a scientific methodology to selecting and testing weighing instruments within an integrated qualification approach. Based primarily on the user's weighing requirements and prevailing weighing risks, the methodology provides a state-of-the-art strategy to reduce measurement errors and to ensure reliable weighing results.

Supporting quality planning

The understanding of weighing process requirements and important scale properties, such as the safe weighing range, is essential to selecting an appropriate weighing system in the framework of the design qualification. The performance qualification takes into account these requirements and risks to establish a specific routine testing scenario for the instrument.

Enabling quality control and improvement

GWP® provides the necessary information to make decisions about your weighing system. By testing the scale in place, weighing experts can certify the weighing process, meet final product quality requirements and ensure the scales are proven to be fit for their intended use. Verification can also identify weighing installations that may not be suited for the particular application and could affect quality.

Managing all phases of the life-cycle

The GWP® standard provides guidance for all phases of the life-cycle—from evaluation of the weighing process and selection of the equipment to installation and calibration and finally, routine operation. Risk- and life-cycle management form an integrated part of the overall strategy of Good Weighing Practice™ to bridge the gap between quality targets and process performance.

Good Weighing Practice™ (GWP®) process.

7. Summary

Quality by Design is a risk-based approach to integrating quality into the manufacturing process. Based on the defined target product quality, the entire manufacturing process is analyzed to identify process attributes that may influence product quality. These critical quality attributes must be managed to ensure consistent product quality over time.

Weighing has a critical impact on product quality. The weighing instrument not only needs to deliver accurate weighing results, it also must ensure consistent measurements over time in often challenging production environments. Furthermore, possible operating errors during the weighing process need to be identified and eliminated.

Good Weighing Practice™ from METTLER TOLEDO provides a standardized scientific methodology for secure selection, calibration and operation of weighing equipment. It offers the right tools to support the quality planning, quality control and quality improvement processes of the Quality by Design concept.

Quality by Design

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Good Weighing Practice™ (GWP®)
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