LabX

WHITEPAPER

Weighing the Importance of Lab Balances in Quality Control Labs

Supporting sample preparation workflows to ensure data integrity and compliance

Quality Control (QC) labs rely on accurate and reliable data. Sample preparation is a fundamental process required by analytical techniques used to generate this data. Lab balances serve essential roles in analytical sample preparation, from preparing solutions and standards to quantifying analytes and more. Ultra-high resolution balances can go beyond standard devices and provide advanced capabilities such as data logging and connectivity to support data integrity and compliance standards.

The requirements of sample preparation in QC labs

The process of sample preparation has direct bearing on the ability to accurately detect and quantify analytes. For this reason, the tools and techniques used in sample preparation must exhibit the highest quality and performance. Quality control (QC) labs are tasked with ensuring products such as active pharmaceutical ingredients (APIs), purified antibodies, and other biologics are free from contaminants. Beyond detecting contaminants, QC labs must ensure the proper functional aspects or Critical Quality Attributes

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(CQAs) remain intact during analyte purification, quantitation, and eventual scale up to production. Lack of adequate quality control can result in resource loss and products that may be harmful to patients.

Essential sample preparation tools in QC labs include:

- Lab water: systems that provide high-quality water free from impurities to avoid interferences.
- Pipettes and tips: tools to help ensure accurate transfer of small-volume solutions without loss of sample integrity.
- Syringe filters: devices designed to remove particulates without contributing extractables and leachable (E&Ls).
- Lab balances: analytical devices that are central to the preparation of reagents, calibration standards, buffers, analyte sample solutions, and other important applications.

The Arium® Pro Ultrapure Water Systems meet or exceed ASTM Type 1 water quality to increase the sensitivity and reproducibility of your analytical results.

The role of lab balances in analytical sample preparation

Analytical techniques such as high-performance liquid chromatography (HPLC), spectroscopy, and elemental analysis each have requirements for high-quality sample and standards preparation. To obtain accurate results, it is therefore necessary to prevent all types of cross-contamination caused by poor quality of water in the mobile phase or during sample preparation processes.

The range of analytical sample preparation methods includes:

- Sample concentration
- Standards preparation
- Solid phase preparation
- Trace element quantification
- Quantification of analytes
- Precise molarity, dilution, and percent concentration of solutions

Analytical labs depend heavily on the use of lab balances when performing these sample preparation methods. The sensitivity of these techniques requires solutions to be of the highest quality to ensure reliable data generation free from background noise and interference.

Lab balances in QC labs

Lab balances can impact multiple aspects of analytical performance in the QC lab environment. For instance, assay Linearity, Accuracy, and Precision, can all be affected by weighing methods and lab balance performance. Understanding sources of error and bias in sample preparation is critical to ensuring that analytical techniques are dependable and QC operations are successful. Lab balances are a crucial tool in helping to minimize the impact of these factors.

Weighing performance and metrics

In the case of standards preparation in the QC lab, there are often challenges including weighing small amounts of samples, zeroing or taring large vessels, or combating human measurement and calculation errors. High-resolution balances can offer a high maximum weighing capacity, allowing users to weigh directly in larger vessels without the need for sample transfers and potential loss. These balances can also utilize low scale interval (readability), as well as low minimum sample weighing capabilities, all of which are important in the analytical lab environment.

There are certain requirements for lab balance performance metrics in the QC environment. For instance, Chapter 2.1.7 in Supplement 10.6 of European Pharmacopoeia (1)

defines the requirements for minimal sample weights in testing protocols for drug manufacturing. To determine the minimum sample weight for repeatability tests, the test load must be < 5% of the balance maximum weighing capacity. For accuracy tests, the displayed value may deviate from the test load by a maximum of 0,05% (EP)/ 0,1% (USP). Companies manufacturing drugs must comply with the local pharmacopeia regulations (US by Chapter 41, EU by EP 2.1.7, ...).

For companies manufacturing drugs for the US market, the United States Pharmacopeia (USP) (2) describes standards for drugs and related products. Chapter 1251 "Weighing on an Analytical Balance" provides important guidance on the implementation and testing of balances in regulated labs.

Ultrahigh-resolution balances are tasked with achieving these performance metrics and effectively supporting QC lab standards compliance.

Data integrity and connectivity

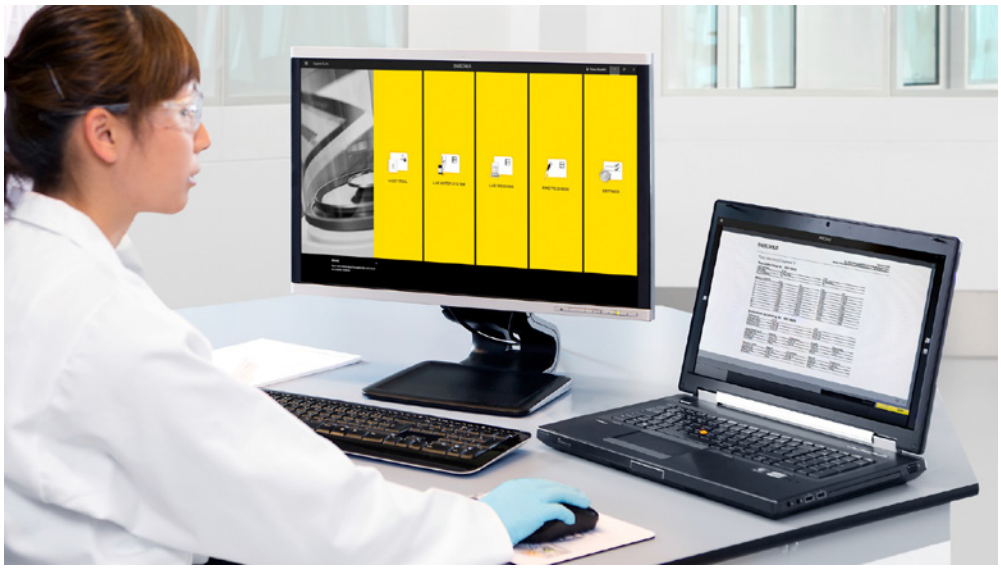
The practice of "Data Integrity" entails a combination of data quality, trustworthiness, reliability, and completeness. Data integrity is essential in supporting not only regulatory compliance but product quality, patient safety, and reliable process outcomes. Data integrity is also a central principle in QC lab performance.

In recent years, the FDA has targeted data integrity violations such as data loss and manipulation, improper batch documentation, insufficient audit trails, and other infractions. QC labs have confronted these issues by simplifying compliance and replacing manual procedures with automated controls.

Automated data integrity functions can include:

- Audit trail
- Secure Data Backup
- Safe Data transfer
- Access Control and User management
- Electronic signatures
- Time synchronization
- Others specified on the 21 CFR Part 11 Compliance Checklist (3)

Ultrahigh-resolution lab balances can help ensure required performance metrics of QC labs are achieved while supporting data integrity improvements and optimization.



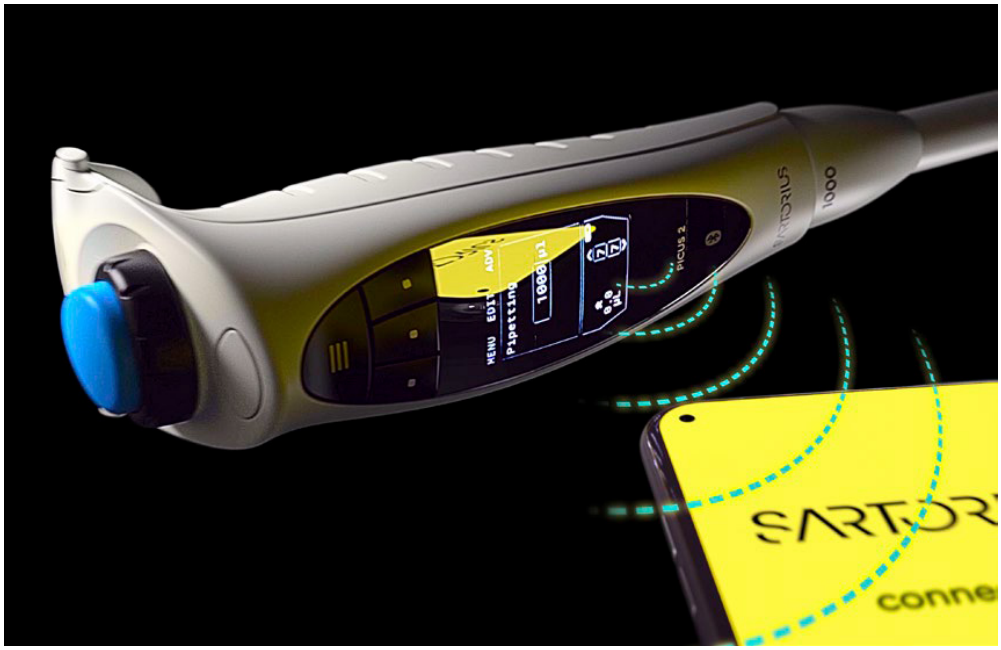
The Cubis® II Family of Ultra-High Resolution Balances

The Cubis® II Ultra-High Resolution Balances from Sartorius are designed for challenging weighing workflows with advanced capabilities to help QC labs. These balances integrate innovative design elements and extended features to support the most stringent levels of data integrity and regulatory compliance.

The innovative design of the Cubis® II ultrahigh-resolution balances addresses environmental challenges such as changes in temperature, air pressure, humidity, and electrostatic interference. Features include:

- Automated motorized leveling to level the balance to ensure accurate weighing results.
- An optional motorized inner draft shield to exclude influences on weighing results due to drafty conditions.
- An upgradable built-in ionizer featuring four ionizer nozzles to provide fast and efficient elimination of static effects.
- Advanced performance features, including a low minimum weight and fast stabilization time, for highly repeatable measurements.
- Stable and reliable performance over the entire weighing range, verified according to USP Chapter 41 and evaluated under actual laboratory conditions.
- On-board cleaning software providing step-by-step guidance for basic and advanced cleaning.

Data management and connected solutions support QC compatibility. The Ingenix® Suite digital fleet management open software solution allows external balance calibrations and pipette performance checks and calibrations. The software and connected solutions follow ALCOA+ principles and CFR part 11 and EU Annex 11 compliance. In addition, the advanced connectivity features enable ELN/LIMS system integration, while hardware and software upgrade options provide investment security and adaptability to future laboratory needs.



Summary

Lab balances are essential in analytical sample preparation workflows. Ultrahigh-resolution balances such as the Cubis® II systems extend far beyond standard devices to provide unparalleled precision, adaptability, and integration capabilities. These systems are designed for optimum sample weighing and robust data integrity, with upgradable hardware and software to ensure compliance with IT standards and 21 CFR Part 11 and EU Annex 11 regulations. These features and capabilities combine -- maximizing operational efficiency in QC labs and regulated environments.

Published in partnership with Sartorius

References:

1. European Pharmacopoeia; 2021
2. United States Pharmacopeia and National Formulary (USP 43 - NF38); 2019
3. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application