Accurate weighing results

GWP®* (Good Weighing Practice™) Life Cycle Management – 5 steps that support the Lean principles perfectly

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A Lean Laboratory focuses on testing products and materials to deliver results in the most efficient way in terms of cost and speed. An accurate result for the customer is a pre-requisite. However, to guarantee accuracy of a weighing device over time requires using the correct balance as well as calibration and routine testing. Following the Good Weighing Practice scientific standard helps you to select the right device, set-up the correct routine testing scheme and define your weighing SOPs.

Lean Laboratory is a management and organization process derived from Lean Manufacturing and the Toyota Production System (TPS) [1]. Lean Laboratory is generally associated with Food, Beverage, Life Science and Pharmaceutical companies.

Implementing Lean Laboratory principles

There are a number of methods and measures that can be used when implementing the Lean principles, but the goal is always the same: Improving measurable performance and/or reducing costs. For weighing applications the Lean principles ensure that the weighing result is accurate. This prevents OOS (out-of-specification), rework and waste, and ensure a minimal use of materials and reagents.

The 5 subsequent steps of the Good Weighing Practice™ lifecycle match and complement the principles of Lean Laboratory perfectly and mitigate potential risks, from the selection of a device to the routine operation of the same:

- Step 1 and 2: Evaluating and selecting the right balance from the start
- Step 3: Correct installation from the beginning by taking into account environmental influences and ensuring proper weighing
- Step 4: Calibrating the device before and after adjustment and/or repair (“as found” and “as left” calibration) to ensure consistent accuracy and trustworthy results
- Step 5: Conducting user tests on the balance in routine operation, following a risk based methodology to maintain accuracy until the next calibration of the device

* The registered trademark GWP is a trademark of Mettler-Toledo in the European Community, USA, China and 11 further countries.

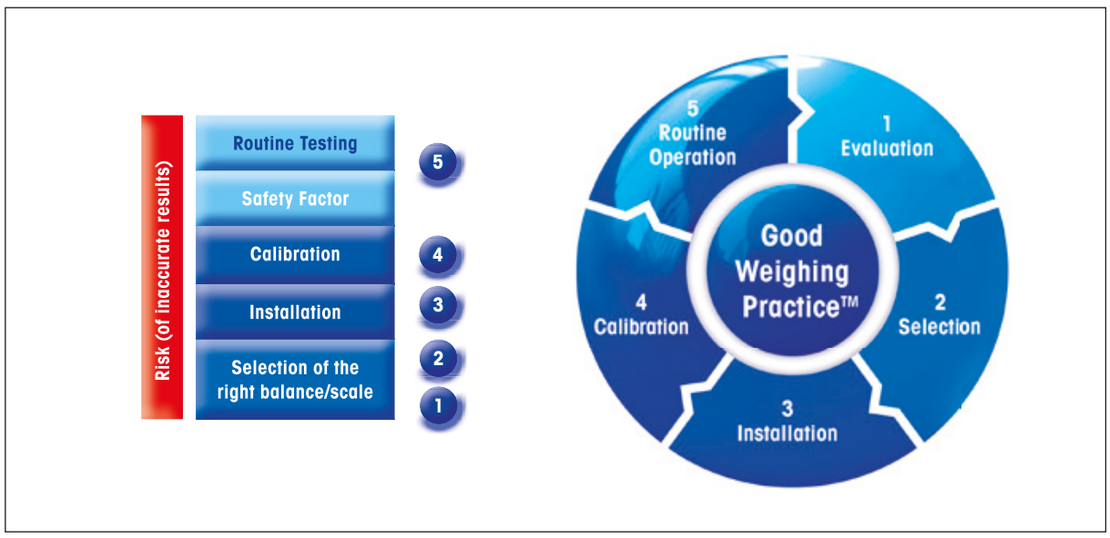

Fig. 1 Risk contributors to accurate weighing results according to the GWP® life cycle

The life cycle shown above is a scientific methodology to selecting and testing weighing devices within an integrated qualification approach. Based primarily on the user's weighing requirements and prevailing weighing risks, it provides a state-of-the-art strategy to reduce measurement errors and to ensure reliable weighing results (see Fig. 1).

The essentials to select the correct weighing device

The understanding of weighing process requirements is essential to select an appropriate weighing device in the framework of the design qualification [2]. Every product sales representative at Mettler-Toledo uses software, which is based on the metrological principles stated in Good Weighing Practice™. Essential requirements such as determining the largest and smallest load to be weighed on the device, the tolerance requirements and the quality standards that should be met, are scientifically matched with the specifications of the balances and scales. This design qualification is free of charge and globally available (Fig. 2).

Free Design Qualification ensures the correct selection of a balance

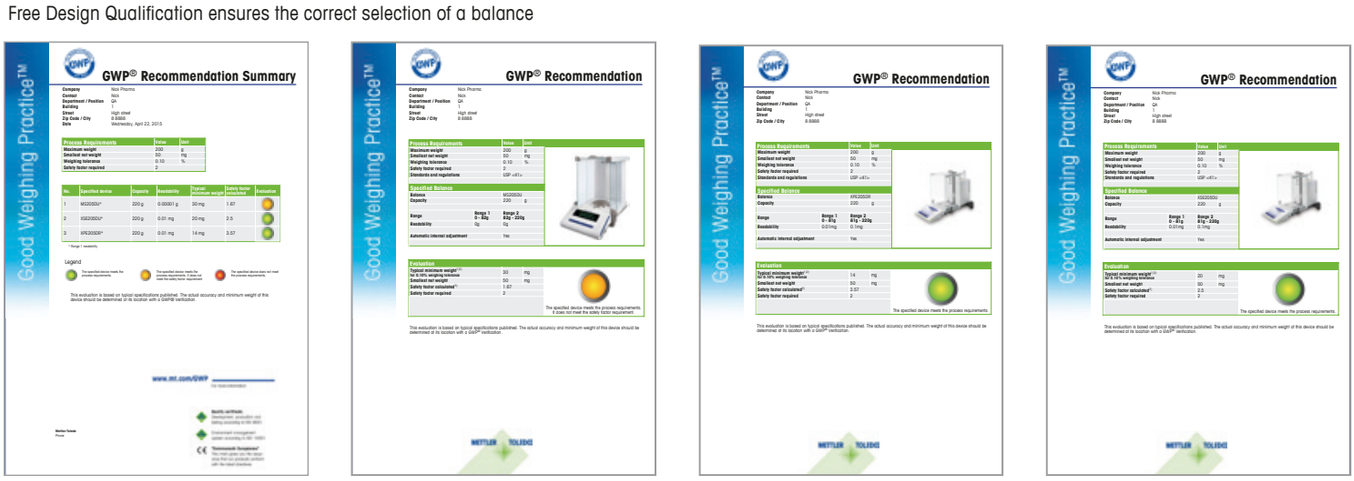

Fig. 2 GWP® Recommendation with a summary overview and single balance recommendations

Routine testing of weighing devices

"Measuring equipment shall be calibrated and/or verified at specified intervals [. . .] against measurement standards traceable to international or national measurement standards."

ISO9001:2008, 7.6 Control of Monitoring and Measuring Devices

"Automatic, mechanical or electronic equipment [. . .] shall be routinely calibrated, inspected or checked according to a written program designed to assure proper performance."

21 CFR Part 211.68 (a), US GMP for Pharma

The statements clearly allocate the responsibility for the correct operation of equipment to the user. But then the user is confronted with questions like: "How often should I test my balance and what kind of tests should I carry out"? In Lean Laboratories time, money and avoidance of redundancy is key. Therefore the testing scheme should be risk-based and answering the following questions:

- The required weighing tolerance of the application
- The impact (e.g. for business, consumer or environment) of a wrong measurement

This can be obtained by doing calibration and routine testing based on individual weighing tolerance requirements and the risk involved in the customers weighing operations (see Fig. 3).

Documents the performance of each balance versus process requirements based on a calibration.
The Safe Weighing Range visualizes the specific area of the specific weighing security of each device.

Fig. 3 GWP® Verification indicating the Safe Weighing Range

The performance qualification takes into account these requirements and risks to establish a specific routine testing scenario for the device. The higher the impact in case of inaccurate weighings, and the more stringent the weighing tolerance requirements are, the more frequently user tests have to be carried out. However, for less risky and stringent applications, testing efforts can be reduced accordingly [3].

Conclusion

By implementing Good Weighing Practice™ as a methodology to provide a risk-based life cycle approach for evaluation, selection, and routine testing of balances and scales, measurement errors in a Lean Laboratory can be reduced and reliable weighing processes can be realized ensuring a steady workflow with accuracy over time.

The key issue to be considered for a successful operation of weighing devices is that users weigh in the safe weighing area of a balance (Fig. 3). Furthermore, it is recommended to apply an appropriate safety factor to compensate for variability in the environment that may affect the accuracy of the measurements.

An understanding of the weighing process requirements together with an understanding of the basic principles of balance and scale properties as measurement uncertainty and minimum weight enables the user to realize an integrated qualification strategy as a basis for achieving qualified weighing processes. This eliminate the source for Out of Specification results, both in the laboratory and the production environment.

Appropriate and meaningful routine tests enable the user to test exactly what is needed to adhere to the specific weighing requirements, and to avoid unnecessary – and costly – testing. Risk- and life cycle management thereby form an integral part of an overall strategy to bridge the gap between regulatory compliance, process quality, and cost consciousness [4].

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