New Require-ments

U.S. Pharmacopeia Convention (USP) defines changes to scales testing procedures

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The U.S. Pharmacopoeia Convention(USP) has recently published a revised version of its mandatory chapter 41 (Balances) plus amendments to chapter 1251 (Weighing on an Analytical Balance). Effective 1 December 2013, the revised chapters mean pharmaceutical companies are now facing the problem of compliance with the new requirements. These amendments define the changed test procedures for scales (US: balances) that apply both to the US pharmaceuticals industry and for companies that export to the USA.

Fig. 1 With GWP® Verification, the minimum weight can be determined precisely for each set of scales.

Scale users and manufacturers have long criticised the fact that the USP's general chapter 41, "Balances", uses extremely vague formulations and compliance with the rules is hard to achieve. In addition, frequent mention has also been made of the fact that the general chapter 1251, "Weighing on an Analytical Balance", no longer reflects the latest weighing techniques. The revision of both chapters as part of the second supplement to USP 36-NF 31 is intended to help medicine manufacturers and suppliers ensure precision, and thus avoid repeated testing and the onerous costs this entails. Here, Mettler-Toledo's global weighing standard Good Weighing Practice™ (GWP®) can help customers to implement the new standards in a structured and effective manner.

High standards for scale testing

Compliance with the new requirements for general chapter 41 is mandatory. The revised chapter defines a fairly sophisticated evaluation procedure for scales. Details are provided of precision and repeatability testing for calibrated scales, such as are used to weigh analytes for substance assays. Since precision can be verified only with the use of weights that correspond to at least 5 % of the scales' capacity (with weights under 5 %, evaluation of systemic deviations is too imprecise), the selection criteria for specimen weights have also been modified appropriately.

Saving time – without losing precision

General chapter 1251 contains additional details about the new procedures, while expanding the scope to cover all scales that are used in analysis procedures. This also envisages a risk-oriented approach to the verification of scale performance. In particular, the text recommends only weighing net samples that weigh considerably more than the minimum weight. This takes into account fluctuations in scale performance that can be traced back to varying environmental factors or the scale operator. This requirement refers expressly to the sample weight itself and does not cover the tare vessel. Beyond this, the recommendations for daily tests have been withdrawn – probably the most important change for pharmaceutical manufacturers. This change is likely to bring about huge time savings, which, assuming scale precision can be guaranteed, will also enable a corresponding reduction in costs.

Ensuring scale precision under the new conditions

While the new scale chapters imply the avoidance of unnecessary testing – so as to ensure the retention of production margins in the fiercely-contested pharmaceuticals market – the text nonetheless makes it clear that this option must in no circumstances influence the precision of the scales. The GWP® weighing standard from Mettler-Toledo can help manufacturers ensure compliance with the new USP rules.

Fig. 2
GWP® Verification helps manufacturers optimise their operating procedures (SOPs).

GWP® verification is tailored precisely to match the respective scale applications and is a unique, risk-oriented service that helps to avoid superfluous or incorrect testing. Since the minimum weight and measurement uncertainty must be determined for each set of scales used within the weighing process, manufacturers not only optimise their operating procedures (SOPs) while ensuring a uniform level of product quality and successful audit results, but, in addition, avoid costly legal disputes and payments of fines on account of products whose composition is inadequate or which does not comply with the stipulated requirements.

Uniform quality – with GWP® Verification

Daily manual testing is finally a thing of the past. This gives manufacturers of pharmaceuticals the opportunity to improve their test equipment monitoring for scales and take a major step towards ensuring that their products remain safe, effective and profitable. Thanks to the unique, systematic guidance provided by the GWP® Verification Service, consistent weighing quality – and thus uniform product quality – can be integrated into pharmaceutical manufacturers' daily production processes without this involving a burdensome schedule of excessive testing.

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Klaus Fritsch has worked at Mettler Toledo since 2005. Responsible for product conformity, he also holds the position of Senior Industry Consultant as regards the relevant regulations for weighing systems. Part of his remit involves active participation in committees and standards bodies. He is a member of the USP Expert Group for revisions to the general chapters 41 and 1251, and advises ASTM, NIST and EURAMET on issues relating to weighing standards and directives. Klaus Fritsch received his doctorate in 1997 from TU Munich.