Risk Management:

The Critical Role of Measurement and Calibration Executive Summary

Measurement is the very cornerstone of any manufacturing process. It governs such things as the proper mix of ingredients, temperature, pressure, and flow – even the electricity that powers the plant. Yet it is often a part of the process that is taken for granted. But because measurement has impact throughout the manufacturing process, the consequences of bad measurement increase as products proceed through manufacturing, supply chain, and consumer purchase.

Effective risk management requires the careful consideration of the impact of measurement on manufacturing processes, quality assurance, the development of requirements and procedures specifically for measurement, and a highly selective choice of service provider.

An <u>effective calibration program</u> is a preventive cost that is often overlooked.

The cost of measurement management is insignificant compared to the investments in manufacturing. Yet the impact on quality, productivity, efficiency and safety is enormous.

What is calibration? The dictionary defines calibration as "the matching or reconciliation of a measuring device of unverified accuracy with another device that is known (verified) to be of standard or superior accuracy."

Many manufacturers, like Johnson & Johnson, have <u>in-house specialists</u> who calibrate all their processing equipment on a regular basis to make sure the equipment is performing within a certain level of accuracy. However, the issue then becomes: how do you make sure that the calibration and measurement devices the in-house specialists use are themselves accurate? The answer is, by testing them against an even more <u>accurate standard</u>, of course.

Using the services of a qualified third party provider for calibration significantly reduces risk by delegating the responsibility to a trained expert, like Transcat, for whom expertise in measurement quality management is core. Only with a rigorous calibration routine by a third-party calibration expert can you have the complete confidence that your

in-house testing devices are accurate. When your testing devices are accurately calibrated, you can be confident that they are not negatively impacting your processes, resulting in a decreased risk of process failure, lower costs and more consistent product quality.

But not all <u>calibration service providers</u> are alike. There are substantial differences, and assessment of these providers requires the same diligence and priority that you would apply to your selection of an ERP vendor.

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With such a high cost associated with any inaccuracy in its manufacturing process, it's imperative that Johnson & Johnson choose not just a competent lab to perform third party calibration – but a lab with superior capabilities, like Transcat.

How can Transcat help you reduce risk?

Calibration across a broad array of disciplines and instruments requires deep knowledge, expertise and experience, and Transcat's calibration leaders are well-known throughout the industry as leading authorities.

"When regulatory auditors see the Transcat name on documentation, they know that the work has been completed properly and as indicated."

That's what our clients who are subject to regulatory compliance and outside auditors tell us. We offer <u>expert calibration and repair services</u> for <u>all types of calibration, test and measurement instruments</u> to assure complete <u>compliance to the standards</u> that affect your industry.

At Transcat, we hold ourselves to the highest standards of excellence and accuracy in the calibration industry. All twelve Transcat laboratories have earned the widest scope of ISO 17025 accreditation in the industries we serve. But Transcat's own quality requirements go well beyond this international standard.

Quality management at Transcat isn't an event; it's a continuous process of training, assessment and improvement. We never cease to consider the effect of our business services on our clients' processes. This is critical to ensuring our clients can effectively mitigate risk in their production processes.

We think about and act on issues that other calibration providers either can't or won't. For example, any competent laboratory can end up with situations where they are not certain about the result of a measurement. This occurs under very specific conditions when the instrument has drifted close to one end of its tolerance limit. Under these circumstances, it's

very important to understand how the instrument reading, the instrument tolerance and the lab's own uncertainty interrelate. Transcat has developed a means of normalizing all this data into one figure called a PCS indicator, that can be used to identify when risk is present and when it is not. While not yet in use on our certificates, the PCS will indicate when to perform an impact study, and when it is not necessary.

We never forget that someone in your organization is making decisions about a process based on values the instrument is presenting them. If these values are incorrect, either because the instrument is being used incorrectly or due to an error in the instrument itself, then the decisions being made might adversely affect the process or ultimately the product itself.

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In sum...

For a company, such as Johnson & Johnson, where consistent high quality and product excellence are hallmarks of all its brands and the foundation of its reputation in the marketplace, the importance of keeping measurements well within established tolerances simply cannot be overstated. With so much at stake, settling for anything less than the best calibration services provider would be an unacceptable risk.

Transcat has the expertise, makes the investment in knowledge and quality, and delivers the <u>metrology services and support</u> to help you minimize that risk.

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