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The Importance of Calibration

What is Calibration and How Important is it in the Life Sciences Industry?

By Frances Aponte-Diaz, Calibration Engineer III, NEXA | EAM

Whether you're a young professional or you just graduated college, starting your career as an instrumentation engineer has a steep learning curve, particularly in the life sciences industry where exacting calibration is a critical part of your job. Customers are dependent on your expertise to ensure their manufacturing equipment is producing safe, quality products according to industry regulation, as the repercussions of poor calibration may be catastrophic. Perhaps that sounds dramatic, but it's no less the truth; which is why it's imperative that from the first time you step onto a client's site, you understand the critical aspects of calibration.

This article will provide you with an introduction to calibration, its history, importance in the life science s industry, and importance of assessing your calibration process and standards. We constantly see customers becoming more aware of the flaws of their paper-based calibration systems and are now upgrading to a computerized calibration management software that offers more reliability and can monitor multiple aspect of their calibration system.

But first, let's establish exactly - What is Calibration?

In simple terms, calibration is the comparison of a known value to an unknown value. Civilizations have been developing references for measurement as early as the Egyptians dating back over 4000 years ago. Before tape measures, and handy iPhone apps, the body was used as a measurement tool. For example, the forearm which was equivalent to 0.54m in length became known as the Royal Cubit, as shown in the image below.

If you consider how long the pyramids have stood the test of time, the precision of their construction still impresses us to this day. We can appreciate how they were so well-constructed and just how fundamental calibration is and continues to be as it helps to ensure accurate measurements for the safety, quality and innovation of most products we use every day.

Why is this important, you may be asking yourself?

Egyptians are no longer building pyramids and there is certainly modern technology to facilitate calibrations. And you'd be right, but respecting and understanding the history of calibration helps to appreciate not only its critical importance, but also our dependency on its accuracy—whether its for biotech manufacturing or producing a light bulb. In other words, our lives literally depend on it.

Now that we've established a brief history lesson – and I hope you're still with me – let's put it in the context of the life sciences industry.

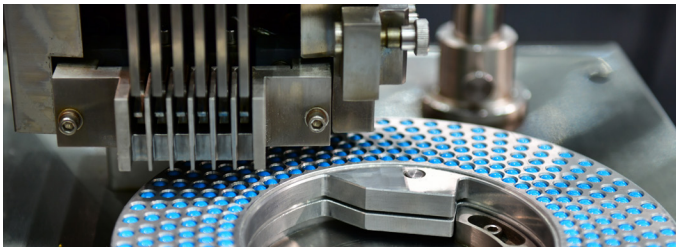
Calibration is a vital step in ensuring tools are working as they should be, giving correct readings, providing a safe working environment for users, and ensuring that companies are upholding their legal obligations.

Remember, we did mention that the action of calibration is a comparison of a known to an unknown. This leads us to discuss Standard Operating Procedures (SOPs).

Recently we had assisted a customer in updating all of their calibration procedures. The procedures they were currently using where too specific for a certain model and manufacturer, creating a gap for other equipment that needed the same type of measurement. This was a critical issue for the customer to have to keep updating the massive collection of SOPs. As specialists in calibration, we were able to reduce the number of SOPs to General SOPs per each discipline. This provided the customer with SOPs that had a wider reach, and simplified the review process from 20 temperature SOPs to 1 SOP.

There are other aspects of calibration, such as studies and risk assessments to determine cost avoidance and meeting certain acceptance criteria on any process. Presented here are a few examples that will demonstrate why they are so important to the calibration world.

We know calibration is important in life sciences due to compliance for two different regulatory agencies: FDA and USDA. Also, most people working in the industry understand that receiving an FDA Form 483 warning letter as a result of inspectional observations is very serious, and one of the 10 most common reasons to receive one is due to "equipment not calibrated/inspected/checked per written performance plan". Therefore, calibration is vital to maintain traceable records on how instrumentation is performing in the different areas of life sciences industry.



Calibration Equipment Assessment

What is Calibration Equipment Assessment?

Calibration Equipment Assessment consists of a cost and risk-based approach to calibration. A possible scenario:

You may have a process in which you must test balances on a regular basis to a certain level of accuracy to meet the criteria of a regulatory agency (i.e., FDA). You decide to purchase the best weights available on the market, believing albeit with good intentions, that this approach will cover any gaps. This is where risk assessment comes into play, and you must understand the pros and cons of your approach.

For example:

Pros	Cons
Accuracy of the weights is 10X better than the balance being tested.	Handling is limited to maintain accuracy. Cost of calibration is high. Constant out-of-tolerance due to handling.

Then you may ask yourself, "how can I have so many negatives for such great accuracy?"

Below is a basic example:

Let's suppose you need to get from point A to point B. So, you purchase a Lamborghini, known for its speed (aside from sleek design) and you know it will do its job. But as would a Ford. While the Lamborghini is faster of course, the make of vehicle is not significant because your "acceptance criteria" is set at 50 mph. The Ford can also get you there, however, and this is important, *for 5 times less the cost*. After doing your assessment, you still meet the acceptance criteria established, and in the process, you saved the client money while achieving your goals. That is a proper "cost assessment" that the client would appreciate.

Keep in mind that when you're performing any type of calibration, you have to have a clear knowledge of what you want to achieve. Think about the end goal and the client expectations.

Now that you know how to select the type of calibration equipment to acquire for your process by a calibration equipment assessment approach, now it's time to assess the criticality of such equipment.

Criticality Risk Assessment

As previously discussed, some may take an extreme approach to ensure everything is critical in their process because of the assumption that everything is important. Of course, your whole process is important, however, not every component of your process is critical. To explain further, in GMP facilities, we have the following hierarchy:

- Product Critical
- Non-Critical
- Process Support
- Environmental/Safety Critical Equipment

Each one of these equipment categories has an acceptance criterion as shown in the chart on the next page.

Category	Criteria
Product Critical	Equipment that is in direct contact with a product, or that its failure will affect a product or client.
Process Support	Equipment that supports the process, but its failure does not directly affect the a product or client.
Environmental/ Safety Critical	Type of equipment that its failure can compromise the environment or the safety of others.
Non-Critical	Equipment that is in place to monitor or to provide visual reference.

There are multiple benefits in taking the approach of categorizing hierarchy, particularly as it provides cost savings, which translates to time savings, for your customers. Further, this approach will help you in determining calibration frequencies of calibration equipment.

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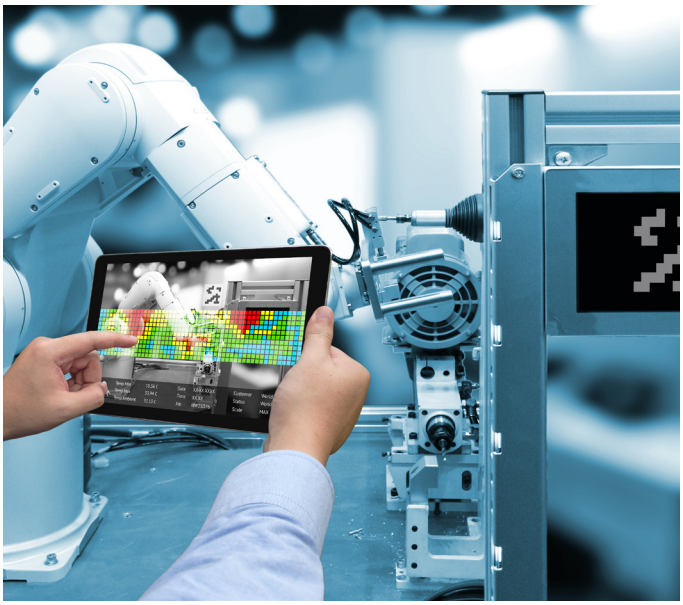
As I hope was demonstrated clearly, calibration is present in everything that we do, but it's especially important in the life sciences industry where one wrong measurement could jeopardize manufacturing of a product and impact those who depend on a product's safety, quality, and availability. As you see, calibration is a big topic—the nuances and intricacies are not all covered here of course—and there will always be something new to learn. But you have to admit it's quite amazing to see its important presence in our daily lives. From the size of your clothing, the speed at which you drive, the groceries you purchase, and yes even your cellphone – all were dependent on calibration. And to think it all started with a forearm over 4000 years ago.



About the Author

Frances Aponte-Diaz is a Calibration Engineer III with NEXA | EAM, and brings over 30 years' experience in Critical Equipment troubleshooting, Calibration, and Preventive Maintenance, Technical Writing, Testing, and Validation in the life sciences industry. She is highly committed to quality and has served as the key person to implement the maintenance and compliance to cGMP, ISO 9001, 17025, and USP requirements. Frances holds an Associate Degree in Instrumentation Engineering from the Institute of Technology - Puerto Rico; earned certificates in Quality Management Systems: Management and Control of Quality; Cost of Quality Analysis and Reporting; and Mastering the Seven Quality Tools; and has been a member of ASQ since 2008. Frances believes strongly in mentoring the next generation of instrumentation engineers and is involved in training new employees entering the life sciences industry. Contact: faponte@nexaeam.com

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