### CALIBRATION IN PHARMACEUTICALS

Through the production and development of drugs and medicine, the Pharmaceutical Industry is responsible for producing products that have a direct impact on the quality of life of the people on the planet.



An area often not thought about however, is the calibration of the technology that has made it easier for Pharmaceutical professionals to more efficiently conduct research and development on the products needed to fight illness and disease.

The Medicines and Healthcare Products Agency regulates medicines, medical devices and blood components for transfusions in the United Kingdom.

When manufacturing medication, factors such as the weight, volume and purity need to be extremely accurate to ensure the safety of those who use them to combat illness and disease. If accuracy is not achieved, this can result in the medication being unable to produce the effects for which they were designed or causing different effects. Both of which can lead to life threatening consequences.

#### **DID YOU KNOW?**

As a number of factors need to be measured within the Pharmaceutical Industry, a range of calibration types are carried out. For example, as some products need to be manufactured and stored at specific temperatures to maintain their quality, Thermometers, Thermocouples and other temperature monitoring equipment must be calibrated. Also, a variety of pressure measuring and monitoring devices are used within pharmaceutical production, such as to ensure the pressure within cleanrooms stay at optimal levels. Therefore, Pressure Calibration needs to be performed. Pipette Calibration is another example of another calibration type that must be implemented within the Pharmaceutical Industry. This is because Pipettes are regularly used to safely and accurately transfer the liquids found inside pharmaceutical products.

However, over time as Measuring Equipment is used, it will begin to lose its accuracy as it becomes susceptible to factors such as wear and tear. Inaccurate readings can result in major consequences.

On August 4 2022, Clinigen Healthcare Ltd issued a recall of three batches of Mexiletine hydrochloride hard capsules as it was identified that some individual capsules on the market may fall outside the individual fill-weight range. This means that there is the potential for some capsules to contain too little active ingredient and for some to contain too much active ingredient. This could result in potential underdosing and overdosing.

This highlights the importance for professionals within the Pharmaceutical Industry to ensure that their laboratory equipment is calibrated regularly as well as to the appropriate standards.

#### THE BENEFITS OF CALIBRATION

Regularly calibrating equipment will minimise any measurement uncertainty and ensure that the equipment is functional thus providing an accurate output in accordance with the regulatory standards.

After the calibration is complete, a calibration certificate is supplied by the service provider, which provides assurance that the equipment is working properly as well as demonstrating the standards used.

For institutions within the Pharmaceuticals Industry, in which their main priority is to research and develop products which fight disease and illness. The Calibration of measuring equipment has a wide range of benefits. For example, it allows manufacturers to produce high quality products which are guaranteed to be able to produce the effects for which they were designed. This furthermore works to improve the lives of those who use them. Calibration also ensures the correct quantities of chemicals and ingredients are found in the produced products, this increases the efficiency of the production process by allowing manufacturers to reduce waste and decrease costs.



#### WHEN SHOULD EQUIPMENT BE CALIBRATED?

The answer to this question will vary depending upon application.

Below are some useful calibration frequencies to consider.

#### Manufacture's Recommendation

When your organisation requires a valid calibration certificate

Annually, Biannually, Quarterly, Monthly

Before/After an important event, project or test

After an accident involving your equipment

## WHO SHOULD RECALIBRATE YOUR EQUIPMENT?

When it comes to choosing which Calibration Service Provider, you should consider the following:

**Laboratory Accreditation:** Accreditation drives confidence in all sectors by underpinning quality of results, ensuring their traceability, comparability and validity. UKAS is the National Accreditation Body for the United Kingdom. A UKAS accreditation ensures the highest levels of impartiality and competence through the continuous assessment process.

**On-site or Back to Base:** Can the provider calibrate your equipment on-site as well as at their own location?

**Reputation and Values:** A brands reputation and values are indicative of the quality of service you will receive. As the importance of calibration has been established, it is crucial to select a service provider with strong values closely aligned with delivering a professional and transparent service as well as a provider with strong experience within the calibration field.

**Price:** Price is a major factor which influences most if not all purchasing decisions. In regards to calibration, it is important to not only compare pricing between providers, but to also examine what is included in the service of different providers. It is also important to identify whether there are any hidden costs.

**Turnaround Times:** It is essential to select a service provider who is able to calibrate your equipment on time so that you keep in line with your own standards. Providers differ on the times in which they are able to calibrate your equipment.

**Customisable Service:** Choosing a provider who allows you to personalise your service offering is key to receiving the most suitable service you require.

# WHO CHOOSE EUROPEAN INSTRUMENTS?



European Instruments are able to perform on-site or back to base Balance, Scale, Weight, and Pipette Calibrations. We offer three different service levels when it comes to calibrating your equipment ranging from UKAS Calibration for those who require traceability to international standards all the way to 'QuickCal' designed for those who may not require extensive measurements & calibration. We're also able to develop a personalised test plan for you to suit your calibration requirements whilst maintaining fast turnaround times.

We also do not set a minimum daily charge on our calibration jobs and offer a competitive rate.

We understand that booking calibration services can be a daunting task. This is due to the complex terminology and wide array of service specifications that need to be taken into consideration, to ensure you remain compliant with your organisations standards. However, because we're an independent organisation with highly experienced staff, we strive to help you pick out the most suitable calibration services for your individual requirements.

We strongly believe it's this transparent approach coupled with our unmatched experience, which makes us the best choice for your next Calibration.