

Professional calibration of quality-relevant measurement positions

The situation

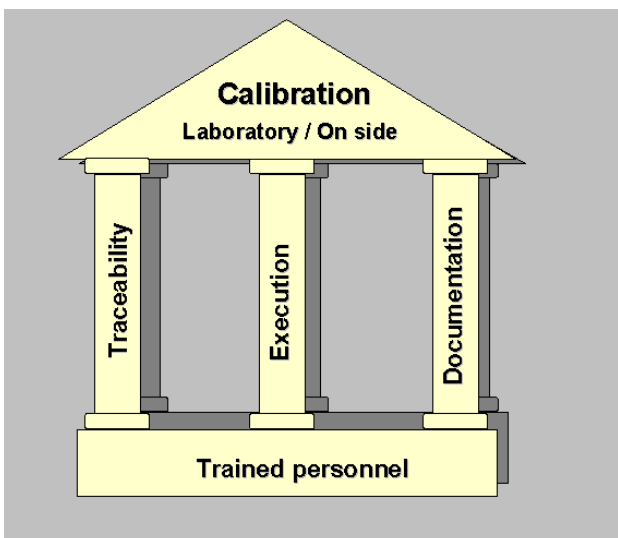
Are you able to provide GMP-compliant calibration documentation of quality-relevant measurement positions for audits and inspections? This is a requirement according to EU GMP guideline, chapter 3.41 "...Measuring, weighing, recording and control equipment should be calibrated and checked at defined intervals by appropriate methods. Adequate records of such tests should be maintained". Correct and reliable measurements are the prerequisite for high quality industrial production. Calibration of quality-relevant measurement positions, well documented and done in a reliable way, are an essential part of qualification of equipment for GMP-compliant manufacturing

Definitions

- **Calibration** is a comparison of measurement value with right value referred by a national standard.
- **Justification** is the adjustment to the smallest possible deviation.

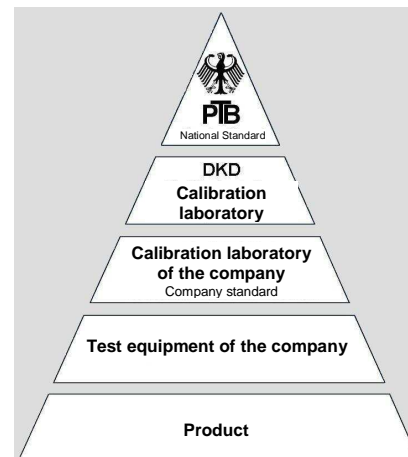
Elements of a professional calibration

After identification and documentation of all quality-relevant measurement positions a suitable method for calibration for each single sensor has to be defined. The following main points constitute calibration:



Parts of a professional calibration are:

Traceability



... that means measurement values that can be related to national standards by a continuous chain of calibrations.

Execution

- Identification of a measurement position
- Selection of the correct measurement utilities (working range, status of calibration)
- Application of the right calibration method
- Documentation of environmental conditions
- Documentation of all quality-relevant displays
- Evaluation of calibration
- Justification (in case of deviations)
- Re-calibration after justification
- Display of result

Documentation

The following information should be given in each calibration documentation (certificate):

- Identification of measurement position
- Numbers and values of calibration points
- Reference utility and reference standardisation
- Environmental conditions
- Results of calibration before and after justification
- Detailed information on calibration cycle, deviation and evaluation
- Date of calibration
- Identification of responsible person
- Identification of calibration method

A copy of each certificate according to each reference utility should be integrated in the calibration documentation.

Trained personnel

According to relevant guidelines personnel executing calibration should be competent in these activities