globetech-group..... an international network of private laboratories

GlobeTech provides the pharmaceutical & life sciences industry with specialized validation, qualification and calibration services to ensure compliance with the industry's strict Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) as well as Good Laboratory Practices (GLP).

As a leading provider of services, we offer expertise in GMP, GDP and GLP compliance. Our experienced team of professionals work closely with your quality assurance departments to ensure you meet the required standards. Furthermore our calibration laboratory is fully accredited and operate in accordance with the EN ISO / IEC 17025

## Validation, Qualification and Calibration are ongoing activities covering development, operation, and maintenance.

- ✓ Validation is a systematic approach to collecting and analysing sufficient data to give reasonable assurance and documented evidence that a process or a facility will, when operated within specified parameters, consistently produce results within predetermined specifications.
- Qualification when the above approach is related to a machine or equipment, rather than Validation, this is referred to as Qualification. Qualification is part of, but not limited to, a validation process, which in turn can be divided into Installation Qualification (IQ), Operation Qualification (OQ), or Performance Qualification (PQ).
- Calibration is a necessary component to ensure of the legitimacy of Qualification and Validation. Calibration is a process that demonstrates a particular instrument or device produces results within specified limits, as compared to those produced by a traceable standard over an appropriate range of measurements. Calibration activities must be performed with qualified instruments by an accredited laboratory.

## GlobeTech broad range of services includes the following:

Calibration, validation and qualification constitute fundamental operations of GMP, GDP and GLP. GlobeTech is dedicated to assist its clients in developing, implementing and maintaining the quality and traceability of the accuracy of their manufacturing, storage & distribution as well as laboratory equipment in order to ensure the full compliance with all international guidelines.

GlobeTech offers:

- Calibration of all type of instruments and equipment on-site and in Lab (scheduled periodic calibration)
- Validation and Qualification (FAT, IQ, OQ & PQ) of environmental rooms and chambers, incubators, refrigerators, freezers and all associated monitoring equipment such as data logging systems etc. Qualification of facility as well as HVAC systems, clean rooms, safety & bio-safety cabinets, production and laboratory equipment.
  - Chamber, Storage room & warehouse Temperature & Humidity mapping
  - HEPA integrity test (DOP etc), Clean room classification

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