

Tech Trends in Thermal Validation

Thermal Validation and Thermal Mapping: deliver MORE with LESS

Use of **heat** is quintessential for pharmaceutical and biopharmaceutical processes and impacts the critical quality attributes (CQA) of pharmaceutical products. Heat is used for cleaning, sterilization and specific unit operations involving a large variety of equipment which must be maintained in a state of **validation** throughout the product life cycle (development, transfer, validation, commercial manufacturing ...)

Current temperature validation practice is based on proven, stable and safe technologies that are however time consuming and not user friendly. Wired systems require thermocouples and here's one big inconvenient: it is like a permanent umbilical cord to the acquisition system (*this baby needs mom's care its entire life!*) Thermocouples need to be passed inside a vessel through a special device - therefore integrity tests are needed; need to be protected against damages during installation, moisture ingress during the study process and require fully recalibration after every retrieval. This along with the never ending untangling that is required makes the job very time consuming and operator's work challenging!

Historically the best advantage of thermocouple systems over data loggers was availability of real time data. With the arrival of **Real Time Data Loggers**, this is no longer the case. Real time data loggers do everything thermocouples do and much more - they represent a significant change and advance in thermal validation.

Real time Data Loggers eliminate integrity break of the equipment to validate, replace pre-calibrations with verifications due to highly accurate 4 wires PT-100 temperature sensors used thus minimizing to half the validation time.

Wireless Data Loggers do not require pre/post calibrations, although some data loggers software allows close-loop calibrations and verifications to comply with regulations. Operating data loggers is easy and efficient: simply program the loggers and place them inside the equipment to validate, regardless if it's an autoclave, freeze-dryer or refrigerator.

Start the cycle - the signal from data loggers will pass through the walls of the equipment and data can be visualized real time on the remote computer under a FDA 21 CFR part 11 compliant environment. The final reports are automatically generated to eliminate the need of data treatment outside the software. Calculations are automatically performed by the software based on existing regulations or users custom made templates.

Manufacturers of **advanced Wireless Data Loggers** eliminate thermal inertia (some using krypton as the body material). The conception of their loggers allows the signal to pass through the autoclaves or freeze dryers walls in any circumstances.

Once the change from Thermocouples to Wireless Data Loggers has been undertaken the results are immediately visible: time savings, comfort during use, user's security and increased productivity!

The methods currently used in thermal mapping and validation have been developed in the 1970's but insignificantly changed since ... it is time to do MORE with LESS.

*In challenging economic times where regulatory demands are increasing and availability of personnel decreasing, it is vital to spend capital wisely. New Technology employing **Real Time Stand Alone Data Loggers** which meet all Thermal Validation Regulatory requirements is certainly a technology worth investigating.*