Case Study 2:
Qualification of study devices

Question

- How do we ensure that the devices used in our studies are qualified and work properly?

proDERM Approach

- The qualification of our devices is accomplished in accordance with EC GMP Guide (Annex 15). It thus takes place on the level of a drug manufacturer and corresponds to the highest possible standards.
- During the qualification of device software we take into account the requirements of 21 CFR Part 11.
- We have expanded the already high requirements according to EC GMP with the aspect of safety. The entire proDERM qualification process has been firmly anchored in our corresponding SOP.

You benefit from

- Meaningful and reliable study data, based on applying the highest possible standards within the qualification of devices, which are used in a defined, climatic measuring environment.
- Optimized study conditions by using regularly calibrated devices.

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Background:

Within the vast majority of our studies, instrumental measurements are applied. Those studies are evaluated on the basis of these measurements. The measurement itself is therefore a critical element in the study execution, since it has a direct influence on the results of the study. In this respect, it must be ensured that the devices used in the studies are adequately qualified.

Requirements according to ISO / GCP:

The ISO 9001 standard indicates that equipment must be suitable for the intended use. It does not provide any information on how to realize this aptitude. GCP makes no specifications regarding the qualification of the devices at all.

Since the existing regulations do not provide any information on how to qualify study devices, it is up to the contract research institutes themselves to come up with a proper qualification plan. Some institutes may only apply the lowest possible criteria within the device qualification process. This strategy does not live up to the scientific approach which we attach to the research contract you have entrusted with us. In all our studies - be it a pharmaceutical or cosmetic one – we apply only devices which have been qualified in accordance with the guideline of the EC GMP.

'proDERM Quality'

proDERM Solution:

We have firmly anchored our qualification concept in a SOP, which includes the following elements:

- Device life cycle
- Demand and procurement planning
- Delivery and acceptance
- Device Qualification on the basis of the phases Design, Installation, Function and Performance
- Risk-based safety assessment
- Operation and usage
- Climatic measurement and environmental conditions
- Responsibilities and documentation
- Calibration, re-calibration and change control

High requirements from our SOP and an equally high number of existing devices in our instrumental portfolio - the associated qualification efforts we do not shy away. On the contrary: By creating the department Development and Technical Services (DaTS), which is dedicated to the qualification of equipment with eight employees, we are able to live up to our own standards and offer you an optimized service.