

Case Study 1:

Qualification of study staff

(to apply technical equipment in clinical studies)

Question

- How do we ensure that our study staff is adequately qualified to apply study devices in the trials?

proDERM Approach

- Qualification based on a two-phase model under consideration of training AND practical experience.
- REQUALIFICATION after a maximum of 18 months
- GAMP-5 validated training documentation and administration software for
 - Documentation
 - Assessment of practical device experiences
 - Personnel planning according to experience

You benefit from

- Regularly trained and thus highly qualified study staff
- Meaningful and reliable results based on properly performed instrumental measurements
- Optimized study performance with experienced staff

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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 is important to make sure that the responsible person carrying out the measurement is appropriately qualified and trained to apply the equipment.

Requirements according to ISO / GCP:

The ISO or GCP guidelines do not specify the frequency of training of a study technician. The guidelines only state that, in addition to adequate documentation of the training, qualification must be sufficient.

The requirements resulting from the guidelines do not live up to our proDERM standards. We believe that the qualification of study staff should be based on regular trainings as well as frequent equipment applications. In order to be able to practically incorporate our high standards we have developed a two-phase qualification model, which enables us to offer an optimized service to you.

'proDERM
Quality'

proDERM solution:

Our two-phase model takes into account not only the training but also the practical experience in using a specific device. The first phase refers to the first six months after training. If a study technician uses a given device in this phase at least five times, his/her qualification is extended. With the extension of the qualification begins the second phase in which henceforth, the past six months are always considered. If a study technician uses a device at least five times within this timeframe, his/her qualification is considered to be sufficient. If not, a requalification has to be done. As a result, this means that a study technician does not need to be trained as long as he/she actually uses a device continuously. However, the period without requalification may not exceed 18 months, regardless of the personal practical experience. That means that training takes place after 18 months in any case.

In order to be able to document the training appropriately and efficiently, we have programmed a training documentation and administration software that a) documents the instrumental training of the study staff and b) evaluates the practical experience of study staff on the basis of the personal usage frequency of instruments as well as c) enables an efficient study and personnel planning based on existing qualifications. We have validated the software according to GAMP-5 requirements.