

Case Study 3:

Optimization of the study environment - the proDERM device stations

Question

- How can we set-up the testing environment in order to optimally integrate and use devices in studies?

proDERM Approach

- Development of mobile and flexible docking stations (proDERM device stations), which allow integration of the measuring devices in ,plug and play' mode and are fully adaptable to the needs of the study and the study staff.
- Validation of the device stations according to EC GMP

You benefit from

- Smoothly designed study set-up and corresponding study execution
- A study set-up adapted to your individual study needs

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Background:

The study environment provides the framework in which the factors ‚qualified staff‘ (Case Study 1) and ‚qualified devices‘ (Case Study 2) interact in the course of the study. Optimal conditions for a trouble-free study execution should be given here. Equipment and hygiene of investigational rooms, safety at work, IT Components – there are many opportunities to create optimized conditions.

Requirements according to ISO / GCP:

From the ISO 9001 standard and the GCP guidelines, various requirements can be derived in terms of the study environment. Nevertheless, there are various components within the testing environment that resemble potential for additional optimization.

The „device stations“ we have developed are a good example for the way we optimize our test environment on a permanent basis. Regardless of existing guidelines, we have asked ourselves, how we can better integrate and use study devices and at the same time make the operation of the devices more comfortable. As a result, we can now include 10 validated ‚device stations‘ in the design of a study, which, with their mobility and flexibility, allow for maximum alignment with the needs of the study.

‘proDERM
Quality’

proDERM Solution:



Our ‚device stations‘ are mobile docking stations for the measuring devices. All of them are equipped with a computer IT-certified for safety, a touch screen, a medical keyboard, a height-adjustable table and multiple sockets. All components are installed to a stable unit on wheels. We were able to realize the following optimizations by the development of the ‚device stations‘:

- Improved adaptability in the design of the study
- More convenient operation
- Improved hygiene conditions due to the use of touch displays or medical keyboard
- Increased responsiveness to unforeseen events within one study conduct