The electronic signature in medical technology

HEALTHY SIGNATURE PROCESSES

The occupational field of medical technology is about health and life. Experience and reliability count. Experience grows over years. Reliability, understood as a technical term, is committed to precision. Manufacturers of medical technology equipment are therefore the focus of various institutions, especially the Food and Drug Administration of the USA (FDA). Their field of competence also includes the monitoring of every single step of manufacturing and consulting companies in medical technology.

The aim is to achieve fundamental traceability of the production chain and the associated communication. This affects all signature processes. Electronic signatures ensure transparency: MOXIS meets all requirements of relevant authorities such as the FDA.

Equipment of operating theatres

Medical technology is divided into the production of medical technology equipment and the engineering services that accompany the production itself, but are also located in the areas of maintenance and repair. Medical technology products can be found in all areas of health care. Every visual aid from the optician is a product of medical technology. The medical technology range includes, among other things, the complete equipment of operating theatres, imaging diagnostics such as MRT and ultrasound equipment, and various test procedures, for example in the treatment of diabetes. Information and communication technology is a natural part of almost all branches of medical technology. The importance of the electronic signature can be seen from the FDA's clearly formulated

BENEFITS

- *FDA compliance*
- *Consistent digital workflow*
- *Significant process acceleration*
- *Transparency for all involved*

requirements for the documentation of medical technology procedures. It does not matter whether it is generally about quality documents, validation or non-conformance documents.

Prevent forgery

An example from the FDA's CFR Title 21, Part 11: "The establishment of and compliance with written policies that hold individuals accountable and responsible for actions taken under their electronic signatures to prevent forgery of records and signatures". MOXIS supports both the qualified electronic signature (QES), which is equivalent to the handwritten signature by law, and the advanced electronic signature (AES). Both signature qualities allow to determine beyond any doubt who has signed (authenticity) and guarantee that the document in question has not been changed after the signature (integrity). In MOXIS, the burden of proof is bound to the document. Subsequent changes to the document result in the signature becoming invalid.

Identification of the signatory

The FDA requirements also specify that the signatory must be identified before the electronic signature is issued. MOXIS meets this requirement not only for QES. When verifying the identity for an AES, the responsibility for correct identification lies initially with the customer. By creating the user in the system, or by authentication via the Active Directory, signing with an AES in MOXIS is made possible. Essential for the use of the electronic signature according to the FDA's catalogue of requirements is (not only) in medical technology processes the traceability of who has signed and thus vouches for a work step: "Every electronic signature must be unique for one person and may not be reused or reassigned by other persons". In MOXIS, the user authenticates himself via the user data of the customer's Active Directory. This ensures that the electronic signature can be clearly assigned to the respective person.

More information about MOXIS in the health sector >>

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