THE MDR JOURNEY

NEWSLETTER No. 11 – February 2020

«Let's make transparency a standard requirement»

Subject: Usability – a hidden challenge

Introduction:

In the November Newsletter, we wrote about the definition of risk management activities conducted for a Medical Device. Very closely connected to the risk management is the concept of usability. To understand this concept, we need to define usability by taking a look into the standard EN 62366:

"USABILITY is the characteristic of the USER INTERFACE that establishes EFFECTIVENESS, EFFICIENCY, ease of USER learning and USER satisfaction"

In simple words, usability is the process of developing a product according to the needs of the user and the designed use. It doesn´t matter if we consider a hair dryer or a smartphone. The product should be usable for the required specification. Necessary for a medical device is the balance between the need of the user and the potential risks of the product. On the one hand, the device should cover all the requirements to cure the patient and on the other hand, the usage should not cause any additional problems, not for the patient nor for the utilizer. Sounds very simple, but in reality, this process is very difficult to process. Getting a usable product means not only to develop the product itself but also many additional features. They are necessary to make sure that e.g.:

- the packing fits the product,
- the instruction for use is understandable for the users,
- the used symbols on the labeling are understandable and referring to regular requirements,
- possible hazards are easy to identify for the using person.

Let´s take a closer look into this process:

Starting the development of a medical device:

In this step, the developing team have to define:

- ✓ the product
- ✓ the intended use for this product
- ✓ how it should look like

Take a pair of tweezers just as a simple example. Define the size, the function and the layout, the material, the intended use of this product.

We must ask ourselves in the development phase:

- Is the product designed to be a single use product or is it made for resterilization?
- Define and validate the process of sterilisation and the recommended methods.

In case of reusable products, the shelf life must be defined or the number of resterilization cycles. Some sterilization methods do not fit for every product, so inform the customers about possible risk.

Are the tweezers used as a standalone product or in combination with other medical devices? If yes, define all acceptable combinations and test for their possible risks.

Disposal and environment questions becomes more and more important, so a clear instruction for disposal is mandatory.

This is extremely important for single use products, but also for reusable products with defects or at the end of their lifetime.

After solving all questions, you need to do testing to see if the products meet the expectations and fulfil the requirements.

Other medical devices may have additional software, contain electrical equipment, measuring functions, alert systems, using radiation or a user machine interface requiring input.

All these functions may also be regarded under the concept of usability to avoid misuse and risks to patient and user. In a nutshell usability process does not stop at the end of the product development process.

Additional part of development:

In this part the usability of auxiliary material and processes, have to be developed. Typical steps are:

- packaging materials,
- possible sterilization methods and processes for packed systems,
- check if the packaging material is suitable for the product, for transport, also for sterile products,
- define the shelf life and expiry date of the packed sterile product, so the user is sure getting a sterile product out the storage,
- prove the duration of sterility with tests and make sure that this information are printed on the label for fast identification,
- preparation needed of additional documents like the instruction for use and other required information for a proper handling.
- Are there any chances for a misuse with the product and what kind of foreseeable risks exist for user and patient? Define the qualification of the user depending on that fact that the instruction will be detailed.

It has to be considered that a lay need a more detailed instruction than a professional does.

The same appears to the labeling. The labeling according to regulatory requirements must be carried out in a way the user understands easily.

All the above described control is put in place to avoid / to minimize risks for the patients and the users of a medical product. Please keep in mind this process never stops. We are in a constant cycle of checking for new risks, react to minimize to existing risk. We do that with a combination of risk management und usability. Afterwards we are checking if the minimization was successfully and if yes, we are checking for new risks to minimize. Only at this stage the medical device is ready for testing in the field!

Real life testing in the field:

Just from the start, the more complex the medical device is, the more functions the device has, the more testing time is necessary.

Please compare the complexness of an X-ray apparatus and the pair of tweezers.

In our example, the tweezers are tested in handling, potential hazards, disinfection stability, and resterialization stability and so on.

Important is the feedback from the testing customers in the field. This may contain possible misuse or new applications.

Is usability given for the product or is there anything that can be improved for better handling? In addition, recommendation for further use is welcome. The results may lead to a redesign process (starting from the scratch) or a placement on the market.

Complaints and post market surveillance:

When a product was placed on the market, it becomes automatically part of the companies post market surveillance process.

The upcoming MDR strengthens the surveillance process in order to make sure that only "safe products" (meaning, product with minimum risks) can be placed on the market.

It is clear that no medical device is without any risk. The target is to identify long time risks of medical devices. We are talking about risks that could not be identified during to development phase of the product.

Due to this, the surveillance process was enlarged to cover different parts of the market in one procedure.

Through the monitoring and checking of the minimum annual repetition the post market surveillance will show possible risks that will pop up first after a longer period of time like problems caused by "as a sheer example" poor quality of the used steel or improper use caused by a not detailed instruction for use.

Feedbacks or complaints of this type always introduces the question if the problem has been caused by improper usability process. Avoiding additional and new risks appearing on the market may result in a review of the usability process itself. Target is again to reduce to risk of the medical device. If risk management shows a usability problem in the worst case, the product has to be redesigned and tested again.

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As you see, usability is a hidden process of working with medical devices, but it is present and extremely important.

Every day you will work with usable products that fulfil your special requirements. Usability helps to meet your expectations of product handling.

STS Medical Group takes care of every single topic of the usability process. Referring to the used material, the intended use or the balance between possible risk and the benefit for the patient, just to name a few. Therefore, reducing risks for the benefit of patient and users, by testing the usability, is one of the main reasons the MDR is strengthening the focus on risk management and usability.

This newsletter is part of our campaign to increase the sensitivity and the awareness of all our business partners, to bring more clarity around the MDR journey and challenges and opportunities around the MDR Art.22 "Systems and Procedure Packs".

We are already today all dependent on an effective cooperation. For the MDR implementation, we require even a closer collaboration in order to ensure we all can deliver safe supply to hospitals and patients in the future.

We are confident we will be able to continue to supply health care competently on customized surgical procedure sets and small kits.

The next MDR Newsletter will be issued in March.

You want to know more about specific topics? Do you have any questions or comments?

Write us MDR2020@stsmedicalgroup.com

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