THE MDR JOURNEY

«Let's make transparency a standard requirement»

NEWSLETTER N. 33 – April 2023

Subject: CAPA process in the medical device industry

Corrective and preventive action (CAPA) process is one of the pillars of the improvement processes that allow device manufacturers maintain the effectiveness of the quality management system according to Regulation (EU) 745/2017 on medical devices (MDR). This is also a requirement according to standard EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes.

The aim of the **Corrective Action (CA)** is to identify and take action in a timely manner to eliminate the cause of nonconformities in order to prevent any recurrence. Corrective actions shall be proportionate to the effects of the nonconformities encountered

The aim of the **Preventive Action (PA)** is to determine action to eliminate the cause of potential nonconformities to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems.

The current and most efficient approach used in CAPA process is systematic process review rather than case-by-case improvement actions.

Which are the sources of the CAPA process?

A CAPA is initiated after an escalation process of non-conformities (including complaints) which in some cases determines the need to initiate corrections or corrective actions. Some examples of processes that are inputs to CAPA are:

- Quality control
- Complaints
- Vigilance
- Post market surveillance
- Risk management
- Internal audits
- Audits from regulatory authorities
- Audits from customers
- Monitoring and measurement of processes
- Management review
- Validations
- Maintenance
- Customer feedback

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Let's have a look to the CAPA process:

The CAPA process typically consists of the following steps:

- Problem definition
- Corrections
- Root cause analysis
- Evaluate the need for corrective and preventive actions to ensure that nonconformities do not recur
- Plan and document action needed and implement such actions, verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device.
- Verification of effectiveness of corrective action taken

CAPA files are internal QMS files that include evidence recording and are typically reviewed in regulatory authority audits.

CAPA investigation typically requires working sessions with the departments involved, subcontractors, product and/or service suppliers. To facilitate the root cause analysis, the following tools are commonly used: 5-why analysis, cause-and-effect diagram (Ishikawa diagram), fishbone diagram, etc.

CAPA corrections and actions may require communication with customers and regulatory authorities.

The overview of the CAPA records is used as an input for the periodic management review with upper management involvement.

How does the CAPA process affect distributors?

Distributors, due to their closer contact to the end user, play a relevant role in the manufacturer CAPA process notifying in a timely manner complaints, possible vigilance events, notifications from local authorities and customer feedback.

Fluent communication between the device manufacturer or procedure pack producer and distributors is key to be agile and responsive in case an issue or potential issue is detected.

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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 efficient cooperation. For the MDR implementation, we require even closer collaboration to ensure we all can deliver safe supply to hospitals and patients in the future.

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

Do you wish to know more about specific MDR topics? Do you have any questions or comments about STS newsletter? Write us at MDR2020@stsmedicalgroup.com.

The next MDR newsletter will be issued in May. We wish everyone productive and pleasant days.

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