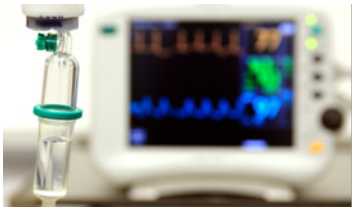
Costumer information for ISO 13485:2016

In March 2016 the new revision of ISO 13485 was published. In contrary to ISO 9001:2015 the ISO 13485:2016 does not follow the ISO high level structure. In addition no reduction of requirements was realized – in contrary in some sections more detailed requirements were added. A higher weight of a risk based approach was implemented and expanded.

Some essentials of the changes are listed as follows:

- The previous version of the standard was focused on the manufacturer of medical devices now in the new revision all participants of the life-cycle are involved.
- A higher focus on risk management requires an evaluation of changes in the processes of the manufacturer. A re-evaluation of potential risks is mandatory in case of process changes (change control).
- The use of information technology is regarded more intensively. Validation of computer-based processes of the quality management system is mandatory.
- Handling and protection of electronic data as well as legibility must be guaranteed during the whole archiving period.
- The specifications for the management review have been expanded.
- The competence of the employees has to be proven and must be assured. Effectiveness tests after training have to be implemented according to the related risks.
- The demands for adequate infrastructure correspond to the safety of the products. Documentation and process flow shall not allow any mix up of products in different stages of production.
- Requirements concerning the work environment and contamination control have been more specified.
- Design verification and design validation must be planned and realized more extensively. Methods and acceptance criteria as well as rationales for the amount of sampling chosen have to be presented. The design validation must be in accordance with legal requirements and clinical performance data.
- The transfer of design results is defined in a separate section. Any design changes should be evaluated for impact on the product, potential risks and the product realization process.
- Supplier evaluation was updated. The requirements for selection and control of suppliers and the realization of changes/nonconformities have been adapted according to a risk based approach.
- Specifications regarding legally required product identification systems (UDI) have been integrated.
- Details for sterile packaging have been amended.

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- Corrective and preventive actions remain included and the results must be justified with regards to undesired effects and potential risks.

In Annex A the changes of the new version are listed. Annex B show a link to the corresponding sections of ISO 9001:2015.

How will be this change executed?

mdc is currently in the process of extension of its accreditation to ISO 13485:2016. We plan to offer certification according this new standard revision in the second half of 2017 after approval by the DAkkS (German accreditation body).

An update to the new standard revision can be realized during a surveillance or recertification audit.

Regarding a transition period the DAkkS will follow the harmonization of the new standard according to the European Directives in the field of medical devices. The end of the transition period will be the expiry date of EN ISO 13485:2012. At the moment there are no defined dates due to the missing harmonization.