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# Molecular Breast Imaging unit - ISO 13485 requirements for management of the process of production from the feasibility study to the clinical validation

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## Background

The ISO 13485 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that meet customer requirements and meet the legislative requirements relating to medical devices and related services. The ISO 13485 was created with the intent to merge together the previous ISO 13485-13488 supplementing and updating the content.

## Methods

The primary objective of ISO 13485: 2003 is to facilitate harmonized medical device regulatory requirements for quality management systems. Consequently includes some specific requirements for medical devices and excludes some of the requirements of ISO 9001 that are not suitable for the purpose of regulation. For this reason, organizations that conform to ISO 13485: 2003 can not require compliance to ISO 9001 unless their quality management systems do not comply with all the requirements of ISO 9001.

## Finding

According to ISO 13485, the validation of the design must be carried out the validation of the design and development in accordance with planned to ensure that the resulting product from design and development to be able to meet the requirements for the application specified or intended use. The validation shall be completed prior to the delivery or use of the product. Records of the results of validation and any necessary actions shall be maintained. As part of the design validation, the organization shall perform clinical evaluations and / or assessments of the performance of the medical device, as required by national or regional laws. Monitoring and measurement are necessary to prepare documented procedures for a system of feedback, to provide for any problems quickly and focused, was added to the paragraph relating to medical systems active / non-active implantable. Control of non-conforming products in which the non-conforming product is accepted on concession only if regulatory requirements are met if the product is to be revoked, it must document the process of withdrawing with a statement of work that is subject to the same authorization and approval procedures equal education original. Analysis of the data has to be established in documented procedures to determine, collect and analyze the data necessary to demonstrate the suitability and effectiveness of the quality management system and to evaluate whether improvements can be made, including the introduction of the feedback and recording of the data analysis. Improvement has to be identified and implemented. Any changes necessary to ensure and maintain the adequacy and effectiveness of the quality management system through quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and revisions management, it is necessary to draw up procedures so that their implementation at any time and that if you do not follow complaints from customers, the reason must be authorized and registered. Corrective actions foresee to update the documents, record the results of any investigation or action taken, we must evaluate the correctness of the action taken and its effectiveness Preventive actions foresee to evaluate the correctness of the action taken and its effectiveness.

## Conclusions

Even if the path from the feasibility study to the clinical validation is complex from a bureaucratic and legislative point of view, especially in the field of nuclear medicine, we can not ignore the great benefits that are derived from ISO 13485:

- For manufacturers of medical devices subject to procedures of conformity assessment with intervention of the Notified Body in Accordance with Annexes II, V, and VI, the certification EN ISO 13485: 2003 provides a presumption of conformity of the quality system ADOPTED;

- For manufacturers of medical devices of class I (self-certification) certification 13485 allows for direct and independent verification activities prepared to meet the requirements of Directive 47/2007 and in preparation for the Eventual market surveillance activities Carried out by the Ministry of Health ;
- For companies That distribute or sell medical products and companies that shops provide services related to devices, the 13485 certification allows you to participate on tenders published by the PA.

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