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THE PUBLIC HEALTH INSTITUTE APPROVES GOOD MANUFACTURING PRACTICE GUIDELINE FOR MEDICAL DEVICES AND IN VITRO DIAGNOSIS MEDICAL DEVICES

On January 17, 2023, the Institute of Public Health ("ISP") –by means of Res. Ex. No. 106– approved the Good Manufacturing Practice Guideline for Medical Devices and In Vitro Diagnosis Medical Devices (the "Guideline").

The issuance of this Guide is framed within the powers that the ISP –through the National Medical Devices, Innovation and Development Agency Department– has to prepare technical guidelines and support the implementation of the regulation for medical devices in Chile.

The Guideline contemplates the requirements and conditions included in the NCh ISO 13485:2017 (Medical Devices – Quality Management System – Requirements for regulatory purposes) and specifies the requirements of a quality management system under which a manufacturer can demonstrate its ability to manufacture and commercialize medical devices that comply with its own specifications, regardless of the type or size of the facility.

The main elements covered by the Guideline are the following:

• **Quality Management System Requirements** : Contemplates the general and documentation requirements to be maintained by the facility.
• **Top Management Responsibility** : Requirements that the Top Management must fulfill and provide to the facility, regarding to the development, implementation and maintenance of the quality management system, such as quality policies, planning, reviews and communications, among others.
• **Resource Management** : The facility must determine and provide the necessary resources to implement and keep its quality management system, comply with current regulatory requirements and ensure a number of competent staff.
• **Performance of MD/DMDIV** : Necessary requirements for the facility to plan and develop the necessary processes for the manufacture of

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MD/DMDIV.

• **Measurement, analysis and improvement** : The facility must keep records of the procedures for the timely management of complaints in accordance to the regulatory requirements. If a complaint constitutes and incident or an adverse event it must be notified in the Technovigilance National System as stated in the Technovigilance Guideline of the ISP.

For further information the Guideline can be found in the following link:
https://www.ispch.gob.cl/wp-content/uploads/resoluciones/32087_106-2023%20OP.pdf

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