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Risk Management in IVD Producer, Relation between Manufacturer and User

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IVD Medical device manufacturers are generally required to have a quality management system as well as processes for addressing device related risks. The IVD manufacturer shall establish, document and maintain throughout the life-cycle an ongoing process for identifying hazards associated with an IVD medical device, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls. Risk management principles should be applied throughout the life cycle of medical devices and used to identify and address safety issues. In general, risk management can be characterized by design and development phases and risk management output must be use as research and development input. Risk-related data from post-production information for the IVD product should be considered if it is available. For this reason post marketing information is very important issue in risk management.

Relation between clinical laboratory as customer with IVD manufacturer is critical point in hazard identification, risk analysis and risk control. The manufacturer shall use one or more of the following risk control options in the priority order listed: Inherent safety by design, protective measures in the IVD medical device itself or in the manufacturing process and information for safety. The users must be note and aware from protective measures and information that use for risk control by manufacturer.

Keywords: Risk Management, IVD Manufacturer, Clinical Laboratory

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