The pre-analytical phase in medical biology Management and regulatory and normative aspects

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Abstract

The act of medical biology includes three phases: the pre-analytical, analytical and post-analytical phases. The pre-analytical phase includes all the steps, from the registration of the analysis request to the processing of the biological sample. Throughout this stage, the management of medical biology examinations is characterized by its obvious complexity because of the number of operators, the multiplicity of tasks and interfaces, the risk of error in the identification of samples, the diversity of sampling sites and the constraints of routing and transferring the examinations. In spite of the development of means to control this phase, notably the implementation of a quality management system, procedures for the management of non-conformities and traceability, as well as the availability of laboratory information systems (LIS), the improvement of sampling materials, the reduction or even the elimination of risks that may affect the care provided remains a permanent challenge for any biologist concerned with the quality and reliability of the results of his patients. Moreover, the Moroccan GBEA regulatory text and its enforceable pre-analytical recommendations as well as ISO 9001vs 2015 with the risk approach and especially ISO 15189 vs 2012 in its chapter 5-4, all emphasize the control of this critical step in order to avoid any risk of error that could negatively affect the diagnostic, prognostic and therapeutic management of our patients. It is therefore essential that every biologist must set an objective to reduce the risks inherent to the pre-analytical phase and contribute effectively to the care chain. Firstly, by the mandatory application of the regulatory requirements of the Moroccan GBEA and secondly, depending on the will of the biologist, by the implementation of a QMS according to international standards like ISO.

Biography

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