ABSTRACT FORM ECAT SYMPOSIUM 15 – 16 SEPTEMBER 2022

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Title:

Method validation for haemostasis assays

Abstract:

On May 26, 2017, the European Parliament and the Council of The European Union adopted the new regulation on in vitro diagnostic medical devices (IVDR) -Regulation EU 2017/746-planned to be applied from May 26, 2022, in substitution to the previous IVD directives (IVDD 98/79 EC). After several health and legal causes due to medical device malfunctions, the European Union (EU) extensively reviewed the previous regulatory, which had remained unchanged since 1998.

The question poses when discussing in-house laboratory developed method for which a clear definition is not provided in the current regulation. Recital No. 29 of the IVDR sheds some light on the meaning of the term when considering that "health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby addressing, on a non-industrial scale, the specific needs of target patient groups which cannot be met at the appropriate level of performance by an equivalent device available on the market. …".

However, the scope of application of the current regulation is evasive as exemplified in the Article 5 of the regulation which states that "with the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices manufactured and used only within health institutions established in the Union, provided that [several] conditions are met".

The relevant general safety and performance requirements described in the Annex 1 of the 2017/746 Regulation comprises (a) the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross-reactions; and (b) the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.

Within this presentation, I will share with you our experience in tempting to validate a hemostasis assay considering the current IVD-R and will also share with you the difficulties resulting from complying with all the requirements provided in the Annex 1 of this regulation.