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Regulatory submissions and quality considerations for combination drug/ device products: A primer

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Combination drug/device products are emerging as a preferred therapy of choice for many physicians, spurred by a strong collaboration between pharmaceutical and medical device sectors. The FDA recently released 21 CFR Part 4 and guidance for industry and FDA guidance for industry: cGMP's for combination products, which implements a framework for combo product regulation and quality. Combination product marketing submissions are governed primarily by the product's Primary Mode of Action (PMOA) which is the product's main therapy mechanism. If a manufacturer is unsure of a product's PMOA, they may submit a Request for Designation (RFD) which prompts the FDA to issue a binding decision on the manner. Combo products are submitted according to the PMOA; PMOA of drug means a product will be go FDA's CDER branch which will require an IND, ANDA, NDA or other scaled submission, whereas PMOA of device will usually be submitted to CDRH, which requires an Investigational Device Exemption (IDE) per 21 CFR 812.

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An introduction to the IUPAC/CITAC Guide (2016): Classification, modeling and quantification of human errors in a chemical analytical laboratory

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This Guide is developed by the project joint team of the International Union of Pure and Applied Chemistry (IUPAC) and the Cooperation on International Traceability in Analytical Chemistry (CITAC). Human error in a routine analytical laboratory is one of the major root causes of atypical test results. In particular, there are out-of-specification test results that fall outside the established specifications in the pharmaceutical industry, or do not comply with regulatory, legislation or specification limits in other industries and fields. Reducing human errors requires a study of the problem: the error classification, modelling and quantification. Classification of human errors in this Guide includes commission errors (mistakes and violations) and omission errors (lapses and slips) by different scenarios at different steps of the chemical analysis. A Swiss cheese model is used for characterization of the error interaction with a laboratory quality system. Quantification of the errors, based on expert judgments, i.e. on the expert(s) knowledge and experience, is applied. Monte Carlo simulation of the expert judgments was used for determination of distributions of the error quantification scores (scores of likelihood and severity, and scores of effectiveness of a laboratory quality system against the errors). Residual risk of human errors, remaining after the error reduction by the laboratory quality system, and consequences of this risk for quality and measurement uncertainty of chemical analytical results are discussed. Examples are provided using expert judgments on human errors in pH measurement of groundwater, multi-residue analysis of pesticides in fruits and vegetables, and elemental analysis of geological samples by inductively coupled plasma mass spectrometry. An introduction to this Guide in the lecture may be helpful for understanding the metrological and quality principles of the proposed solutions.

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