ABSTRACT

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Validation is an integral part of every analytical method. Its aim is to demonstrate that the method is suitable for the intended use. This work provides an overview and comparison of documents related to the validation of bioanalytical methods. The work includes guidelines that are currently valid in Europe, the USA or have general validity. At first, attention is paid to the history and developments in this area. Subsequently, the parameters that need to be tested in the validation study are described and are divided according to the regulatory authorities. The following chapter compares the latest versions of the guidelines regarding the validation of separation bioanalytical methods issued by the EMA, FDA, and ICH. Although the individual methodologies are similar in many aspects, there are still differences among them. Hopefully, the differences will be eliminated in the framework of harmonization and only one methodological guideline could be used worldwide. Finally, it follows a detailed statistical evaluation of the use of the EMA and FDA guidelines for the validation of separation bioanalytical methods during the years 2016-2020 in four scientific journals. The obtained data show that the use of FDA guidelines is preferred over the use of both EMA and FDA, and subsequently also favored over the use of the EMA guidelines alone.