Abstract

This thesis was aimed of the legal requirements and the comparison of specific requirements for validation of bioanalytical methods resulting from the requirement administration Food and Drug Administration (FDA) in the US and European medicines Agency (EMA) in the European Union. It was found that both agencies based on a different legal basis. FDA is part of the federal system. Publishes its own laws and the regulations which have binding legal force . In contrast, the EMA is a non governmental agency and only serves as an advisory comitte of the European Union. Both agencies have issued their instruction - Guids. The FDA issued a Guidance for Industry - Bioanalytical Method Validation and EMA issued Guidaline on bioanalytical method validation. Both manuals are only as recommendations and They haven´t legal lability.

Both manuals contain similar informations. Both agencies differ from the arrangement of the chapters and an emphasis on individual issues, but the basic parameters that are discussed and Theky are the same selectivity, carry over, LLOQ and petting of the calibration curve, accuracy and precision of the method, system suitability, and cross validation.

There were no fundamental differences between the two instructions, they only differ from the criteria that recognize the individual parameters. Major difference exists only in the definition of cross validation and in his understanding of individual agencies. FDA Guidance is not as detailed as an instruction from the EMA, but this difference is due to the fact that the legal basis on which it is based is different. FDA use this Guidance only like advise for laboratories how to apply specific legislative requirements in practice. EMA guideline is not have binding legal force and the guideline for the validation should be performed in order to fulfill all the conditions. The validation should be in accordance with guideline could be considered valid and that, in accordance with good laboratory practice. EMA guideline is not legally binding and therefore depends on each lab, if these recommendations will follow or not.