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Gaps in analytical methods registered by pharmaceutical labs

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First of all, it's important to talk about the current regulation where we are. We are in the Europe Union, where the Regulatory Authorities of each country is responsible of the approval of the marketing authorization of drugs and medical devices except the cases of centralized procedure (innovative products). These approvals are accepted by the member countries of the European Union once they are approved by European Medicines Agency (EMA). The main issues founded come from analytical methods approved by mutual recognition procedures. During the author's professional experience he has observed many different gaps in the approved analytical methods. In his opinion there could be several factors involving the following: evaluators poorly trained in the evaluation of analytical methods, the ability of the pharmaceutical industry to get the approval of methods that don't comply with the pharmacopoeia requirements, lack of data integrity in data management. The purpose of this conference is to talk about the gaps founded, how they can modify the analytical results and the responsibilities of each department involved in the validation of the analytical methods. The author is going to talk about concrete cases without mentioning specific laboratories but showing the weaknesses of their way of work. Some of the gaps he refers to are: dissolution methods with stirring speed of 200 rpm; use of non-standardized sinkers (ph Eur proposition); hiding chromatographic parameters; non-traceable chromatograms and no system suitability established. To conclude, we don't have to panic as most of the gaps founded are due to a lack of updates of the dossiers. This updates require an administrative process, such as variations, which means paying additional fees. Due to this, the pharmaceutical industry tries to widen the time to make these payments. This situation could be solved if the Regulatory Authorities control the dossiers updates in a more exhaustive way.

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