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Bioanalytical Papers: Science behind the Scene

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The reporting of scientific findings is an essential step of research. Conference presentations (either lectures or posters) and research papers are different ways to present novel results in science. Learn, discuss, teach and share – are classical foundations of Academic-based research. I would like to share a few of my thoughts in regard to the bioanalytical publications, which are predominant in the field of instrumental analysis, chromatography and mass spectrometry.

In the past century, research was mostly carried out in academic institutions. Nowadays, an industry-based (and commercially oriented) research program becomes a substantial contributor to public knowledge. The major difference between Academia and Industry (in terms of research) is compliance. In comparison to academic-based research, industry must comply with regulatory guidelines, which is a primarily imperative. Of course it does not mean at all that scientist from academia can built calibration curves using only 3 points, however academia research is not subject to audit and is not necessary to file for method approval from the (compliance) administration. Here becomes the paradox. From the industry/production standpoint, a validation procedure is a crucial part of the related documentation. In general, from the scientific side, a validation protocol is only technical steps aimed to asses method performance. Validation from the scientific viewpoint is an understanding and overcoming of intrinsic problems and bottlenecks. Actual research begins in understanding of all these various factors that unfavorably impacts method parameters and characteristics, such us recovery, sensitivity, linearity, ruggedness, etc. In order to adopt a well-validated published method in another institution, it will require complete re-validation. Therefore, primary attention to the technical side of a validation procedure has very limited (if any) scientific value and usefulness in research articles. Such straightforward technical information is most suitable to an online appendix and not to the main sections of the research paper. The goal of a quality research paper in a high-ranked journal is to report novel aspects or findings and avoid publishing technical documentation instead. From technical papers it is expected, that discussion of method development and validation linked to improvement of the assay performance will be included. Otherwise, it is difficult to evaluate quality and efficiency of the proposed method, as well as expertise of the author. Description of the validation protocol and preparation of standards and calibrators is neither an evidence of the expertise or an important lesson to the readers, unless the paper revolves solely around technical findings and those finding are of value to the broader scientific community.

This leads to the other important point in research publications, - understanding of public interest. Certain analytes, such as drug candidates or proprietary compounds have definite value only for the developer and I don't see justification of publication of analytical paper in this case. Quite often, such simple technical application/validation assays are developed in support of drug development, metabolic or pharmacokinetic studies. In this instance, brief description of the method development and validation will fit better as a part of the experimental section of a clinical paper, aimed for discussion of obtained clinical data.

For full size research papers, detailed description of validation should not occupy the experimental section. It would be sufficient to state that the method validation was performed according to FDA/USP guidelines followed by reference. Complete validation description could be placed into the online appendix. Validation data should not be presented as results, while the assay improvements can be de discussed in the discussion part of the paper. Unfortunately, some bioanalytical papers are clogged with extensive and excessive straightforward technical content, which is hides real findings and scientific importance. At the end, I would like to remind the authors, that a good scientific paper is a good lesson, which shares knowledge, experience and wisdom for the scientific community.

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