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Preface

Method validation, comparison and transfer

This special issue of *Journal of Chromatography B* is devoted to validation, comparison and transfer of analytical methods. All the papers presented here, published following the regular procedure of peer-review, are representative of the importance gain by methodological issues in biomedical, pharmaceutical, chemical, food and other important fields of analytical life sciences.

The demonstration of the ability of an analytical method to quantify accurately is of great importance to ensure the quality of analytical results, i.e., their reliability and the risks linked to their use. Because method validation is not specific to a particular sector (e.g. pharmaceutical industry), but applies to numerous disciplines including medicine, biology or chemistry, the main criteria to fulfill are similar or should be similar since the aim of analytical method validation is to demonstrate that it is suitable for its intended purpose. The emergence of common analytical platform has lead to common methodological questions which should be addressed, taking into account the characteristics of the industrial sector, matrix of the samples or analytical technology employed.

Because the need to validate methods is mandatory, proper guidelines were elaborated to help the scientist to validate his analytical procedures. The analyst refers to these guidelines and regulatory documents, and therefore the validity of the analytical methods is dependent on the guidance, terminology and methodology proposed in these documents. However, it remains the responsibility of the analyst to select that validation protocol that is most appropriate for its intended purpose. Consequently, clear definitions of the different validation criteria used to assess the method validity are of prime importance. Furthermore, the harmonization of validation of analytical procedures was developed by numerous members of the scientific community in order to understand the objectives of a procedure and to propose protocols that will include these criteria and these objectives.

Hence, this special thematic issue emerged as an important state-of-the-art of method validation in various analytical fields, as well as a contribution with respect to method comparison and method transfer. Because statistical evaluation of validation results and *validation reporting* are major challenges for every analyst, statistical and experimental approaches based on accuracy profile and on total error are presented in different types of applications. We strongly believe that the concept of total error, as documented in the most recent guidelines, will drive the modern methodological aspects in method validation, comparison and transfer and make the bridge between various disciplines and scientists.

The articles presented in this issue have been written by many of the most active scientists in the field within both academia and industry. The authors present their respective views of the current state of their field of expertise. In this volume, five reviews are presented with three of them concerning method validation. These review articles compare the guidance given in four disciplines, present some important concepts for ligand-binding assays with a special focus on selectivity and calibration aspects, and provide an overview of the importance of matrix effects determination for bioanalysis in method validation as recommended by FDA guidelines. While the need for method validation is obvious, the procedures for performing appropriate method comparison or transfer program still require clarification. Two review articles in this special issue are dedicated to these issues. In addition, six contributions propose particular methodological issues for method validation. These papers intend to cover important still open aspects concerning definition, notion of risk, determination of limit of quantification, as well as other fundamental issues such as sample stability and method robustness. The special issue includes 19 research papers which emphasize the importance of validation and other analytical aspects in various thematic domains. Starting with methods dealing with biological samples including blood and urine, method validation in such complex matrices remains still of utmost interest according to the solution afforded by scientists to improve quantitative determination. For the latter, alternatives and animal matrices are well represented with applications dealing with samples such as hair, nasal secretions, and muscle. As toxicology emerges as an important topic for qualitative and quantitative methods, food and natural product analyses remain important issues to follow according to the matrix complexity and short time response delivery. Finally, other analytical approaches dedicated to macromolecules or closely related compounds demonstrate their ability to implement total error as decision criterion for method validation.

As guest editors of this special issue, we would like to express our thanks to all contributors for their important work, as well as to the referees whose voluntary but essential duty helped keep high the quality of both original research papers and review articles. We would also to express warmly thanks to Dr. Dimitrios Tsikas for his important collaboration, support and advices in the elaboration of the present volume and during the editing process.

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