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Editorial

Biopotency Assays, a Model with Integration Feature for Quality Control Research of CMM

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As known, the development of quality control (QC) and quality assessment (QA) in the products of Chinese materia medica (CMM) is difficult and challenging. Some of the well-known analysis methods, such as IR, UV, HPLC, NMR GC-MS, and LC-MS have been applied in chemical components of the QC of CMMs and have gained significant impact and advancement in modern analytical fields. In fact, the variables of CMM quality are caused by intrinsic and extrinsic factors such as species difference, organ specificity, seasonal variation, age, cultivation, harvest, storage, processing methods, and manufacturing practices. Therefore, some methods including macroscopic, microscopic, DNA fingerprint, and chromatographic fingerprint have been also used to evaluate the quality of CMM. Therefore, the facing forward such complex factors, drug regulatory authorities, and pharmacopoeias can not establish the QC method and technical guidelines for traditional and herbal medicines, and also can not guarantee that all of methods will be practical and effective. With the development of translational research, interdisciplinary and multi-technology integration research models and ideas brought the opportunity and challenge to enhance and develop the QC research of traditional and herbal medicines.

I am very carefully read this article titled “Biopotency Assays (BA): an Integrated Application to Quality Control (QC) of Chinese Materia Medica (CMM)” (CHM, 2014, 6(4): 256-264), and have studied that Dr. Xiao's team recently published articles related this field. In this paper, the authors with extensive knowledge, lofty vision, innovation, and sensitivity of experience for more than 10 years, analyzed the current status on the QC with chemical as the leading quality standard of CMM (including traditional and herbal medicines), and pointed out the shortcomings, combined with the model of QC of medical products, put forward the supplementary of the QC methodologies.

BA has its own advantage to relate the effect, but the focus on one or two pharmacological activities is also not enough and can not be thought as totally relating to the clinical efficacy. Just as authors said, “The introduction of BAs in the QC of CMM reveals a combination of multiple disciplines, technologies, and methods, which takes the advantages of biological detection and chemical analysis to promote the development of QC pattern for CMM. But BAs applied to the QC of CMM do not mean to replace chemical analyzing methods completely”. In fact, chemical analysis is more likely used to determine the authenticity of CMM. Therefore, BA is more suitable to be applied for the evaluation.

To prove the efficacy and safety of CMM, I think that more scientific evidence using the established BAs *in vitro*, *in vivo*, and in clinic trials is based mainly on their constituents and QC to ensure the their efficacy and safety. QC methods need the innovation of new tools and models. The developed and validated methods should be able in application and prediction of the efficacy and safety of CMM. Although this method has such a problem, but the ideas, concepts, and methods of the integration application are worth advocating. This article to promote the modern research of CMM and to improve the quality standard makes a useful attempt to broaden the thinking and vision.

After reading this article, I think that the readers will not only learn the idea of the development of QC methods, but also enhance the vision of innovation and development. A Chinese proverb says “Only when all contribute their firewood can they build up a strong fire”. Scientists should unite to get more strength, it will be able to see more and better methods, techniques, and models of QC for improving the quality of CMM.