JOURNAL OF
MOLECULAR AND APPLIED BIOANALYSIS

EDITORIAL ARTICLE
PUBLISHED: 21 July 2017

# Importance and Challenges of Instrumental Analysis in Drug Development

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## EDITORIAL

Demand for instrumental analysis in pharmaceutical industry is soaring in recent years (Mullin, 2017). Among the instrumental analytical methods used in the whole drug development process, the analysis using Chromatographic analysis techniques is the most widely used one (Uslu, Lingeman, Ozkan, Palit, & Dogan-Topal, 2012; Siddiqui, AlOthman, & Rahman, 2017). Chromatographic analysis is a family of closely related separation methods which have been used for the quantitative and qualitative analysis of raw materials, drug substances, drug products, and other compounds in biological samples in pharmaceutical industry.

These days, drug companies, and other biotech firms are facing challenges in hiring and retaining experienced chemists to work with chromatographic instruments (Mullin, 2017). On the other hand, probably due to sometimes-repetitive nature of the chromatographic analysis, one may assume that only a chromatographic instrument and a chemist are simply enough to perform a chromatographic analysis, and the chemist's experience and knowledge on the analysis are often neglected.

The importance of instrumental analysis should never be undervalued. The data from the instrumental chromatographic analysis often guide very critical studies, such as toxicity, pre-clinical, clinical and stability studies. Poor instrumental chromatographic analysis and thus inaccurate data often result in product safety issues, even compliance consequences. Therefore, a well-trained chemist is indispensable in obtaining accurate and reliable analytical results.

In instrumental chromatographic analysis, method development is very crucial. Regulatory guidelines require methods to be acceptable in terms of linearity, sensitivity, accuracy, selectivity, and carryover. To develop a good chromatographic method, a chemist should have good knowledge of the theory or principles of chromatographic analysis, such as effects of different chromatographic parameters and modes, particularly the surface properties of packing materials inside the columns. Some requirements, such as resolution, sensitivity, and ranges of quantitation, should be well understood during method development. A good method developed by a knowledgeable professional can also ease potential problems in the method validation process and the method's lifecycle management.

In conclusion, having experienced analytical chemists to develop analytical methods is very important in drug development. Contract research organizations (CROs) have been significantly expanding their analytical services to keep pace with the growing needs (Mullin, 2017). Some of these CRO laboratories have met regulatory requirements and have well-trained analytical chemists. Seeking help from CRO services is a good alternative to having in-house instrumental set-up.

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