
THE IMPACT OF THE INNOVATION IN SEPARATION SCIENCE ON THE DEVELOPMENT OF NEW ACTIVE PHARMACEUTICAL INGREDIENTS AND PRODUCTS

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Recent innovations in Separation Science led to significant increase of options available to the analytical chemist working in the pharmaceutical development arena faced with a separation challenge. For example novel retention mechanisms, column and stationary phase dimensionality, enhanced selection of stationary phase chemistries, advances in sample preparation and finally, enhanced instrument capabilities are all variables to consider during the initial stages of method design. All of these innovations can offer increased productivity and throughput in analytical laboratory however, as the complexity with respect to choice has increased, so did their potential to become hindrance in selection of the optimal experimental conditions. Such enhanced choice can be exemplified by the range of HPLC stationary phase chemistries and morphologies

In this presentation we will review some of these innovations, explore the drivers for change and provide some real examples. The discussion will take into account the changing landscape with respect to both increasing regulatory pressure and environmental concerns (e.g. Green Analytical Chemistry).

Some of the evolving trends in the pharmaceutical industry towards Quality by Design and enhanced knowledge management will also be discussed with emphasis on how these changes could implicate chromatographic method development in the near future. Examples of how some of the predictive tools can be employed in the process of chromatographic method development will be provided.