Process Analytical Technologies, promoting innovative techniques Tools and methods to improve process understanding

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From a general point of view and in accordance with the FDA's proposals process analytical technologies are contributing to a better understanding of our pharmaceutical processes with the best possible quality as a goal. Encouraged by the pioneer experience acquired with the introduction of near-infrared spectroscopy the analytical community is nowadays more readily moving to novel technologies for rapid and non destructive analysis of samples.

Near-infrared spectroscopy became in the last years a well established and powerful analytical tool for pharmaceutical products and ingredients. The dramatic development of powerful low-cost computers and the application of chemometrical methods made it possible to build adequate calibrations and models. In addition the non destructive treatment of the samples, the reduced sensibility to measurement conditions, and the speed of measurement revealed NIR as a promising candidate for performing reliable in-situ analysis.

Before moving to the production line the potential of application of any analytical technique more or less suitable for PAT has to be explored at an early stage and in the product development phase. Nonetheless the access to this new type of process information is de facto the step forward to the understanding of available but until now hidden data and this can occur at any stage of the lifecycle of a product.

Recent technological advances made it possible to acquire a newer and much deeper insight into the galenical matter by adding more dimensions during the data collection. Moving from a sample volume scanned by one averaged spectrum to a two-dimensional scanning of the sample surface opens a new field of observation. But here, the story of the chemical imaging techniques is only beginning. The extraction of data by adequate image analysis tools offers new opportunities, such as focusing on the determination of parameters like dissolution and active content in intact tablets by taking into account the exact distribution of all materials. Also, the use of NIR imaging in connection with a pilot blender revealed a high potential of in-situ observation and control of the processes.

As an extension of the well accepted multidimensional analysis of spectroscopic data, emerging computational tools from the data mining community are available to support process knowledge discovery. These are based on algorithms for the exploration of large data bases in order to extract semantic links which are pertinent for the explanation of process events and gaining knowledge. The goal of data mining is to extract rules and models for the understanding of connections and to assist the process of decision making. Data mining sits at the interface between statistics, mathematics, and computer sciences. Complex processes do accumulate with time huge amounts of data. How to take advantage of an understanding of the buried knowledge? How to get an operational feedback from already existing – but latent, sleeping – empirical knowledge? Such questions are key starter for data mining projects and are a component of PAT.

At last but not least, PAT invites us to consider pharmaceutical processes with a more scientific approach. The objective of physical pharmacy could be to provide scientists and practitioners with multidisciplinary and theoretical background to handle out problems met in their practical work. A better understanding of the physics behind the processes in the various branches of pharmacy is expected.