Separation sciences towards the year 2030 – what are the major directions and how can the pharmaceutical industry benefit from these?

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Separation sciences have seen dramatical developments in the last two decades. New technological advances have pushed some techniques close to the physical limits. The quest for advanced separations and analytical characterizations are growing in pharmaceutical industries. New therapeutic concepts and more complex drugs impose new challenges on analytical procedures and separation sciences. In addition, regulation authorities ask for new analytical specifications of well established products. Separations in particular by HPLC are supporting pharmaceutical industry in all stages of development and production of pharmaceutical products. It comprises support of early developments in drug discovery, in vitro and in vivo pharmacokinetic testing, synthesis and process development, process control, impurity profiling, final product release, dissolution and content uniformity testing. Upcoming drug products such as peptide and protein therapeutics, gene therapeutics and nanomedicinces are subject to principally the same testings, but may be more challenging and may need more than one assay. Automation-facilitated workflows allows workers with little training in separation science to use existing often generic methods efficiently. For final release testing and quality control, a robust well-developed method that can be readily transferred all over the world may be of prime importance. On the other hand, in the early phase of development in modern drug discovery flexible and rapid problem solving is of paramount importance. There is an effort to streamline method development in order to quickly adjust the method to the needs. The advent of UHPLC with sub-2µm fully porous particle and core-shell columns, complementary stationary phase selectivities, fast parallel column screening approaches, the use of SFC certainly support the needs in this area. On the other hand, advanced concepts such as well-ordered pillar array columns, multi-dimensional separations and their hyphenation with information-rich multiple and or multi-stage detection systems, ion-mobility separations as an additional dimension bring advantages in fields where the separation of highly complex mixtures in order to gain a comprehensive picture of a pharmaceutical product is in the focus. Overall, separation science will remain a key enabling technology in pharmaceutical industry, yet advances are needed to cope with new challenges.