New challenges in modern pharmaceutical analysis: An industry perspective

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We will discuss the new analytical challenges in modern pharmaceutical industry in the context of emerging drug discovery and delivery paradigm, regulatory guidelines and industry R&D efficiency.

The emerging drug discovery paradigm and delivery technologies are expanding the traditional druggable space. New drug modalities are more complex than the traditional small molecules. Some examples include antibody-drug conjugates (ADC). polymer conjugated small and large molecules, PLGA and hydrogel long acting delivery products. Furthermore, more and more new drug candidates come into development with multiple chiral centers. At the same time, regulatory expectations are rising globally, for instance of genotoxic impurities test and control at different stages in the manufacturing process and final products.

The new drug modalities pose emerging challenges to modern pharmaceutical analysis. Traditional method development and characterization approaches are being challenged. New analytical technologies as well as strategies are required to efficiently deliver high quality data to characterize the drug properties *in vitro* and *in vivo*, control manufacturing processes as well as ensure drug safety.

We will discuss the recent advances in both technology and strategy, and the development of a new multiplexed platform to address these challenges. Cross functional collaboration is pivotal to tackle these new challenges. Case studies will be presented to reveal the complexity of the hybrid drugs, the comprehensive profiling of targeted and non-targeted impurities, *in vitro* characterization for *in vivo* correlation, separation of compounds with multiple chiral centers and genotoxic impurities strategies.