Drug Release Methods to Support a Search for Ideal Nanosized Drug Carrier
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The challenge associated with the efficient delivery of biological molecules like proteins, peptides and nucleic acids has provided a rapid thrust in the development of nanomaterials based parenteral drug formulations including liposomes, micelles and albumin-bound, polymeric, or metal nanoparticles. These nanomaterial based formulations have provided a competitive edge in formulating combination drug products containing both large biological and small molecule drugs, by improving their release kinetics and efficacy, in comparison to the conventional dosage forms. Understanding and controlling the pharmacokinetics of drug products containing nanomaterials is an interesting but time consuming area in drug delivery research. However, greater regulatory scrutiny of drug products containing nanomaterials and substantial increase in the development of nanocarrier formulations in biotech companies, have triggered the need for new, robust and less time consuming methods for assay of drug release from nanocarriers. A good understanding of the amount of free versus encapsulated drug is highly desired to evaluate potential PK properties before any in vivo evaluation. Additionally, at the later stage of drug development, batch to batch consistency and bioequivalence of the drug product are highly reliant on a robust drug release method.
While many methods are currently available to evaluate drug release from nanocarriers, including both direct and indirect methods, the most appropriate method for any particular formulation depends upon a combination of existing experience, scientific intuition and trial and error. Presently, the most common drug release methods (dialysis, centrifugation and various separation methods) are time consuming and do not adequately address all concerns. Clearly, there is a need for new, more robust and less time consuming methods.
In this presentation a short review of the existing drug release methods as well as an introduction to alternative approaches suitable for highly demanded high-throughput screening of nanocarriers will be presented. Several examples of using drug release methods to support research and development of nanocarries, including evaluation of new formulations and identification of potential risks to safety, quality and efficacy will be presented.