**Formulation development of protein injections based on biophysical stabilization**

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Drug development is an extremely complicated and challenging process. Formulation scientists are exposed to multiple lines of investigation including diverse disciplines, often with conflicting goals and integration of the data to achieve balanced formulations. Protein drugs can suffer issues of physical and chemical stability. Typical examples of the physical instability are denaturation (reversible or irreversible), aggregation, surface adsorption, and precipitation. In order to optimize protein formulations, a lot of formulation efforts are usually focused on the physical issues together with chemical ones. One of the important goals of formulation process can be to arrive at the correct formulation quickly. Moreover, development of stable protein formulations needs intimate knowledge of the proteins’ physicochemical properties. Understanding the mechanisms of protein degradation is important in designing and evaluating formulations. This presentation describes briefly on the different types of interactions of the major protein degradation pathways. The analytical methods to detect protein degradation are introduced, along with generalized strategies to suppress protein instability with relevant excipients. Thermodynamic background will also be introduced shortly together with its application in studying the physical stability of protein drugs and their interactions with several factors.

