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Particle analysis methodologies to study protein aggregates

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The presence of proteinaceous (aggregates) and non-proteinaceous particulates in biological drug manufacturing is of great concern due to potential effects on product safety, efficacy, and immunogenicity. Therefore, FDA requires that aggregates and particles be closely monitored. SEC-HPLC is the most commonly used method for aggregate detection and quantification; still there are limitations to SEC for analysis: SEC cannot detect insoluble aggregates as well as sub-visible and visible particles, the conditions required to perform SEC often dissociate reversible aggregates. Therefore, complementary analytical methods (such as DLS, fluidic imaging, fluorescent imaging) are essential to ensure that a broad range of aggregates/particles are detected. This poster will present multiple aggregates analysis tools that will present the complete profile of protein aggregates.

Biography

Yuanchun Zeng has completed her Bachelor's degree from Sichuan University of China. She was in Department of Molecular and Microbiology in Tufts Medical School for 4 years as Research Associate, working on Rho terminated RNA translation and transcription complex. She has worked for couple of years in US Genomics on genomic DNA analysis. She has been working for seven years in Bio-analytical lab of Merck-Millipore on biological products related product quality analysis.

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