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Applications of microchip-CE for high throughput screening of protein quality

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There is now a growing market in development of biosimilars or follow-on biologics though very few have been approved. Biologics are complex and heterogeneous in molecular structure and poses many challenges for the manufacturers of biosimilars in demonstrating comparability between the original biologics and the biosimilar. To address some of these challenges will require high throughput screening (HTS) experimentation in both upstream and downstream process in order to better understand the critical process parameters and assure that the quality of the biosimilar is compatible to the reference product. HTS studies to test the effect of cell culture changes on post translational modifications of protein therapeutics or to monitor its purification process produces large number of samples that can greatly exceed the capacity of modern analytical laboratories. With increased samples comes the demand for high throughput analytical platform with high precision, automation, and ease-of-use. Microfluidic-based assays for screening protein product quality are finding wide use because they address the limitations of SDS-PAGE and conventional CE-SDS. The assays leverage microfluidic technology to reduce analysis times dramatically compared to conventional techniques, 60 sec or less per sample. In this presentation we will describe the use of Microchip-CE platform (LabChip GXII) for a number of screening assays include purity assessment of monoclonal antibodies under reducing and non-reducing conditions, N-glycan profiling, and determination of protein charge heterogeneity.

Biography

Bahram Fathollahi is the Director of Microfluidics R&D at Caliper, a PerkinElmer Company. He leads an interdisciplinary team of scientists and engineers on development and commercialization of microfluidic platforms and assays in life sciences and diagnostics. He continues to lead collaborations with small and large biotechnology companies on the adoption of microfluidic assays for high-throughput screening applications. He received a Ph.D. in Chemical Engineering from UCSD and B.S. degree in the same field from UCLA.

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