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Analytical methodology and toolkit for improvement of quality attributes and process optimization of biopharmaceuticals

The development of biologics implies thorough knowledge of protein structural and dynamic properties in order to better manage challenges related to product characterization, abnormalities — and, related to this, lack of activity, specificity, efficacy, and safety aspects. The common practice of expanding the analytical description of the proteins during later steps of the development leads to uncertainties, such as degradations, aggregations, instability, lack of reproducible results; and this causes delay in the entire process. With a solid methodology applied to both the sequence and the selection of appropriate analytical tools, and with a focus on correlations and causation, short-term and long-term process- and product-related difficulties could be overcome. Improvement of professional expertise and decline of the risks could result. Furthermore, a combination of low-cost multiple techniques from the very beginning of the pre-clinical process will make it easier to understand data on protein structure, functions, and dynamics and would enable further selection of more sophisticated and rigorous techniques to meet the regulatory requirements and to advance the analytical spectrum of in-house methods for validation purposes. The usefulness of the incorporation of classic spectral techniques into industry practice, which have been widely used in academic research groups for protein structure, activity, and dynamics, will be discussed.

Biography

Anelia Atanassova is a Founder and Sr. Scientist of BioGlobaX Inc., which provides R&D, consulting and training services to the biopharmaceutical industry in collaboration with research groups from the University of Toronto and worldwide. She has over 20 years of experience with protein pharmaceuticals, having worked on a large variety of projects in academia and industry with natural and recombinant proteins. Her areas of expertise cover a broad spectrum of bioinorganic chemistry, biophysical chemistry, biochemistry, structural biology, bioinformatics, physiology and toxicology. She obtained BSc in Chemistry, MSc in Biophysics and Neurophysiology, and PhD in Biochemistry from Sofia University and received Post-doctoral training in Metalloproteomics and Structural Genomics from the University of Toronto.

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