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Automation of biologics formulation stability testing: Achieving equivalent results with less manual effort

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Biologic drugs can be inherently prone to degradation and instability, which can make designing safe, stable and effective formulations challenging. To develop a stable and effective formulation, scientists perform multiple screening, robustness and stability studies throughout drug development to build a strong knowledge base. However, personnel are often limited in the number of formulations they can screen in any given study due to the rigors of current manual workflows, short timelines and often limited resources. Automation of formulation screening, forced degradation studies and preparation of analytical samples can increase efficiency and throughput, but must provide comparable results to current processes and analytical methods. Therefore, a set of automated processes were developed by a team of scientists to provide equivalent results to traditional manual processes. Automated systems and their procedures were used to evaluate multiple formulations of two drug products, and then results were compared to those from manual processes generated at the biopharmaceutical company, which developed the drug products. Multiple formulations of both protein drug products were investigated. Each formulation was first stressed by stirring, heat or agitation, and then analyzed by fully automated visual inspection, and semi-automated UV/Vis, DLS and SE-UPLC. Software running the integrated automation system also managed data, so that reporting results was easily performed. For both drug products, formulation robustness rank-orders resulting from automated procedures were comparable to those from manual methods. We also describe productivity gains achieved by incorporating automation into formulation development.

Biography

Russell Burge earned a PhD in molecular biology and biochemistry from The Scripps Research Institute in La Jolla, California. He worked on characterization of aptamers as part of Post-doctoral training at the University of Colorado, Boulder. He worked as a Formulation and Analytical Development Scientist at KBI Biopharma, where he contributed to numerous biopharmaceutical development projects. He is an Applications Scientist at Freeslate where he designs and performs demonstrations of automated systems used for research and development of pharmaceuticals. His additional contributions to Freeslate range from market research to the development of new technologies and products.

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