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Extended Abstract
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Drug Delivery 2015 : Automation of biologics formulation stability testing: Achieving equivalent results with less manual effort - Russell Burge - Freeslate Inc

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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 rankorders resulting from automated procedures were comparable to those from manual methods. We also describe productivity gains achieved by incorporating automation into formulation development. A biopharmaceutical, otherwise called a biologic(al) clinical product, or biologic, is any pharmaceutical medication item fabricated in, removed from, or semisynthesized from natural sources. Not the same as completely incorporated pharmaceuticals, they incorporate antibodies, blood, blood parts, allergenics, physical cells, quality treatments, tissues, recombinant restorative protein, and living prescriptions utilized in cell treatment. Biologics can be made out of sugars, proteins, or nucleic acids or complex mixes of these substances, or might be living cells or tissues. They (or their forerunners or segments) are segregated from living sources—human, creature, plant, contagious, or microbial. Wording encompassing biopharmaceuticals shifts among gatherings and elements, with various terms alluding to various subsets of therapeutics inside the general biopharmaceutical class. Some administrative offices utilize the terms natural restorative items or remedial organic item to allude explicitly to designed macromolecular items like protein-and nucleic corrosive based medications, recognizing them from items like blood, blood parts, or antibodies, which are generally extricated straightforwardly from an organic source. Specialty sedates, an ongoing grouping of pharmaceuticals, are significant expense tranquilizes that are regularly biologics. The European Medicines Agency utilizes the term propelled treatment therapeutic items (ATMPs) for prescriptions for human utilize that “depend on qualities, cells, or tissue engineering”, including quality treatment meds, substantial cell treatment meds, tissue-built meds, and blends thereof. Within EMA settings, the term propelled treatments alludes explicitly to ATMPs, in spite of the fact that that term is fairly vague outside those specific situations. Quality based and cell biologics, for instance, regularly are at the front line of biomedical research, and might be utilized to reward an assortment of ailments for which no different medicines are available. In certain wards, biologics are managed by means of various pathways from other little particle medications and clinical devices. The term biopharmacology is some of the time used to portray the part of pharmacology that reviews biopharmaceuticals. Ibuprofen is utilized basically to treat fever (counting post-inoculation fever), gentle to direct agony (counting help with discomfort after medical procedure), excruciating feminine cycle, osteoarthritis, dental torment, migraines, and torment from kidney stones. About 60% of individuals react to any NSAID; the individuals who don’t react well to a specific one may react to another. It is utilized for provocative infections, for example, adolescent idiopathic joint pain and rheumatoid arthritis. It is likewise utilized for pericarditis and patent ductus arteriosus. In certain nations, ibuprofen lysine (the lysine salt of ibuprofen, at times called “ibuprofen lysinate”) is authorized for treatment of indistinguishable conditions from ibuprofen; the lysine salt is utilized in light of the fact that it is more water-soluble. In 2006, ibuprofen lysine was affirmed in the U.S. by the Food and Drug Administration (FDA) for conclusion of patent ductus arteriosus in untimely newborn children weighing somewhere in the range of 500 and 1,500 grams (1 and 3 lb), who are close to 32 weeks’ gestational age when common clinical administration, (for example, liquid limitation, diuretics, and respiratory help) isn’t effective.A biopharmaceutical, otherwise called a biologic(al) clinical product,[1] or biologic, is any pharmaceutical medication item fabricated in, separated from, or semisynthesized from natural sources. 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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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