

Analysis of Single-Use Bioreactors: Difficulties and Points of View

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EDITORIAL

The application of single-use bioreactors is an ever-expanding area in pharmaceutical bioprocessing. Alice O'Hare, Commissioning Editor, spoke to three experts in the field and discussed the current status and future direction of single-use bioreactors in the bioprocessing community. The rising demand for biosimilars and bulk quantities of antibodies has pushed pharmaceutical plants to become more creative and flexible in enhancing their productivity. How do you predict single-use bioreactors will aid this development? What are the merits, as well as flaws, of using this type of bioreactor, as opposed to reusable stainless steel bioreactors? Single-use bioreactors provide an excellent option to adapt the production capacity to the market demand. This is especially attractive to the biosimilar industry as it allows managing the capital investment into production capacity and reducing the financial risk associated with this. Compared with stainless steel, the upfront investment is significantly lower and capacity can quickly and easily be increased as market demand grows due to considerably shortened lead times. Here, not only the volume range from 500 to 2000 l is attractive, but also the reduced need for water for injection and steam, which adds to the investment demand and facility footprint. When it comes to innovative antibody drugs, we mainly see a trend to control development costs and increase flexibility in the clinical phase [1]. Single-use bioreactors eliminate the need for cleaning validation and avoid cross-contamination in a multiproduct facility. A recent press release suggested that there is a divide between the USA and Europe in terms of uptake of single-use bioreactors. Thermal degradation testing conditions should be higher than

recommended ICH Q1 Accelerated testing conditions. Samples of solid-state drug substances and finished products should be exposed to dry heat and wet heat, whereas liquid drug products can be exposed to dry heat. In your experience, would you agree with this? What do you think might be contributing to this? Based on our market insight, we cannot really support this finding. We see that the uptake of single-use bioreactors is mainly driven by the activity of the different regions regarding development of new disease treatments and biosimilars [2,3]. In addition, existing production capacity comes into play and company strategies regarding manufacture of clinical material. As the USA is indeed leading in the field of developing innovative treatments, we see a strong uptake of single-use bioreactors, but Europe and Asia are not far behind, especially as we have a very strong market presence in all regions. Single-use bioreactors: challenges and perspectives.

REFERENCES

1. Sowjanya B, Rambabu K. Development and validation for the simultaneous estimation of Brexpiprazole and fluoxetine in drug substance by RP-HPLC. *Euro J Biomed Pharm Sci* 2018;5:411-417.
2. Amit G, Rajendra P. Gradient high-performance liquid chromatography method for determination of related substances in Brexpiprazole API. *Int J Dev Res* 2018;8:21416-21424.
3. Sravani A, Naga Durga CH, Uppalapati D, Suneetha CH, Suresh P, Tirumaleswara RT, et al. Method development and validation for the estimation of Brexpiprazole in drug substance By Rp-Hplc method. *Indo Am J Pharm Res* 2017;7:8560-8565.

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