RAPID PROTOTYPING OF A SINGLE-USE BIOREACTOR: CONCEPTIONAL DESIGN STUDIES TO FINAL PRODUCT

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It is widely acknowledged that single-use bioreactors can increase flexibility, reduce production costs, and improve productivity. Consequently, a multitude of single-use bioreactors, which greatly differ in geometry, size, agitation principle, sensors, and cultivation performance, have been developed over the last decade. In modern biomanufacturing processes, mechanically driven bioreactors, including stirred, wave-mixed and orbitally shaken systems, dominate due the extensive anecdotal and published information as well as readily available engineering data, and scale-up capabilities. These single-use bioreactors are primarily used for seed train and inoculum production but are also employed for vaccine and monoclonal antibody manufacturing.
Driven by market adoption and evolution, Finesse Solutions has recently focused on expanding its SmartVessel™ bioreactor family. Based on fluid dynamic investigations that were conducted during early design studies, prototypes of a new single-use bioreactor were built by using rapid prototyping techniques. A variety of rapid prototyping techniques, such as stereolithography (SLA), laser sintering and 3D printing are now viable for this application and currently available for commercial use. Additionally, a large variety of different plastic materials are also available. Finding materials suitable for use in a cGMP environment is however still challenging; the polymers have to meet special requirements, including the absence of animal-component derived material, Bisphenol A (BPA), latex free, phthalate free – and must also be free of cytotoxic and carcinogenic components. Ideally the materials that meet the aforementioned criteria are also gamma irradiation compatible to levels in excess of 40 kGy.

Based on a case study, this presentation provides some insights into the developmental process from conceptional bioreactor designs to a final product. Special focus is on the rapid prototyping that can enable faster time to market and reduced costs and the dichotomy between a rapid prototyped part and a molded part. Furthermore, aspects of the material selection with regards to cGMP compliance and stability for gamma irradiation are discussed.