Molding a Single-Use Plastic Part: From Design to Validation According to the FDA Process Validation Guidance

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Plastic parts are commonly used in the regulated industry: as consumables in laboratories, as critical components in manufacturing areas for packaging as well as for single-use products, and, of course, they can be major parts of medical devices. The plastic part and its injection process are the subject of this paper. From product development to manufacturing, what are the key points to consider? This paper discusses step-by-step how the recent evolution of process validation driven by the 2011 US Food and Drug Administration *Process Validation Guidance*, considering the product lifecycle approach, can be applied to new molded parts used in the regulated industry. According to this guideline, process validation is defined as the collection and evaluation of data from the process design stage throughout production that establishes scientific evidence that a process is capable of consistently delivering quality products.

This approach consists of having continuity between product and process development steps, process qualification, transfer to manufacturing, and maintaining a validated state during the product commercial life. Plastic part development according to a product lifecycle approach can have great benefits on product performance and process control, and allows more efficiency and faster development. The new product EZ-Fit ™ filtration unit was developed following this “new” approach.