

Product Realization: The Processing of Bioabsorbable Polymers

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Abstract

The properties of bioabsorbable polymeric implants strongly depend on the cumulative history of the multitude of physiochemical events that happen to the polymer and the implant along the "process" of product realization. Performance characteristics should be considered at various points in the device life cycle. For example, this could be immediately post manufacturing (when most common quality testing occurs), or at surgical implant time zero, and also at various time points throughout the healing response (degradation kinetics). All of these criteria are important for design and manufacturing validation and the design dossier. They can be realized only through careful polymer selection or formulation, and appropriate processing. This chapter describes challenges encountered when manufacturing products of bioabsorbable polymers with the properties to deliver the desired critical performance criteria. This chapter does not intend to be a recipe of processing parameters for bioabsorbable polymers, but instead, using a pragmatic description of manufacturing challenges, this chapter seeks to heighten appreciation of bioabsorbable polymer processing and the overall process of product realization. The goal is to enable product developers and purchasers to effectively interact with a competent manufacturing group to express expectations, define reasonable objectives, and understand underlying costs.

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