A Matter of Materials: Molding

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New material offerings are critical to medical device manufacturers as they provide new opportunities in the development of cutting edge technologies. This three-part round-up features three new materials that are impacting medical device manufacturing in the areas of adhesives/coatings, molding, and extrusion. This part focuses on molding.

Novel products for individual therapies, such as imaging for diagnostics, new antibody treatments, biomarkers, tissue engineering, nanocarriers, and gene-based and stem-cell therapies, may reach the market by 2020.[1] For many of these advanced pharmaceutical technologies, glass may not be the logical or preferred choice for containment and/or delivery. Technological advancements in therapeutics and diagnostics should be matched by innovations in containment and delivery systems.

Glass as a primary contact material for pharmaceutical and biopharmaceuticals has hurdles to overcome with respect to suitability. The need for silicone lubricants, breakage, particles, and leachables are among the major concerns. To combat the risks associated with glass, modern polymeric materials should be considered. The manufacture and processing of polymers allows for flexibility in molding and forming throughout a drug product’s lifecycle. Qualification of such materials is dependent on intended use, and risk assessments should be considered early to support development and protection of the drug product throughout its lifecycle.

The Daikyo Crystal Zenith cyclic olefin polymer (COP) is a class of polyolefins in which the performance characteristics are enhanced. The synthesis allows for better control of the molecular structure with fewer side reactions and less need for

performance additives. Precision molding can be optimized for the intended use and once the materials are qualified, forming can be adapted as needed. This class of polymer has few ingredients and offers the desired properties of transparency and break resistance. It also provides a strong moisture barrier and is easy to sterilize.

Cyclic olefin polymers are high-performance materials possessing the valuable properties necessary to manufacture, store, protect, and deliver drug products without many of the weaknesses inherent to glass. It is especially suitable for biologic applications since many of the COP's quality attributes specifically meet the challenging needs of this market.

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[1] Breakage and Particle Problems in Glass Vials and Syringes Spurring Industry Interest in Plastics. IPQ in the News 7, August 2011.

Click here to view the extrusion focus [2]; click here to view the adhesives/coatings focus [3].

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