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Short-run niche extends into medical molding for Donnelly

By Clare Goldsberry

Donnelly Custom Manufacturing Company (Alexandria, MN) has made the move into medical molding as part of its "Short Run" strategy, with the attainment of its ISO 13485:2003 Medical Device Quality certification. While the perception is that medical molding consists primarily of long runs of disposable components, Ron Kirscht, president of Donnelly, says that more than ever, there is a growing need for short-run manufacturing expertise in the medical products supply chain.

"This is an industry where there has been explosive growth, a profusion of new product introductions, and the need for advancement in methods and availability remains great," Kirscht says. "We recognize that not every medical product is a high-volume disposable, consumable, or internal product in nature and application. There are medical products used to measure, monitor, analyze, and support the delivery of medical services and the use of medical products. The marketplace for products of this nature tends to be an area that is sometimes underserved or overpriced due to the lack of leadership in short-run molding."

Donnelly plans to ensure this niche is properly served. ISO 13485:2003 is a benchmark for medical device manufacturing and takes Donnelly's ISO9001:2000 certification a level higher, with the new certification requiring additional documentation, root cause analysis, and corrective actions required for customer complaint handling. With ISO 13485:2003, the potential adverse affects of rework are more heavily analyzed and finally, process validation is enhanced because injection molding is considered a special process and cannot be validated by part inspection alone.—cgoldsberry@modplas.com