## Lessons Learned during the Development of HumaPen<sup>®</sup> Memoir<sup>™</sup>, an Insulin Pen with a Memory Feature

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## Abstract

Insulin pens are developed to address specific needs of diabetes patients for their pens, such as ease of use, portability, and discreetness. Like many consumer-based products, the development of insulin pens can pose significant challenges to the development team in that they must balance substantial accuracy requirements with aesthetic desires. The HumaPen<sup>®</sup> Memoir<sup>™</sup> team learned valuable lessons throughout the development process that may be worth highlighting. A keen understanding of the unmet needs of the patient population and a skillfully planned product generation map are critical to successful device development. A development team must decide whether to use a Quality Functional Deployment or system engineering-based development plan and, additionally, recognize where proof of concept ends and product development begins to maintain a strict timeline for the project. A proficiency in understanding and managing technical risk is critical to ensure a timely and high-quality product launch to the marketplace.

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Abbreviations: (ISO) International Organization for Standardization, (KPI) key performance indicator, (LAD) logical architecture diagram, (QFD) quality functional deployment

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