

Implications of the New Food and Drug Administration Draft Guidance on Human Factors Engineering for Diabetes Device Manufacturers

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Abstract

This article discusses the implications of the new Food and Drug Administration's draft guidance on human factors and usability engineering for the development of diabetes-related devices. Important considerations include the challenge of identifying users, when the user population is so dramatically broad, and the challenge of identifying use environments when the same can be said for use environments. Another important consideration is that diabetes-related devices, unlike many other medical devices, are used constantly as part of the user's lifestyle—adding complexity to the focus on human factors and ease of use emphasized by the draft guidance.

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Abbreviations: (FDA) Food and Drug Administration, (HFE/UE) human factors engineering and usability engineering

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