Reviewer’s report

Title: The Role of the User within the Medical Device Design and Development Process: Medical Device Manufacturers’ Perspectives

Version: 1 Date: 16 December 2010

Reviewer: Mary Beth Privitera

Reviewer’s report:

Authors,

This article is very much needed within industry practices. Your findings are on target with common attitude and belief within the US medical device development industry. My only criticism is in sample size- while the information you present is in well organized and in an appropriate depth more subjects (device manufacturers) should be included. I am recommending this as a discretionary revision as even without this addition, the article is directive and helpful.

Further, I recommend clarification in the conclusion section as I am not clear as to what HF principles/practices can be modified to better accommodate the MDDD industry partners. Rather I believe the intent of the authors are to make industry developers more aware of truly utilizing HF practices. My rational is simple that HF techniques have been developed over time and are proven successful- the same can be said of engineering practices and techniques, yet engineering is never ignored while HF can be not utilized, misrepresented and/or in contrary fully integrated.

Many thanks for taking time to write this article.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests'