How Can Researchers Assist with Product Development?

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Translation of research into clinical practice is the goal of many researchers, yet it occurs far too rarely and is often reliant upon good fortune rather than good process. In an ideal scenario, the research is completed and translation is simply a matter of implementing manufacturing processes that create the desired product in a way that is compliant with specifications and regulations. This almost never happens in practice. Rather, the product must be developed while the final research questions are addressed. Researchers have an important role to play, however it is necessary to use a different way of identifying and solving key issues to be addressed. Where research typically asks open ended questions such as “How can this be improved?”, product developers typically ask “How can this be made to be good enough?”. Implicit in this question is a definition of ‘good enough”, or in other words, a clear definition of success.

At the Bionics Institute we have recently codified this transition under a comprehensive ISO9001 certified Quality Management System. Already this is being used in three major projects that are transitioning from pre-Clinical to Clinical phase of development. Using an industry-standard staged development process, such as used to develop microfluidic products at MiniFAB, we create a set of simple tools to manage this early stage of product development. Using a risk-based approach to defining work to be done, and implementing a method to rigorously correlate experimental results to target specifications, we are able to complete research and demonstrate clinical efficacy in a manner that is consistent with international regulations. While this does not guarantee commercial success, it certainly smooths to the transition, supporting next stage investment and significantly de-risking commercial product development.