Harnessing Experience for Efficient Medical Device Product Development

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Transitioning new research ideas into commercial products is difficult. For medical device design, the task is especially complicated because the commercialization of research ideas requires interdisciplinary teams that understand the nature of the clinical application as well as the abilities of the technology. Device development is complicated by the need to work within a regulated environment which requires well defined processes and significant testing to demonstrate the safety and efficacy of the device. An experienced development team, well versed in the design and manufacturing of medical devices, can greatly enhance the success of a commercialization program. A study of actual programs shows how experience can reduce development times. There are several factors that affect the success of new medical device development including the use of effective development tools and the innovativeness of the product concept. Successful product development may use a number of tools to assist with planning and control of the project. However it is difficult to measure the effect of experience on the success of new product development. In this work, several medical device development programs were studied to determine the role experience plays in improving the time to market for medical devices. Time to market is measured along several dimensions including complexity, technological invention, and uniqueness of clinical application. All designs were completed by the same company. As time progressed, the time to market improved even for complex designs with new technology. Over a ten year period of time, ten significant medical device development projects were executed. All required development of complex electromechanical systems with moderate to high complexity, and more than half developed products for new clinical applications or utilized new technology. After the development group had acquired at least five years of development experience, it was clear that the development times were improving by almost 50% over the predicted development times. Among the factors that contribute to this effect are the development of experts, the creation of design frameworks, and the optimization of processes which improve product development times while reducing project and regulatory risk. Experts with specific experience in systems engineering, program management, electromagnetic compatibility, manufacturability, and usability along with expertise in electronics, mechanical and software design can significantly reduce design times. Technology platforms central to medical devices such as blood and fluid pumps, sensor interfaces, real-time control systems, batteries and power systems are necessary for rapid development. Processes including project planning and tracking, requirements management, configuration management, risk analysis, and manufacturing design transfer are essential for streamlining development as well as ensuring support for regulatory submissions and audits. It has been challenging to demonstrate this effect, which has been anecdotally known for some time, in a quantitative manner. Doing so required studying an organization with not only significant experience over time, but breadth of experience in terms of program risk and complexity. The results of this study quantify the significant benefit of organizational experience in reducing time to market.

Mid-IR Contact Probe for Examination of Live Cell Cultures

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Continuous monitoring of live cell cultures and in-vitro tissues is a major challenge in the study of model systems for cancer research. Specifically, monitoring chemical changes often requires the cells to be stained with specific fluorophores (limited chemical content) or harvested from culture (precluding longitudinal study). Recently, mid-infrared spectroscopy is being increasingly applied to measure chemical content of cells and tissues. There are no reports, however, of in-vitro monitoring of cell cultures. The major reason is the high absorption of water in this spectral region and lack of instrumentation to address this need. This project seeks to apply mid-IR in a non-destructive manner to live cell cultures and tissues while maintaining rich information content. We accomplish this by the design of a contact-method probe. We have designed a fiber optic-base beam guidance geometry and coupled it to a total internal reflection sensing element. The entire sensor is coupled to a commercial spectrometer, thus allowing for rapid translation to other laboratories. It is believed it can be a cost effective solution using current technologies with adequate SNR for down-stream chemometric analysis. One of the major design challenges was to optimally guide and utilize light from the spectrometer within the constraints of leveraging as many commercially available components, processes, and methods to most quickly translate this idea into a working device. Our major task was optical modeling and subsequent fabrication of the device. The optical models show 6 percent throughput is possible using currently available parts; 1 percent is required. The design was implemented with the optical system placed wholly within a single chassis. While a single chassis design allows for miniaturization, it presents substantial alignment challenges due to the lack of degrees of freedom for movement. These challenges are the current work focus. Proof of principle studies are on-going. We anticipate that the goal of continuous cell monitoring and in-vitro cell spectroscopy will be attained upon final integration of the device with our experimental setup.