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## Honors Research Assistant Program

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**Title:** Drug-Device-Biologics convergence and policy and new venture creation

**Description of the Research:** The traditional pharmaceuticals industry is faced with the prospect of convergence from medical devices and a new breed of biotechnology products—biologics. Combination products or products that combine technologies from drugs, devices or biologics are the next new innovations in this industry. Innovative companies are finding ways of combining emerging device technologies with drugs and biologics to offer therapeutic benefits more than those offered by drugs or devices acting alone. But commercializing combination products poses unique challenges. To begin with, the integration of drug, biologic, and device development requires blending engineering, chemical, and biological fields creating new technical, organizational and regulatory challenges.

The student involved in this project will be given an overview of nature of convergence happening in this industry. We will be using archival databases that are public records such as those with the FDA as well as some proprietary databases that we have purchased as part of this project. Given the hub of medical device companies around the Twin cities area, we also plan to engage in some field work and interviews as part of this project. This research will be published in top academic journals and will help in understanding the role of knowledge in shaping the boundaries of new ventures. For example, given the nature of combining engineering, organic chemistry and biological knowledge for a single product, how do new entrants in these converging fields go about setting the boundaries of their innovations?

**Responsibilities of the Student:**

1. Help in organizing and developing databases related to combination products
2. Assistance in developing and maintaining archival databases
3. Help in fieldwork such as interviews with medical device and drug companies
4. Verifying data accuracy and help in adding other variables to the dataset.

**Approximate Number of Hours/Schedule:**

The student may choose the hours that are most convenient for him/her. The work-plan is for one research assistant working during fall semester for a total of 100 hours.

**Qualifications:**

1. Knowledge or experience with using keyword search and ability to work with large databases.
2. Familiarity with database programs like Excel is preferred.
3. Strong organizational and planning skills.
4. Excellent writing skills