



VALUE & IMPACT INHEALTH

Stanford University - Program in Biodesign

Medical Device Development Models

Stanford University Program in Biodesign

October 1, 2006 – September 30, 2007

This grant is for a 1 year \$288,457 study to examine and describe in clear terms the various means that bring medical devices to market and their continued evolution in the post market environment.

The investigators will work to:

- Develop a comprehensive model of the medical device iterative development process.
- To clarify the differences between medical devices and pharmaceutical/biotech development and approval pathways.
- To provide a concise taxonomy of medical devices that takes into account differences in their development, the nature of product lifecycles, and the different innovation and regulatory characteristics.
- To provide recommendations for different stakeholder groups

Methodology

- Literature review of existing device and drug models
- Construction of a functional device taxonomy
- Analysis of the development of devices underpinned by case studies and in-depth interviews
- Development of a core model, with variations

Investigators

Principal Investigator: John H. Linehan, Ph.D., Consulting Professor of Bioengineering in Program in Biodesign and the Department of Bioengineering

Co-Principal Investigator: Elisabeth Paté-Cornell, Ph.D., Professor of Engineering and Professor and Chair of the Department of Management Science and Engineering

Co-Principal Investigator: Paul Yock, M.D., Professor of Medicine, Bioengineering and Mechanical Engineering, and Founding Co-Chair of Department of Bioengineering and Director of Program in Biodesign

Investigator: Jan Pietzsch, Ph.D., Consulting Assistant Professor in the Department of Management Science and Engineering, and President and co-Founder of Wing Tech, Inc.