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Stanford researchers publish comprehensive model for medical device development

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In an effort to increase understanding of the medical device development process and help companies execute the bench-to-bedside process of product development more effectively, researchers at Stanford University have published the first comprehensive model representing the medical device development process.

Published in the June 2009 issue of the *Journal of Medical Devices*, the model was constructed based on best-practice analysis and interviews with more than 85 seasoned experts actively involved in the development, commercialization, regulation, and use of medical devices.

"Medical devices contribute significantly to the continuous improvement of healthcare," says lead author Jan Pietzsch, Ph.D., consulting assistant professor in the department of management science and engineering at Stanford University. "Depending on the type and complexity of the technology, the device development process can take anywhere from 15 months to several years. As a result, successfully bringing innovative products to patients hinges on knowledge of and planning for this process."

Presented in linear form with five major phases and four decision gates, the model describes a process that is applicable to a broad range of medical technologies and innovation settings. According to the authors, the model is used by the developers of both highly sophisticated premarket approval (PMA) and premarket notification (510(k)) devices, for which FDA approval typically requires some risk-appropriate form

of bench or clinical data, as well as by the makers of less sophisticated devices that may be exempt from most regulatory requirements. The five major phases and decision gates include:

- Phase 1/Gate 1: Initiation, opportunity, and risk analysis.
- Phase 2/Gate 2: Formulation, concept, and feasibility.
- Phase 3/Gate 3: Design, development, verification, and validation.
- Phase 4/Gate 4: Final validation and product launch preparation.
- Phase 5: Product launch and post-launch assessment.

Pietzsch adds that the medical device development process has become increasingly complex in recent years because of the advent of advanced technologies, stricter regulatory requirements, and the increasing importance of reimbursement decisions.

The Role of FDA's Quality System Regulation

The study results demonstrate that a significant portion of the development process is governed by regulations that influence the manner in which medical devices are developed, approved, and brought to market. The pace at which such regulatory requirements can be met determines when the device will reach the clinic.

Specifically, FDA's Quality System Regulation plays a substantial role in the development process and serves to assure the public that critical elements of safe design practices are followed. However, the researchers point out that such standardization does not always permit product

developers to streamline their processes where it would make sense. In turn, such rigidity can inhibit innovation, which often occurs in a less-structured way.

"Clearly there are benefits associated with having a rigorous process and clearly defined procedures for all stakeholders in the process—from investors and engineers to researchers and regulators," says coauthor John Linehan, Ph.D., professor of medicine and biomedical engineering and director of the Center for Translational Innovation at Northwestern University, and a consulting professor of bioengineering in Stanford University's BioDesign Program. "The challenge for companies inventing and developing technologies is to strike a balance between sufficient process rigor and enough room for flexibility and creativity."

Drug-Device Differences

Among the key results of the study is a detailed explanation of the significant differences between medical devices and pharmaceuticals, and the corresponding differences in their development processes and regulatory requirements. Such variations have dramatic downstream effects that distinguish the capital requirements, product development methods, clinical testing requirements, manufacturing methods, and overall life cycle for products in the two sectors.

"Drug-device differences underscore challenges associated with developing combination products, such as drug-eluting stents, which play an increasingly important role in healthcare innovation," says Pietzsch. "It is our aim to contribute to a greater understanding of such differences, particularly as policymakers and regulators work to design the least burdensome approaches to medical device regulation."

The article emerged from research performed by the authors as part of a study, "Medical Device Development Models," funded by the Institute

for Health Technology Studies (InHealth). A review of the background, mission, and statutory requirements for medical device regulation in the United States was published by the authors in the December 2007 issue of the *Journal of Medical Devices*.

More information: J. Pietzsch, L. Shluzas, M. Paté-Cornell, P. Yock, and J. Linehan, "Stage-Gate Process for the Development of Medical Devices," *J. Med. Devices* 3, 021004 (2009).

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