Value-driven Engineering and U.S. Global Competitiveness

Value-driven Engineering – Frequently Asked Questions

What is Value-driven Engineering?

Value-driven Engineering is a strategy in medical device development that embraces simplicity. Value-driven Engineering endorses quality and improved, patient-centered care and promotes innovation and efficiency across the healthcare system. The process marries American ingenuity and innovation that will advance the U.S. past the trends of other countries like China, India and Brazil who are focused on frugal and reverse engineering. Different from frugal engineering, which focuses on reduced manufacturing costs, Value-driven Engineering focuses on improved clinical utility and reduced complexity to the end user, as well as cost efficiency across the entire healthcare continuum.

Why is this important to the United States?

U.S.-based companies dominate the roughly $350 billion global device industry and account for approximately 40 percent of the world market for medical devices and instruments. Of the 46 medical technology companies with more than $1 billion in annual revenue, 32 are based in the United States.

However, because emerging countries prioritize frugal medical engineering, the gap between America and the rest of the world is shrinking. Value-driven Engineering provides the opportunity for the United States to maintain global leadership in innovation. Public-private engagement and investment in the nation's biomedical device industry are critical to the quality and viability of the healthcare system and its formidable job creation.

How will this impact jobs and our healthcare?

U.S. corporations are among the first in the world to develop medical device technology, but U.S. consumers may be among the last to benefit from that technology. Increasingly, U.S.-based medical innovators are going outside the nation's borders to seek clinical data and more streamlined approval processes for new products, in an effort to yield new revenue. Global competitors also are taking American products and working on ways to make them less expensive.

What are the core, defining principles of Value-driven Engineering?

- Quality is never sacrificed for the sake of a "cheaper" or "less costly" version;
- Clinical utility is driven by patient-centered demand;
- Reduced complexity for the end user; and
- Cost savings and efficiency across the health system.

Adoption of Value-driven Engineering will be the key to U.S. competitiveness in the development and manufacturing and development of cutting edge medical devices.

How will Value-driven Engineering create jobs?

While frugal engineering, as seen in other countries, has traditionally focused on stripping out expensive materials and features to provide low-cost products, this "value-driven" approach will accelerate the evolution of the U.S. bioinnovation economy and boost the higher-education research and development engine that is the best in the world.

What is PAVE?

The "Platform to Advance Value-driven Engineering," or PAVE, is a unique blueprint to marry American ingenuity and innovation with a renewed commitment to create medical devices that are simple in design and cost effective, yet support premium healthcare. PAVE is a platform to foster the nation's funding mechanisms, regulatory incentives, public-private collaboration and educational leadership to incorporate Value-driven Engineering principles into the U.S. biomedical device industry.

This platform calls for collaboration across government with the private sector. PAVE is founded on the need for a public-private partnership that will bring necessary parties together around the shared goal of advancing biomedical innovation. PAVE also calls for the U.S. government to consider regulatory approval and coverage incentives for Value-driven Engineering products together with funding opportunities that encourage Value-driven Engineering device innovation.

How will VdE be implemented within the biomedical device sector?

Some of the recommendations outlined in PAVE include:

- *Funding Architecture* – Building on current models, high-functioning, cross-agency pooled funding mechanisms should be adopted to extract the highest value from every research dollar, and promote commercialization of Value-driven Engineering products.
- *Adoption of a Regulatory Framework* – Value-driven Engineering scoring metrics should be developed utilizing PAVE concepts, and products with Value-driven Engineering criteria should be provided a "fast-track" priority status for regulatory approval. The FDA should incentivize for the application of Value-driven Engineering principles to the development of medical devices.
- *Training and Inspiring the Innovators* – A guidebook of best practices should be developed and distributed for all disciplines, including academia, industry and non-academic partners who are close to the practice of Value-driven Engineering. Young people should be empowered and motivated to be innovative by gaining access to venues to further their technical abilities. Funding should be provided to support the development and establishment of short-term courses at universities on VdE engineers with America's biomedical industry.

Who is supporting the VdE effort?

Leading biomedical device researchers, executives and thought leaders from across the country are participating in the process that identified Value-driven Engineering as a driver for innovation and improved health care. A subset of this group helped identify the PAVE blueprint.

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