AMR RESEARCH CUSTOM EXECUTIVE SUMMARY IN COLLABORATION WITH SIEMENS

December 2009

Designing Medical Devices To Improve Patient Outcomes

by Fenella Scott, Wayne McDonnell, and Michael Burkett

Medical device and diagnostic instrument manufacturers continuously face complex challenges in new product development and launch (NPD&L). One of the industry's biggest obstacles is the tall silos companies have built around product development, manufacturing, quality management, and marketing functions.

Because of changing market demands and increased scrutiny of healthcare costs, companies must be able to quickly and efficiently develop products that best meet patient needs. Most medical device manufacturers are put to the test every time they attempt to bring a new product to market. Challenges range from managing supplier compliance and manufacturing process variability to product quality/safety and supply chain traceability.

Add an ever-increasing degree of global portfolio complexity to the mix, and it's easy to understand why medical device manufacturers are looking for business process and information technology improvements. Specifically, these companies need to design and manufacture new products faster, better, and cheaper than ever before. The goal is two-pronged: time to market to maximize the top line, and deliver new products with a lower overall cost profile to optimize the bottom line.

Studying medical device innovation processes

AMR Research recently conducted a study to understand the state of new product commercialization capabilities and to evaluate the use of PLM application technologies in the medical device and diagnostic instrument industry. The study also evaluated the importance of having the appropriate simulation and modeling tools to not only design products that meet global and local requirements, but also to carry those designs through technical transfer and launch processes.

The study surveyed 97 respondents who were responsible for NPD&L processes and associated decisions regarding tools and technologies to support PLM initiatives. We surveyed five industry sub-segments in the United States: analytical instruments and diagnostic substances; orthopedic, prosthetic, and surgical devices; surgical instruments and medical appliances; cardiovascular implants and instruments (e.g., stents); and imaging hardware and software (e.g., X-ray and CT scans).

The majority of the survey respondents were decision makers in product development, marketing/general management, product supply (manufacturing and supply chain), and quality/regulatory. The companies ranged in size, with the smallest firms starting at $200M in annual revenue and larger firms with $1B or more in annual revenue (more than 50% of the overall sample).

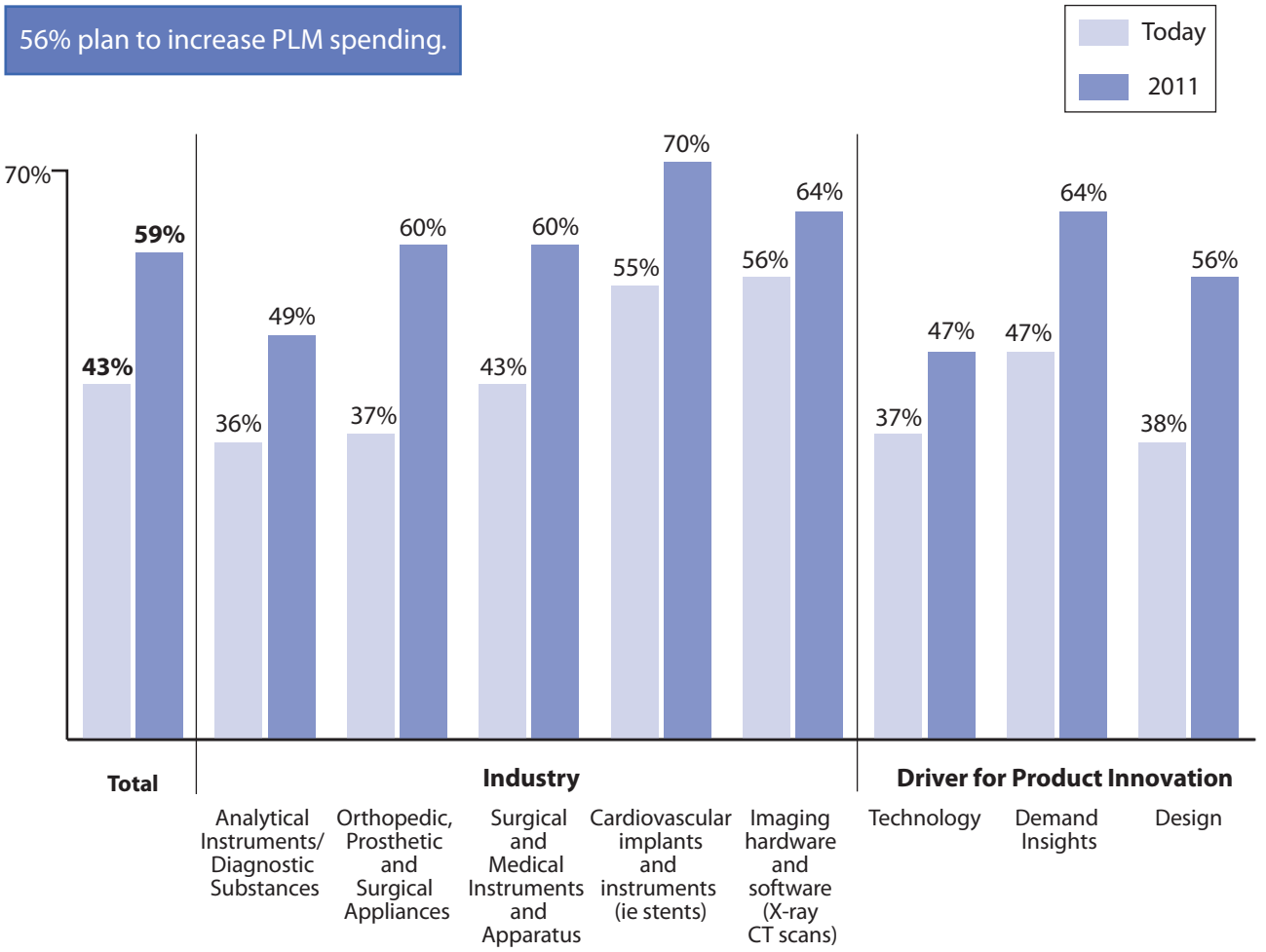
Spending trends for technology and services

More than half of the medical device manufacturers surveyed plan to increase spending on technology and services to support innovation projects between now and 2011. Orthopedic, prosthetic, and surgical devices; surgical instruments and medical appliances; and cardiovascular implants and instruments were the industry

sub-segments that projected the biggest increases in PLM spending. The largest driver for these investments was improving design capabilities, followed closely by developing capabilities to capture demand insights. These reflect the importance of not only understanding customer needs but also validating innovations against those needs through more rapid design iterations.

With the industry emphasis on cost-effective innovation, we believe that medical device manufacturers now realize the benefits of tightly integrating product design and technical transfer with manufacturing process planning and launch execution. There is an opportunity to tie together all the processes, supporting applications, rich streams of data, and most importantly people and organizations under one product launch platform. If not connected to product design or launch activities in a demand-driven supply network (DDSN), PLM processes and technologies become just another application to manage specifications and projects. Medical device manufacturers are realizing the potential value of establishing enterprise-wide innovation processes and embedding those processes into their supply chain capabilities.

Figure 1: Percentage of products supported by PLM



Q. What percentage of your products is currently being supported by the product lifecycle management technologies you just mentioned? By the end of 2011, what percentage of your products will be supported by the product lifecycle management technologies you just mentioned?

N = 97 (Total sample)

Source: AMR Research, 2009

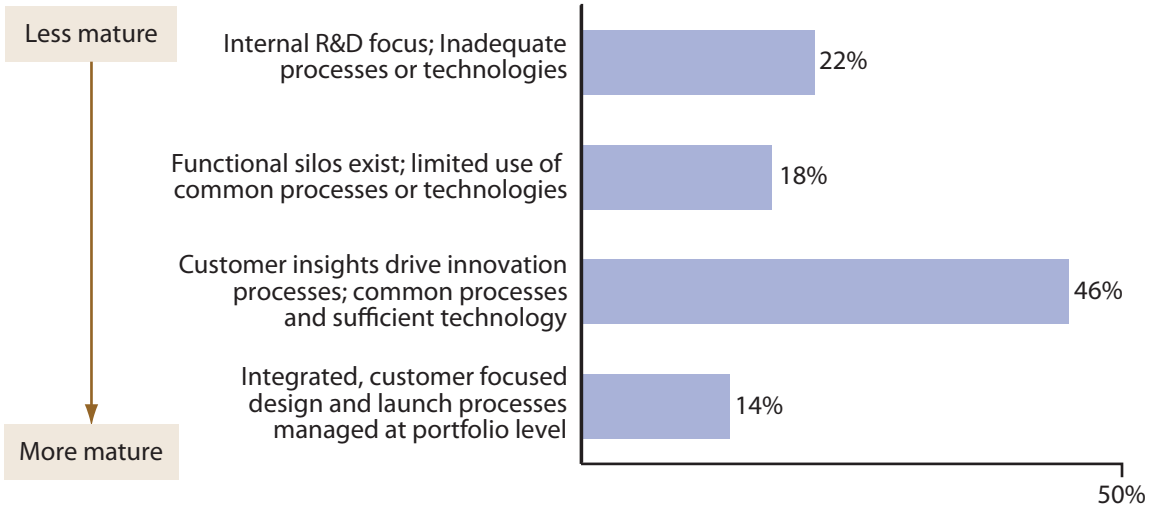
The state of product commercialization

A mature demand-driven supply network constantly innovates across the extended value chain by tightly connecting demand management and reliable product supply with new product innovation processes. To achieve this integration, companies need an information and decision support platform to capture customer insights and drive improved innovation processes and practices from R&D through technical transfer and on to product launch. In order to chart the course for process improvements and prepare the organization for the associated change, companies must first determine the maturity of their product innovation processes.

• The medical device manufacturers surveyed were asked to select a category of product innovation capabilities that best represents their company's existing processes. Only 14% described their processes and capabilities as mature in terms of an integrated, cross-functional innovation process. Furthermore, 40% still have functional silos that present a challenge to successful integration of innovation capabilities. To take advantage of industry trends like the development of patient-specific devices, companies must break down these functional silos and integrate new product commercialization processes.

• Companies face challenges at these different levels of product innovation maturity. Those on the lower end of the maturity scale don't have the metrics to measure and promote innovation effectiveness. The more mature demand-driven organizations have trouble linking innovation and operations excellence strategies or overcoming regulatory challenges that stunt creativity.

Figure 2: Product innovation maturity



Q. Which of the following best represents your company's product innovation capabilities?

N = 97 (Total sample)

Source: AMR Research, 2009

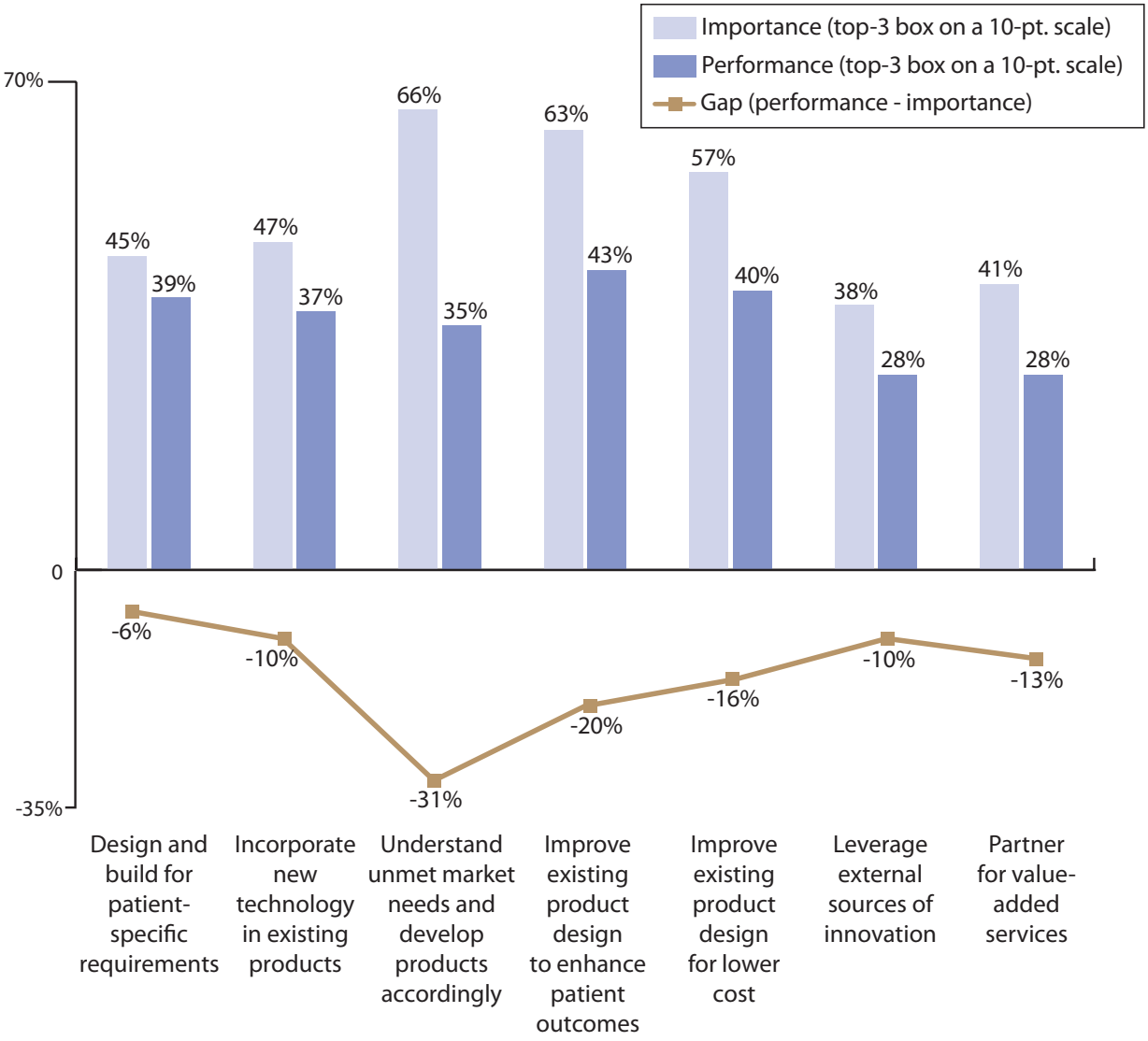
Gaps to bridge for future success

Companies also struggle with the development of capabilities focused on capturing patient experience data for identifying patient needs, and transferring those insights back into R&D and innovation. According to our survey, the most important measure of success for new product innovation is the ability to understand the market and develop products to address unmet market needs (see Figure 3).

However, companies reported falling short on the execution of these capabilities most often. The second biggest gap was the ability to improve existing product design capabilities and tie them directly to better patient outcomes. AMR Research sees this as not only a concern for new product development and launch teams, but also for commercial organizations.

The ability to link the selection and use of medical devices to patient outcomes is a growing concern in the context of U.S. healthcare reform. These gaps correlate to the PLM investment priorities highlighted in Figure 1.

Figure 3: The biggest gaps



Q. Please rate the importance of the following capabilities to the success of your company's product innovation goals? How would you rate how effectively your company performs each of these capabilities?
N = 97 (Total sample)

Source: AMR Research, 2009

To achieve product commercialization excellence, product development needs to dynamically connect with the demand and supply components in a demand-driven value network. PLM supports patient-focused activities by capturing patient-centric product attributes and requirements and then connecting those key data with both product and process design activities. Then, to support technical transfer and product supply-focused activities, PLM captures bills of materials and process requirements and links them with plant and facility design, supply chain design, and strategic sourcing processes.

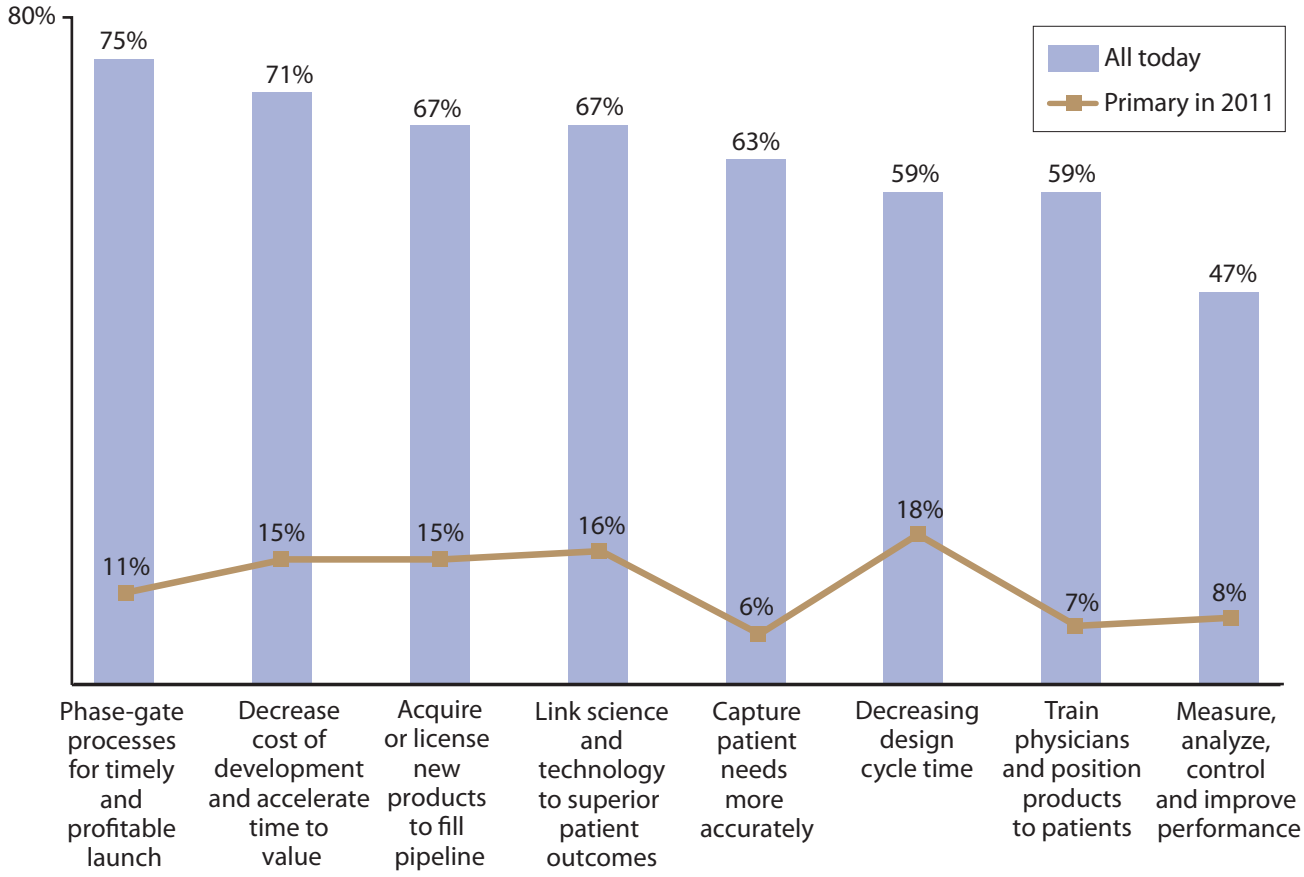
Product innovation strategies

What's driving new product innovation strategies at medical device companies, and how will those drivers change in the next few years? Our research study indicated that medical device manufacturers rely on phase-gate processes to guide new product introductions with the goals of timely and profitable launch (see Figure 4 on the next page). They also focus on decreasing the cost of development and accelerating time to value.

However, the main driver of new product innovation strategies in 2011 will be decreasing overall cycle time of the design process. We believe this finding points to a slow-moving shift toward the development of personalized medical devices. With personalized medical devices, a medical device company will be forced to quickly incorporate patient-level clinical data, adapt an existing device platform to the patient's needs and specifications, and compliantly deliver that device to the care provider.

PLM can help facilitate these strategies. It provides capabilities for managing the spectrum of activities required to bring an entire portfolio of programs and products to market. A PLM dashboard provides senior leaders from across the enterprise visibility and analytics to balance complex product portfolios across assets and resources in a prioritized manner. At the program or product team level, PLM strategies help streamline collaboration and provide a platform for iterative product design, document, and change management.

Figure 4: Enabling strategies



Q. Which strategies are enabling product innovation today? What will be the primary strategy for product innovation investments in 2011?

N = 97 (Total sample)

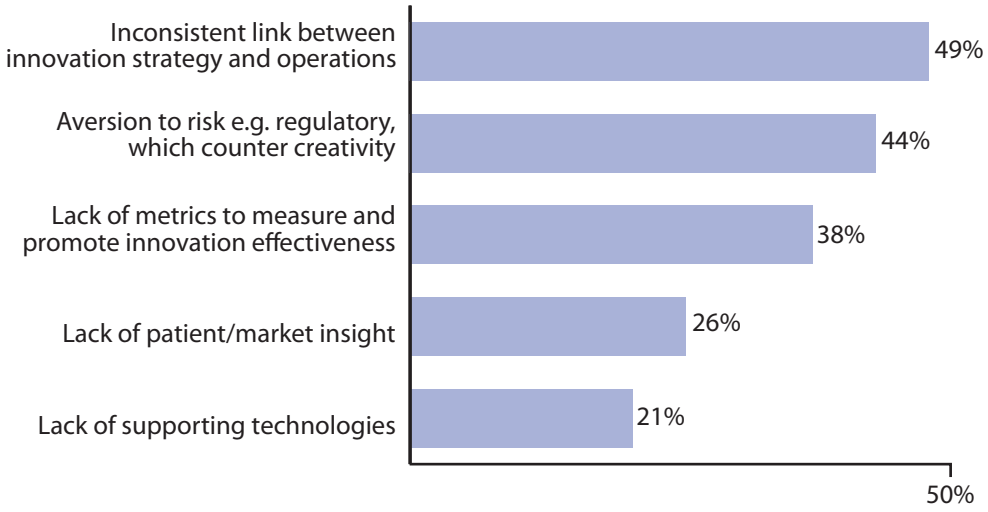
Source: AMR Research, 2009

Integrating innovation and operations excellence

Operationalizing innovation converts product ideas from the lab to profitable and reliable products that can be manufactured on a global scale, but our research found an inconsistent link between innovation and operations strategy. To remove this obstacle, companies need to improve knowledge sharing between product supply and development organizations along with analytics to support trade-off decisions.

The study also points to regulatory requirements stifling creativity. We often find that a legacy of manual processes make change difficult in a regulated environment and create a demand for more automated methods to speed validation and ensure compliance.

Figure 5: Challenges to operationalizing innovation



Q. What are your company's main challenges to operationalizing innovation?

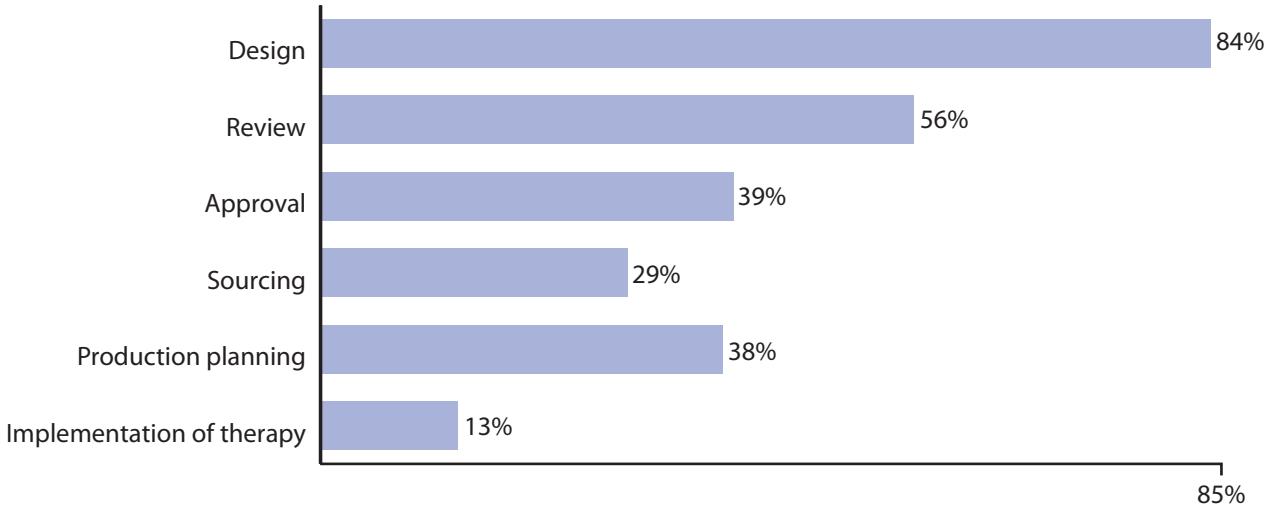
N = 97 (Total sample)

Source: AMR Research, 2009

The struggle to link innovation to operations can often be solved through the use of technologies that support digital prototyping, modeling, and simulation, which are used by the vast majority of companies surveyed during the design phase. However, the use of simulation to support production planning and product supply processes remains low. Companies can address the inconsistent link between innovation and operations identified in Figure 5 by increasing use of simulation techniques and digital process planning.

Design-for-supply is enhanced when manufacturing process capabilities are exposed to product development and access to digital designs allow manufacturing engineering to prove-out manufacturing processes in parallel with product development.

Figure 6: The role of simulation



Q. Does your organization use digital prototyping/modeling/simulation (CAD, CAM, CAE) to develop new products during:

N = 97 (Total sample)

Source: AMR Research, 2009

Beyond launch: Linking medical devices to outcomes

We would be remiss if we did not mention the growing need for medical device companies to link the selection and use of devices, diagnostic equipment, and related supplies with patient outcomes. This requires pushing PLM thinking—and ultimately functionality—to extremes in order to capture provider-level use and patient-level experience information and incorporate it into product design and therapy delivery. In our healthcare research, we see life sciences manufacturers, pharmacies, payers, and providers alike searching for strategies, execution methodologies, and analytical reporting capabilities that will allow them—as a connected value chain—to focus more on patient outcomes.

Sure, there are a lot of financial and physical supply chain considerations and concerns associated with this effort. But eventually those life sciences manufacturers that can objectively link better patient outcomes with selection and use of their products—designed specifically for better patient outcomes—will not only realize more market share but may even garner more favorable reimbursement rates. With the raging debate over U.S. healthcare reform and its emphasis on the provider space, medical device manufacturers are likely to feel the heat of reform early and often.

We welcome comments at fscott@amrresearch.com, wmcdonnell@amrresearch.com, and mburkett@amrresearch.com.