Medical Device Industry Playbook
Accelerating Innovation in a Perfect Storm
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The challenging macroeconomic business and regulatory climate is wreaking havoc on the medical device industry. Despite the storm this climate has created, medical device manufacturers are striving to design and implement effective, profitable innovation engines that not only capitalize on market opportunities but also contend with an evolving healthcare environment and increasing regulatory compliance.

This playbook explores the medical device industry’s most significant challenges and opportunities in innovation while sharing leading practices and key recommendations.
Industry Climate: Pressures

Industry Consolidation

Hospital mergers and consolidations are accelerating. Over the last four years, there has been a surge in the number of hospital mergers\(^1\). In 2012, the number of deals was more than twice what it was in 2009 — and each of those deals may involve multiple hospitals.

In early 2014 Community Health Systems, Inc. (CHS) completed its $7.6 billion acquisition of Health Management Associates. CHS’s hospital chain is now the largest in the US, measured by sheer number of facilities owned and operated. CHS now owns, leases or operates 206 hospitals in 29 states, with approximately 31,000 licensed beds\(^2\).

The resulting hospital and payer mega-networks can leverage economies of scale, broaden their market reach and strengthen their negotiating power with medical device manufacturers.

UnitedHealth Group Inc.’s Shared Clarity subsidiary plans to purchase the vast majority of heart stents needed for its 135-hospital network from device makers Medtronic Inc. and Abbott Laboratories in exchange for big discounts on product costs\(^3\).

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Regulatory Environment

FDA regulatory approval times are lengthening. Elapsed time from submission to final decision has increased 61 percent, from an average of 100 days to 161 days\textsuperscript{4}. Additionally, the reclassification of products and evolving international filing requirements are causing delays in market entry for new and modified products. Instead of focusing on growing the top line with new, innovative products, skilled resources are being diverted to maintain compliance as a result of new regulations.

- **RoHs** (Restriction on Hazardous Substances)
- **REACH** (Registration, Evaluation, Authorization and Restriction of Chemicals)
- **UDI** (Unique Device Identification)

Margin Pressure

The macroeconomic environment and broad healthcare reforms driven by the Affordable Care Act are putting never-before-seen pricing pressures on the industry. The mandatory 2.3 percent excise tax impacts investment in research and development, clinical trials and manufacturing systems. Profit pressures are not just felt by manufacturers; the changing reimbursement environment has made providers even more cautious about investments. In addition, healthcare providers are aggressively attempting to standardize procedures and the corresponding procedure kits to obtain better outcomes and to drive their costs down by leveraging volumes in price negotiations.

\textsuperscript{4} Government Accountability Office (GAO), February 2012
Emerging Markets Growth

Driven by demographic changes and expanding public healthcare spending, Asia Pacific, China and India are expected to see the fastest growth in the coming years. China’s medical device sector alone is projected to be worth $53.5 billion by 2020, more than doubling from $20 billion in 2012\(^5\). While this growth opportunity can be a source of new revenue and growing profits, many top executives are challenged with expanding sales in these markets.

Recommendations

• Shift from the ineffective approach of trying to sell products designed for U.S. markets into markets that have very different price points and regulatory requirements
• Establish design centers in the emerging markets staffed by teams that understand the specific needs and requirements of those markets

Mobile Connectivity

The global healthcare industry in the next decade will be a highly interconnected environment composed of large data networks, cloud computing, and mobile, connected devices. These technologies are also quickly evolving to support personal health monitoring and self-diagnosis. The wearable medical devices market, valued at $2 billion in 2012, is expected to reach $5.8 billion in 2019\(^6\), growing at a CAGR of 16.4 percent from 2013 to 2019.

Recommendations

• Develop strategies to incorporate and leverage emerging technologies
• Open external paths to market by sourcing ideas and leveraging technology from suppliers, customers and design partners
• Meet the growing need for remote patient monitoring by incorporating mobile technologies into products

\(^5\) RnR Market Research, The Medical Device Market: China; Publisher Name : Espicom Limited, 29-Jan-2014.

Business Model Innovation

Manufacturers are moving beyond traditional business models to open new opportunities for growth.

Recommendations

- Go **BEYOND THE PRODUCT** and expand offerings to include services and solutions
- Example: DePuySynthes Geriatric Fracture Program’s mission is to improve the complete care of the elderly fracture patient through education and access to centers with co-managed care and standardized protocols.
- Go **BEYOND TREATMENT** and focus on less invasive approaches to monitoring a patient’s health
- Example: Google is developing smart contact lenses that measure the glucose levels in diabetics’ tears. If successful, Google’s newest venture could help to eliminate one of the most painful and intrusive daily routines for diabetic patients.
- Go **BEYOND THE HOSPITAL** and focus on providing care that is more accessible and cost effective
- Example: Target Corporation’s Target Clinic® and CVS Minute Clinics® offer convenient health care when consumers need it – no appointment necessary.
Industry Playbook: The Medical Device Innovation Engine

Medical device organizations must use every weapon in their arsenal to adapt to the changing marketplace and capitalize on opportunities. Business as usual is not an option.

Leaders adapting their innovation engines and evolving their business models to position products and businesses to thrive in this challenging environment are focusing on three areas:

1. **Growing top-line results** by adapting business strategies to the new climate, then aligning their products and portfolios, i.e. “making the right choices”

2. **Protecting the bottom line** by optimizing business processes so they can execute with excellence, balancing regulatory compliance with speed to market

3. **Leveraging software systems** to facilitate compliance while optimizing and streamlining business processes
Industry Playbook: The Medical Device Innovation Engine

**Business Process Optimization**

- **Protect the Bottom Line**
  - Execute With Excellence

**Product & Portfolio Innovation**

- **Grow the Top Line**
  - Make the Right Choices

- **Product Pipeline**
  - Market Planning
  - Clinical and Economic Value
  - Value-Added Services

- **New Product Development**

- **Launch**

- **Globalize**
1. Grow the Top Line: Make the Right Choices

**Balanced Portfolio Management**

Robust product portfolio and resource management capabilities are needed to improve decision making. Leaders should demand a thorough evaluation of each opportunity and must ask the right questions when managing the development pipeline:

- How well do projects align with business strategies?
- How compelling is the business case?
- How well understood are the commercial and technical risks?
- Is there a good mix of projects ranging from line extensions to new products to new platforms?
- Is there an appropriate balance of risk and reward across the complete portfolio?

**Key Plays**

- Balance project portfolios across all dimensions; companies must be vigilant to nurture the budding opportunities and to prune the thorny weeds that sometimes lurk in a portfolio “garden”
- Adapt product portfolios to the changing marketplace and focus on innovative products and services that bring true customer value

**Clinical and Economic Value**

Developing innovative, new therapies to improve clinical outcomes will always be the fundamental value proposition in the healthcare marketplace. Going forward, there will be increased emphasis on demonstrating economic value. This will require new commercial models that adapt to changes in healthcare delivery systems and to the changing needs of a broader set of stakeholders that include providers, payers, physicians and patients. Success in a system that rewards value over volume requires technology, services and solutions that embed both clinical and economic value.
Key Plays

- Adjust innovation strategies to the new competitive landscape and to markets that encompass the entire patient care continuum
- Develop product solutions in key areas:
  - **Accelerated detection** and diagnosis
  - **Increased patient compliance** based on education and ease of use
  - **Operating room efficiency** and standardized surgical protocols
  - **Reduced complications**, length of stay and readmissions
  - **Value delivered** over the entire span of care from injury or disease through rehabilitation
- Deploy voice of the customer (VOC) and open innovation methods

Voice of the Customer (VOC)

- Go beyond listening to the customer
- Thoroughly understand the complete use case for the product by interacting with the entire range of potential customers
- Gather information about all interactions with the product across the full value chain
- Gather a 360-degree view of the customer
  - E.g. focus groups, individual interviews, contextual inquiry, ethnographic techniques, etc.

Open Innovation

- Go beyond the four walls of the organization
- Explore the purchase and licensing of processes and inventions (e.g. patents) from other companies
- Challenge front end teams to employ new models for open innovation
  - E.g. product platforming, idea competitions, customer immersion, collaborative product design and development, innovation networks
2. Protect the Bottom Line: Execute with Excellence

Flexible and Scalable Processes

Companies’ systems and processes have evolved over the years. Lean/Six Sigma and other approaches have made significant strides in improving efficiencies, but bloated, overly complex quality and design control systems slow the pace of innovation.

Key Plays

- Allow for a scalable process and flexible workflow based on risk to accommodate project types ranging from simple product changes to the development of new-to-world solutions
- Develop scalable new product development processes and design control rigor based on the complexity of the project and the risk of the device design
  
  E.g. a new breakthrough platform product vs. a line extension

Separate But Parallel Processes

Maintaining compliance by aligning business processes with quality systems requires a careful review of the process with key stakeholders from Regulatory, Quality and R&D. Separation of business processes from quality system requirements, such as in gate reviews, can reduce the risk of audit findings by removing business procedures that are not required by regulatory agencies from the quality system documents. Deliverables such as business plans, go-to-market strategies, sales plans and support plans do not go through the same level of process adherence scrutiny as design control deliverables do.

Key Plays

- Establish two separate but aligned systems as an alternative to the single process structure
- Set up business-oriented processes that allow room for judgment and flexibility as a supplement to rigorous design control procedures
- Use gate reviews to make the business decisions to continue, redirect or cancel investment based on defined gate objectives and phase exit criteria
• Use design reviews to ensure that the design is meeting customer requirements and technical objectives
• Fulfill regulatory requirements without burdening development teams with complex, difficult to interpret and non-value-added procedures

Phase Gate Governance
Executives must maintain consistent participation throughout the development process, probing assumptions, understanding project risks and supporting high-potential projects with resources. Clear guidelines that govern phase review approach and decision making behaviors must be established.

Key Plays
• Make it clear to participants what decisions are being made and how decisions are made
• Make sure the review meetings contain representation from the right functional areas and contain only the information needed to make the investment decision
• Ensure that that robust front end work is completed to select the projects that fit with business strategy
• Ensure that there is an optimal mix of projects that balance risk and reward
• Encourage teams to kill projects quickly that do not meet established business objectives while not usurping the project team’s responsibility

Empowered Core Teams
Industry leaders have embraced the concept of managing projects by establishing a cross-functional core team. The core team membership grows and changes as the project progresses through the product development phases. While the team may only initially include Marketing and R&D representatives, the full cross-functional team should participate in project planning and schedule development.

Key Plays
• Take responsibility for project performance by resolving issues and making trade-offs
• Practice effective phase gate reviews to enable resource allocation to the more promising projects
• Make recommendations supported by data and rigorous analysis at gate reviews
3. Accelerate Innovation: Optimize Software Tools

Many companies still rely on manual, paper-based document systems where product attributes and data elements are captured in MS Office documents or PDF files, and sent to document control for management and archival. This practice has resulted in data that is not readily accessible or extractable. Document control personnel that are gathering data for reports or submissions to meet the evolving new regulatory and compliance requirements must perform exhaustive searches through disconnected systems to find and extract the required information.

Key Plays

- Consider software systems across ideation, project and portfolio management (PPM), product lifecycle management (PLM) and quality management systems (QMS)
- Leverage industry experts to help identify and select systems that have the best organizational fit
- Implement systems to create and manage product data across the lifecycle, from project initiation through development, launch and global rollout
Brave the Storm

Medical device companies that embrace today’s stormy climate are able to proactively develop the systems and processes needed to accelerate innovation in spite of the numerous business and regulatory challenges.

For more information on how to adapt your organization’s innovation engine, contact:

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