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STRATEGIC INSIGHTS INTO THE ORTHOPAEDIC INDUSTRY

JUNE 2011



ARTICLE

Integrating Internal Strategies to Impact a Successful Product Launch

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Your company is ISO 13485 certified and has internal processes in place. Individual departments have well-established SOPs. Yes, you have successfully introduced several products to market on a project-by-project basis. If it's not broken, why fix it? Why the need to integrate strategies?

"Strategy Integration" has emerged as the new catchphrase in the medical technology sector. As companies face daily challenges of bringing new products to market, they continuously seek ways to drive efficiency, reduce internal costs and expedite product approvals to drive profitability.

In addition to the daily operational activities, successfully launching a product requires the combined efforts of several key functional groups: regulatory affairs, clinical research, reimbursement and marketing. The Regulatory team has to navigate the maze of FDA; Clinical Research is tasked with satisfying enrollment in a timely manner while producing data to meet the needs of key stakeholders, Reimbursement will grapple with the Federal health-care system for payment constrained within a cost-contained environment, and Marketing has to create a value proposition to produce the return on investment that shareholders expect from forecasted sales.

In the end, the individual strategies of each functional group will impact the others. If the individual strategies are integrated early in the product development phase, the better the chance of a timely, successful launch. The clinical trial protocol will impact FDA clearance. The approved labeling will dictate what is medically necessary for payment. The target market will be determined by who will pay and who will buy. Yes, the needs of FDA, payers and the market are different, but are all very much aligned.

A well-designed, departmentally-integrated strategic plan (a.k.a. your Blueprint) will drive efficiency, decrease time to market and ensure coverage and payment, while driving market adoption and generating revenue, thus increasing company profitability. We see our business change day to day as a result of many uncontrollable factors in the

healthcare environment. It is important to be as flexible as possible with your Blueprint.

There is no one right way to build the strategy; however, several key components are necessary to build the foundation of the plan.

Critical Components of the Blueprint: Your Roadmap to Success

Product Development Phases

Phase I: Conceptualization
The product idea is conceived.

Phase II: Verification
Determining whether the product can be manufactured.

Phase III: Validation
Is the product reproducible, marketable, will it get approved?

Phase IV: Commercialization
Will the product sell? To whom, and for how much?

Milestones

Milestones do not belong to the individual groups represented, but to the entire organization. Identify what you want to achieve within each product development phase and agree on ownership. It is also critical to put metrics into place to track and analyze the success of the project.

Key Integrated Activities

These key activities will support the identified milestone in each phase. Two, three or four key functional groups may be involved in an activity. Keeping in mind that the Blueprint is a flexible process, you may need to involve other key functional groups to successfully complete the activity.

Analyzing Success

After completion of the project, it is important to review the process and determine what was effective, what wasn't and what can be changed to ensure a higher success rate for the next project.

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Successful Product Launch...

Tying It All Together

Exhibits 1-4 depict the four phases of product development, including key milestones, key integrated activities and functional groups involved in the successful launch of a medical device.

Integration will have a different meaning to every department and every company. However, the underlying message is simple. By identifying the appropriate milestones, involving the appropriate

key functional groups, creating realistic milestones and maintaining flexibility along the way, companies can successfully create and implement an integrated plan without the process becoming too complex. The end result will be a new process for future projects that will not only ensure a successful product launch, but also drive efficiency, reduce internal costs, expedite product approval and most importantly, have a positive impact on a company's bottom line.

Phase I Milestones: Marketing Assessment and Strategy; Individual Functional Strategies, Integrated Business Plan, Secure Project Funding/Buy-in from Senior Management

EXHIBIT 1: PHASE I, CONCEPTUALIZATION

<i>Key Integrated Activities</i>	Reimbursement	Clinical	Marketing	Regulatory
Identify product specs			✓	✓
Determine pricing strategy	✓		✓	
Identify geographic areas for commercialization (US - OUS)	✓	✓	✓	✓
Develop claims matrix	✓	✓	✓	✓
Determine indications for use	✓	✓	✓	✓
Develop individual strategies	✓	✓	✓	✓
Final integrated business plan	✓	✓	✓	✓

Phase II Milestones: Finalize Design, Bench Testing, Publication Strategy, Pre-clinical Studies, Pilot Feasibility Study, Pivotal Clinical Protocol Design, IDE and Ethics Submissions

EXHIBIT 2: PHASE II, VERIFICATION

<i>Key Integrated Activities</i>	Reimbursement	Clinical	Marketing	Regulatory
Update individual strategies	✓	✓	✓	✓
Monitor market changes and competition	✓	✓	✓	✓
Establish bench test requirements and test plans		✓		✓
Develop risk management plan		✓	✓	✓
Pre-clinical studies		✓	✓	
Develop clinical protocol	✓	✓	✓	✓
Build relationships with key stakeholders (customers, agencies, payers)	✓	✓	✓	✓
Establish clinical trial reimbursement	✓	✓	✓	✓
Select investigators	✓	✓	✓	✓
Develop study budget	✓	✓	✓	
Develop patient recruitment plan (including materials)		✓	✓	✓
Develop publication strategy	✓	✓	✓	✓



Successful Product Launch...

EXHIBIT 3: PHASE III, VALIDATION

Key Integrated Activities	Reimbursement	Clinical	Marketing	Regulatory
Update individual strategies	✓	✓	✓	✓
Implement publication strategy	✓	✓	✓	✓
Update risk management plan		✓	✓	✓
Monitor market changes and competition	✓	✓	✓	✓
Continue market development activities		✓	✓	✓
Build relationships with key stakeholders (customers, agencies, payers)	✓	✓	✓	✓
Execute clinical trial	✓	✓	✓	✓
Implement clinical trial reimbursement strategy	✓	✓	✓	✓
Execute patient recruitment	✓	✓	✓	✓
Finalize pricing strategy	✓	✓	✓	✓
Finalize marketing and sales plan			✓	
Execute regulatory submission, agency interaction and approval		✓		✓
Develop payer value proposition	✓	✓	✓	✓

Phase III Milestones: Conduct Pivotal Trial, Clinical Trial Reimbursement Strategy, Collect, Analyze and Report Data, Submit PMA/510(k), Execute Publications

EXHIBIT 4: PHASE IV, COMMERCIALIZATION

Key Integrated Activities	Reimbursement	Clinical	Marketing	Regulatory
Update individual strategies	✓	✓	✓	✓
Implement publication strategy	✓	✓	✓	✓
Update risk management plan		✓	✓	✓
Build relationships with key stakeholders (customers, agencies, payers)	✓	✓	✓	✓
Monitor market changes and competition	✓	✓	✓	✓
Execute sales and marketing plan	✓	✓	✓	✓
Field reimbursement support	✓	✓	✓	✓
Submit coding applications (coding, pass-through/add-on)	✓	✓		
Call on payers	✓	✓	✓	✓
Post-market study strategies and claims expansion	✓	✓	✓	✓
Ongoing regulatory compliance, monitoring and reporting activities		✓		✓

Phase IV Milestones: Regulatory Approval, Sales & Marketing Implementation, Post-market Study, Obtain Coverage and Codes, Publications

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