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## Best Product Selection Practices Speed Time-To-Market for Orthopaedic Products

The orthopaedic industry is driven by a constant need for innovation and new technologies. This push for new products must be balanced between short-term incremental improvements and long-term breakthrough technologies requiring long lead times for regulatory approval. OEMs can find this balance through the use of a structured product selection process, which can in turn result in better product success rates by focusing the development group on fewer, more promising projects. The use of more formal product selection processes has increased in the past few years, according to recent research by Goldense Group, Inc. (GGI). While the research was not specifically focused on orthopaedics, it is clear from the results that the overwhelming usage of structured processes has penetrated the orthopaedic industry as well.

### R&D Study

Increased opportunities in the orthopaedic and medical device industry in general have attracted suppliers of other technologies to venture into medical products. This increased competition, combined with the consolidation of many orthopaedic suppliers, further pushes the need for innovation and product successes. In order to understand the effects of these factors on industry and on research and development (R&D) practices, GGI conducted its 2002 Product Development Metrics Survey. Every two years, GGI conducts its survey to assess different aspects of advancements in R&D practices; the 2002 study focused on R&D capacity management.

GGI's 2002 survey aimed at determining the maturity of product selection processes and investigating how companies are loading their R&D pipeline. Survey participants were asked the number of steps in their product selection process as well as the number of products or projects screened at each step of the process, to determine the aggregate project approval rate and level of loading. The 2002 survey questionnaire was mailed to a wide distribution of product development professionals across a range of industries in North America, Europe, and Asia. The surveys were completed during July,

August, and September, 2002, and replies were received from 83 companies. Medical products companies comprised 11 percent of the respondents, the second largest category after industrial products (19 percent). Four survey respondents were from large orthopaedic device companies or large firms with orthopaedic divisions, and the remainder of the 11 percent were from medical and health products companies.

### Product Selection Process

All new products begin as ideas, whether for an improvement to an existing product or a totally new concept. Yet companies cannot work on every new idea that arises. Most companies use a structured process to select which ideas to develop into products. A simple, 1-Step Process involves a single go/no go decision for all concepts considered for development. A more robust selection process, the 2-Step Process, incorporates at least two meetings to review all ideas before proceeding to full development. In between these two steps, the activities of product definition and project planning are performed, consisting of customer requirements gathering, technical and marketing feasibility analysis, programs planning, and resource requirements planning, among other estimation activities. The best practice process, the 2.5-Step Process, features a preliminary concept review at the front end of the 2-Step Process to screen in/out initial product ideas so as to minimize investments in definition and feasibility analysis time on poor or less desirable ideas. This frees up resource time, so a better job can be done defining and estimating the projects that really do have the most merit. Projects can be pushed forward, tabled, or killed at any of these decision points.

The use of the more rigorous 2-Step or 2.5-Step Process has increased from 2000 to 2002, as shown in Figures 1 and 2. In 2000, only 66 percent of respondents used a 2-Step or 2.5-Step selection process, but that number had increased to 80 percent by 2002. In the medical products sector, usage of 2-Step or 2.5-Step selection processes went from 55 percent in 2000 to 67 percent in 2002, a similar increase compared to industry as a whole. This

maturation of the product selection process indicates that companies are making more well-informed, robust decisions about which ideas to develop into products. Better up-front decisions translate into strategic advantage when the most promising projects become the biggest successes in the marketplace. The advantages of a more thorough product selection process are also evident in the effects on product approval rates and resulting loading of the development group.

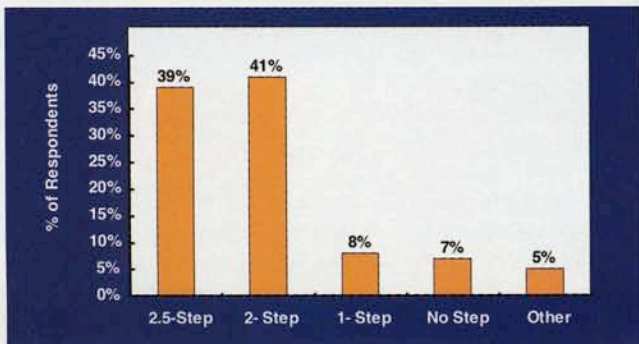


Figure 1. Use of product selection processes in 2002.

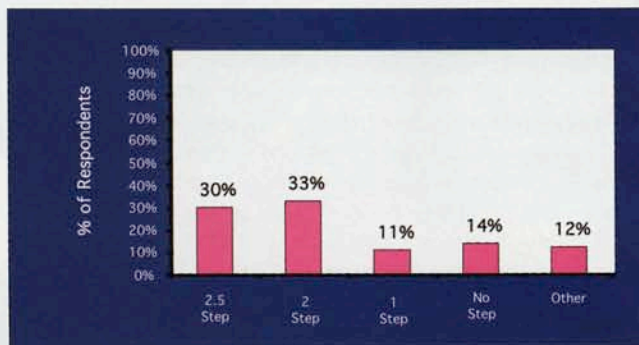


Figure 2. Use of product selection processes in 2000.

### Product Selection Approval Rates

More effective early decision-making results in lower product selection approval rates and thus fewer products sent on to the development pipeline. Figures 3 and 4 show the dramatic gains realized by using a 2-Step Process. When all of the projects were considered cumulatively, the approval rate for companies using a 2-Step process was 29 percent, while the 1-Step process companies sent 78 percent of projects along for development. The 1-Step companies are overloading their development groups more than two and a half times compared to their 2-Step counterparts. Clearly the 2-Step process provides a better screen to avoid clogging the development pipeline. The research also shows that the 2-Step process has improved since 2000, when the cumulative approval rate was 59 percent, double the 29 percent rate in 2002.

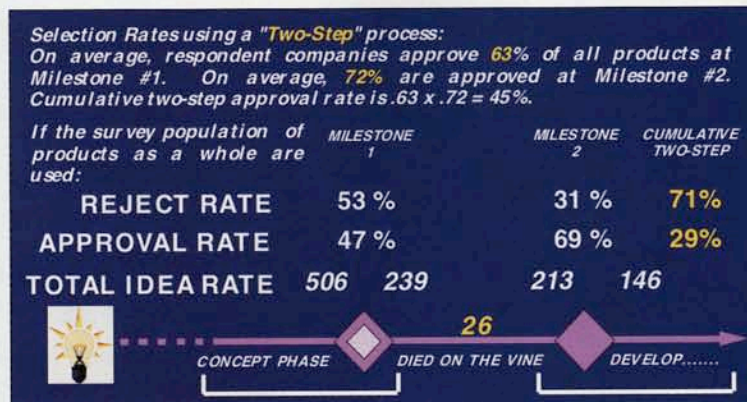


Figure 3. Product idea approval rate for 2-Step selection process companies

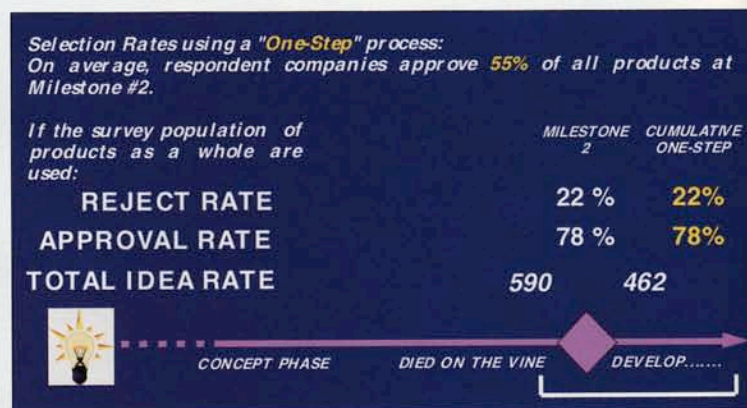


Figure 4. Product idea approval rate for 1-Step selection process companies.

Orthopaedic companies certainly want to increase their product success rate in the marketplace. Rather than trying to develop as many products as possible, they would be better off concentrating on the few most promising potential products. The limited resources of development departments are typically overloaded by 150 percent to 270 percent, causing cost and schedule overruns. The need to dedicate resources for preparation for regulatory reviews spreads development even thinner. The key is to use a 2-Step selection process to make wise decisions up front about which projects not to pursue, to preserve precious resources for only the best projects.

New product failure rates in general range from 30 percent to as high as 90 percent in some industries, with little improvement over the past few decades. Product failures cost significant amounts of money, not only to clean up the mess, but also to re-instill customer confidence and company image. Recent examples in the orthopaedic industry include failures of hip replacements associated with polyethylene wear, such as Hylamer polyethylene, and failures due to stem loosening as in the case of the Capital Hip System. Each of these cases resulted in a recall of all patients with the particular implant, and where surgery was required, the company paid for the surgery—quite an expensive fix. Perhaps these problems could have been avoided by more

up-front work before launching the products to the market. Consider also the wasted time and money spent to develop a product that ultimately fails in the market. As more companies adopt 2-Step product selection processes, however, we would expect to see new product failure rates drop.

### Advanced Research & Advanced Development

Many orthopaedic and medical companies also need an advanced or preliminary process and activities to screen potential solution technologies, either biological or physical, to reduce the risk of selecting a technology that is too premature or not yet ready for commercialization into products. While GGI's research did not focus on "approval rates" for these advanced research and development activities, the research did focus on the process. Most companies use a similarly structured processes for selecting and developing these advanced technology projects, but they execute them with fewer decision makers and less overall formality. As Figure 5 shows, approximately half of the survey respondents used the same selection methods for advanced research projects as used for R&D mentioned above. For those that did not use the same structured methods, the selection process is largely more informal.

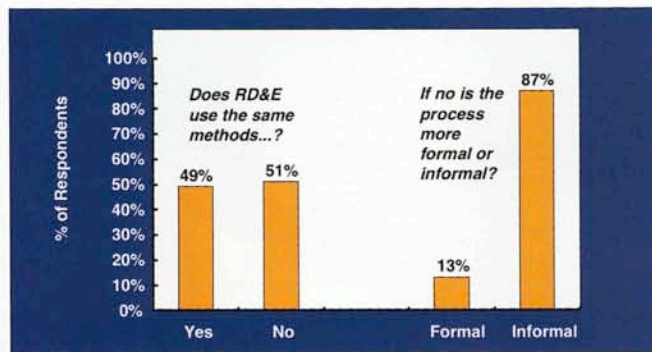


Figure 5. Product/Project selection methods for advanced research and development.

### Conclusions

GGI's research has shown that the increased formality and apparent maturation of product/project selection processes leads to more efficiency in the development function. Wise front-end product selection decisions typically reduce the number of product ideas being worked on and at the same time result in faster time to market. Weeding out of weaker ideas early on, we expect, will also drive up new product success rates in the years to come. Orthopaedic companies will also benefit from the incorporation of 2-Step or 2.5 Step product selection processes to begin their product development process.

Companies whose products require regulatory approval prior to being launched to the marketplace, that also wish to be fast to market, must specifically focus on the phases of their process that are fully within their control. The Concept, Feasibility/Definition, and Development I/II Phases are largely controllable from both time and cost perspectives. The Clinicals Phase is less

controllable. Orthopaedic companies, and many diagnostic/medical/health products companies as well, experience much more inefficiency during the early stages of definition and development. Scientists must work jointly with engineers, and neither group generally knows how to speak the other's language. By selecting fewer but higher quality ideas to work on, both during feasibility/definition and development, companies including orthopaedic providers can speed time-to-market for development activities that are largely within their control. Scientists and engineers will communicate more effectively and efficiently when their assigned workloads do not exceed 100 percent of their real capacity, and when they know they are working on the few best ideas that will make their company successful in the future.

*Editor: Bradford L. Goldense is Founder and CEO of Goldense Group, Inc. [GGI], a seventeen-year old Needham, Massachusetts consulting and education firm concentrating in advanced business and technology management practices for line management functions. Mr. Goldense has consulted to over 150 of the Fortune 1000 and has worked on productivity improvement and automation projects in over 400 manufacturing locations on four continents. Mr. Goldense has been a guest on Alexander Haig's World Business Review and has appeared on Public Television, PBS The Business & Technology Network, and CNBC (as paid programming). Brad has authored or been quoted in over 150 articles on competitive product development and manufacturing. Prior to founding GGI in 1986, Mr. Goldense held positions at Computer Sciences Corporation's Index Group, Price Waterhouse, Lester B. Knight & Associates, and Texas Instruments.*

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