

# Accelerating Speed to Market

From Concept to Finished Device, Development Efforts Can Benefit from 'Thinking-Out-of-the-Box' Approach

**T**ime to market for an IVD medical product is a key objective in any product development program. As the IVD market contin-

ed resources to make it happen. Because many companies do not have or cannot afford to utilize internal resources to meet the demands of the program, outsourcing has become an effective way of filling the void.

## Outsourcing a Mainstay

Outsourcing is far from a new concept. As early as the 1500s, Michelangelo acted as a head contractor to commission a team of craftsmen to help bring massive artistic efforts, such as the ceiling of the Sistine Chapel, from concept to reality. Through the 1700s and 1800s, prisoners and other laborers were hired by governing bodies to build roads, railroads and water storage and distribution stations in the U.S. and France. While outsourcing diminished in the late 1800s and early 1900s, it picked up again in 1930 when Battelle essentially invented contract R&D.

Within the past few decades, outsourcing of manufacturing has become a common practice, particularly in the electronics industry. That paved the way for the medical device industry to adopt this approach. In fact, the global market for outsourcing IVD product development and manufacturing is \$8 billion, with a foreseeable future growth rate of 20-25%, according to several industry estimates.

Access to world class technological and process innovations not available internally is a big reason why outsourcing can speed up the development process. Such expertise and skills can move a company ahead of its competitors in the race to intro-



ues to grow at an attractive rate, the ability to shorten the development cycle is critical to financial reward.

Although "conventional wisdom" has been the watchword of the industry in the past, many IVD product developers are now taking more unorthodox approaches in directing their programs to remain on the fast track. Such approaches may involve a bit more exploration into uncharted waters where more risks are ventured in an effort to gain commensurate rewards.

No matter how conventional or unconventional the approach, a fundamental element of any IVD development program is to establish a timeframe and assemble the associat-



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duce a unique medical product. At the same time, the IVD company can maintain its internal focus on core activities without the need to build staff and overhead or endure heavy capital expenses.

Key factors for successful outsourcing include determining a strategy, developing a plan and identifying the processes or activities to be outsourced. The first step in determining a strategy is to clarify organizational goals and define what is to be achieved by outsourcing and then recognize core competencies and align them with core processes.

Identification of an "outsourcing manager" who can serve as the pivot person on the project is vital to the success of the program. The manager's initial responsibility is to prepare a plan and communicate it to all associated parties within the company. This phase is followed by a determination of the scope of the project, assessment of the internal organizational support and, finally, specifying the processes and activities to be outsourced.

Successful outsourcing relationships are by no means guaranteed. Among potential pitfalls are a misunderstanding of the realities of development programs by either party and a lack of communication with or trust in the service provider. This can lead to reluctance to share important information and/or over-controlling of the provider's creative processes by the outsourcing company.

## Fast-Tracking Example

Diabetes Mellitus (DM) is a complex disease involving glucose metabolism that is reaching epidemic proportions worldwide. The market for diabetes products is very large and expanding. The market portion specific to glucose monitoring exceeds \$4.6 billion worldwide. Of the more than 17 million Americans with DM, one million have

been diagnosed with type 1 DM, 11 million have type 2 DM and approximately 6 million remain undiagnosed. By 2025, some projections show that one in four people may be affected, which means that as many as 300 million people worldwide may develop this disease.

Diabetes sufferers understand the unique challenges of monitoring blood glucose levels. For those who must monitor once or more daily, the process can be painful and time-consuming. However, accurate and consistent monitoring is essential to managing the disease and can help prevent complications such as heart and kidney disease, blindness, stroke and amputations.

While organizations such as Roche, Johnson and Johnson Lifescan, Bayer and Abbott offer blood glucose monitoring devices, certain market needs for pain reduction, testing speed, accuracy and precision and ease of use were not being met. As the



*The BD Logic went from concept to finished product in 18 months.*

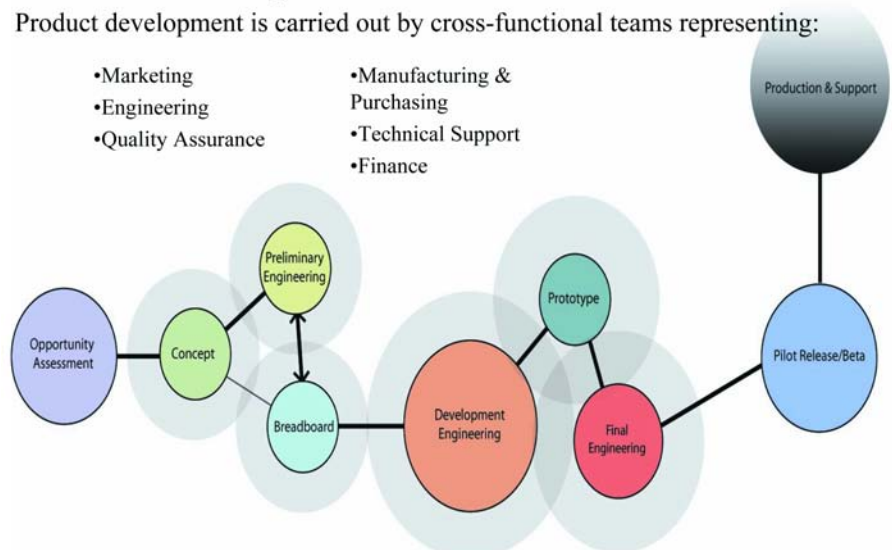
first company to introduce a whole blood glucose biosensor by an electrochemical method in 1987, Nova Biomedical developed a new sub-micro liter glucose monitoring system inclusive of a meter and test strip.

In 2000, Nova Biomedical contracted with Becton Dickinson (BD) for worldwide distribution of this technology. The partnership, whose goal was to introduce in record time this innovative blood glucose monitoring and diabetes management system, launched the products in Canada in October 2002 and in the U.S. in

## Optimization Process

Product development is carried out by cross-functional teams representing:

- Marketing
- Engineering
- Quality Assurance
- Manufacturing & Purchasing
- Technical Support
- Finance



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January 2003. The products, introduced as the BD-Logic Blood Glucose Monitor and BD-Latitude Diabetes Management System, received FDA clearance and are now available in the market.

The BD project leveraged Nova's proprietary diagnostic technology and expertise to produce the most advanced device in the blood glucose monitoring field. Development of these products from concept to market was completed in only 18 months, which includes design and development of the handheld device, custom production equipment and manufacturing set-up.

Nova Biomedical developed and manufactured these products in conjunction with several companies. Two firms in particular contributed to this successful product launch: Herbst Lazar Bell (HLB) and Foster-Miller Inc. (FMI), both of Waltham, MA. HLB provided industrial design and human factor analysis for the meter, and FMI assisted Nova with the development and manufacture of proprietary process production equipment for the glucose strip. These two companies invited Nova to participate in Technology Partners, a co-marketing group that provides medical device development and manufacturing from a single contracting entity.

## The Outsourcing Vendor

Important factors in the selection of an outsourcing vendor include the scope of resources, value-added capability, track record, breadth of portfolio, references/reputation and commitment to quality. Secondary considerations include cultural philosophy, location and flexible contract terms. Structuring an outsourcing partnership is not unlike any relationship in that both sides have to be willing to do what it takes to succeed. Establishing open communication between the partners at the outset is among the keys to this success.

## Assembling a Team

Once product design and function specifications and time to market goals have been established, the next phase is to assemble a team capable of integrating all of the marketing, engineering, quality assurance, manufacturing, purchasing, technical support and finance functions required to carry out the program. Cross functional services provided by Technology Partners include field research, product/device design, prototyping, proprietary process development, manufacturing equipment design and build, mechanical/electrical/software design, testing, certification, manufacturing and field support/depot repair.

## Work in Progress

The formal product development process begins with an opportunity assessment of the market size and potential, competition and the technical and financial barriers to overcome. This process incorporates the following components:

**Concept:** At this stage, exploration of the overall design including investigation of hardware and consumables is undertaken. In addition, feasibility studies are conducted to assess the time, costs and resources required to create a pathway to success.

**Preliminary Engineering:** In this phase, engineering sketch concepts and storyboards are developed from which preliminary layouts and databases can be created to form the early concept documentation. Preliminary materials and process reviews are conducted as well.

**Breadboard...“Works Like:”** The breadboard or “works like” stage is the point where an initial “alpha” working model is created toward proving the efficacy of the concept. Here, engineering development in terms of processes and materials con-

tinues while attention is also directed toward validation issues.

**Development Engineering:** The development engineering stage involves the finalization of engineering specifications and materials requirements. At the same time, required modifications to the alpha breadboard can be made toward modeling of a “beta” device. Preparation of a device master record is also initiated at this stage, while software design and database development continue to progress.

**Prototype “Looks Like...Works Like...:”** At this “advanced” alpha stage, several replicable, testable prototypes are fabricated for early beta testing and validation in the development laboratory and also by selected end users. At the same time, a preliminary agency review is conducted.

**Final Engineering:** The goal of the final engineering stage is to release the product for pilot production and formalize the documentation package. Data, observations and experience from the alpha tests are scrutinized in preparation of the final specifications, tolerances, bill of materials, engineering drawings and software. A final manufacturing review is conducted, and preparation of the device master record continues to move forward.

**Pilot Release/Beta...“Works Like...Looks Like...Made Like...”** At this stage, the majority of the manufacturing protocols are formalized toward development of pilot devices. These include setting up a “focus factory” and development of assembly and test procedures, release protocols and packaging/shipping requirements. Concurrently, training for technical support staff, independent lab and agency testing, regulatory agency submission and final confirmation research is ongoing.

**Production and Support... The Moment of Truth:** By this time, the product has been released

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for manufacturing ramp-up in anticipation of product launch. Documentation is updated based on beta testing and submitted for 510(k) approval. Because the process has evolved from its inception, it is important to consider the following questions to make sure that any changes along the way are reflected in the final package:

- Does the product literature reflect current product design specifications?
- Are the market assumptions still valid?
- Has product performance significantly changed?
- Are all reliability issues resolved?
- Are all design issues resolved?
- Are all quality issues resolved?
- Has the updated forecast been reflected into the manufacturing schedule?
- Has the financial plan been updated?

To promote communication during the development process, Nova

establishes a product line quality committee comprised of representatives from Nova and client participants. This committee acts as an oversight group to address quality and operational issues before they reach a problem stage.

## Communication Is Key

With any innovative product development program and launch, rapid enhancements are required to maintain a competitive strategic advantage in the marketplace. A crowning illustration is the new BD Paradigm Link, the world's first "intelligent" insulin pump and glucose monitor system. Developed jointly by Nova Biomedical, Medtronic MiniMed and Becton Dickinson, this new wireless system helps remove the guesswork in insulin dosing, making it easier for patients to manage their diabetes. Relying on the key product development principles described earlier in this article, BD shipped the first prod-

uct in July 2003, just nine months after the initial concept meeting in September 2002.

No matter how creative the product idea, speed to market for an IVD product depends on a strong partnership between the OEM supplier and the client. Establishing an open line of communication from the outset is essential in assuring that the project remains on the fast track every step of the way, from launch through shipment. ❖

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