BY ELISABETH PENA

Sea Change

TURNING THE TIDE

The Product Life-Cycle Management Wave

Commonly thought of as a strategy for the end-phase of a drug, **LIFE-CYCLE MANAGEMENT INCREASINGLY IS BEING DEPLOYED BY LIFE-SCIENCES EXECUTIVES EARLIER IN THE DEVELOPMENT PHASES** to maximize product value, provide greater benefits to patients and physicians, and combat the impact of the dying blockbuster model.

Thought Leaders

RICHARD M. BAYNEY, PH.D., MBA. VP, Decision Analysis and Portfolio Management, Johnson & Johnson Pharmaceutical Research & Development, Titusville, N.J.; J&J PRD performs worldwide research and development work for the pharmaceutical business units of Johnson & Johnson worldwide. For more information, visit jnjpharmarnd.com.

RICHARD DALY. Senior VP, Marketing, Takeda Pharmaceuticals North America Inc., Lincolnshire, Ill.; Takeda Pharmaceuticals North America is a wholly owned subsidiary of Takeda Pharmaceutical Company Ltd., Osaka, Japan, and is a research-based global pharmaceutical company. For more information, visit tpna.com.

ROB FRANCO. Lead Director, Life Sciences Practice, Pittiglio Rabin Todd & McGrath (PRTM), Waltham, Mass.; PRTM is a global management consultancy that helps companies translate business strategy into breakthrough results through operational transformation in product life cycle, supply chain and operations, and customer life cycle. For more information, visit prtm.com.

TERRY HISEY. VP and National Leader of Life Sciences, Capgemini, New York; Capgemini is a provider of consulting, technology, and outsourcing services. For more information, visit us.capgemini.com.

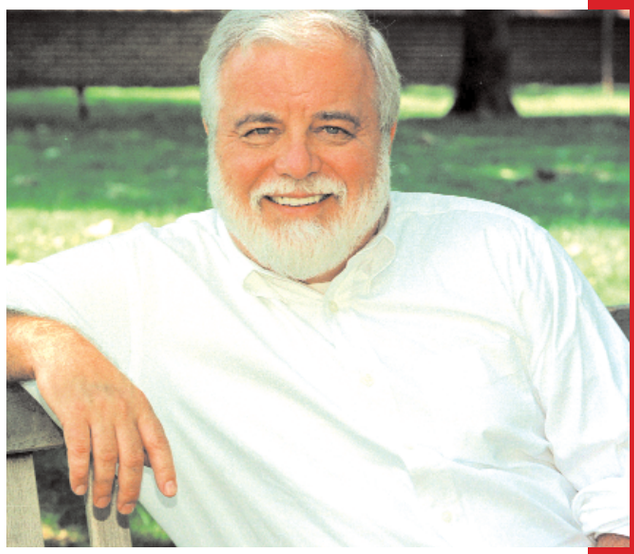
MIKE JANSEN. Director, Pharmaceutical Industry Business Consulting, Agile Software Corp., San Jose, Calif.; Agile is a provider of product life-cycle management solutions with a broad suite of enterprise-class PLM products

Richard Daly
Takeda Pharmaceuticals North America Inc.

PLM IS A LOT LIKE TRYING TO FORECAST THE WEATHER ON A TUESDAY SEVEN YEARS FROM NOW. But a company is obligated to try and predict where the market is going and what value its compound is going to deliver, and then try to match up its sustainable competitive advantage with the market need.

Dr. Donald Phillips
Vox Medica

THERE IS NO LIFE-EXTENSION TEMPLATE FOR THE LIFE OF A PRODUCT. One has to look at a whole plethora of issues, which is why the earlier that product life-cycle management is considered, the easier it is to extend that product's life later on.



In a recent report from Capgemini, analysts call product life-cycle management (PLM) one of the most important priorities for the industry, if not the most important, saying it addresses integrated operations such as marketing, sales, manufacturing, distribution, and so on.

The fourth annual Vision & Reality report surveyed 74 senior pharmaceutical industry executives in 12 countries and found that 90% of those senior executives believe that product life-cycle management is important for their future prosperity, with 60% saying its importance will increase significantly.

As the industry's drug-development model transitions away from a blockbuster-based one, experts interviewed for this Forum believe that the earlier incorporation of life-cycle management strategies in the development process will help maximize the value of their products and help replace the revenue lost by blockbuster patent expirations.

The Capgemini report found that only 19% of executives surveyed believed their ability to implement PLM strategies was excellent, with more than 15% reporting a poor or very poor ability. Industry analysts say a first step for life-sciences companies is to become proactive about PLM, as opposed to the reactive PLM strategies companies have traditionally employed.

and services. For more information, visit agile.com.

DARIUS NAIGAMWALLA. VP, Brand Management Practice, Campbell Alliance, Raleigh, N.C.; Campbell Alliance, a specialized management consulting firm serving the pharmaceutical and biotechnology industries, helps clients develop strategic and operational plans, as well as improve the efficiency of their internal operations. For more information, visit campbellalliance.com.

DONALD J.M. PHILLIPS, PHARM.D. CEO and Principal, Vox Medica, Philadelphia; Vox Medica is a healthcare communications company. For more information, visit voxmedica.com.

SHANKAR RAMAN. Director of Business Development, Eastern Region, UGS, Plano, Texas; UGS is a global provider of product life-cycle management (PLM) software and services. For more information, visit ugs.com.

BRUCE E. SCHNEIDER, PH.D. Executive VP and Chief of Operations, Wyeth Research, Collegeville, Pa.; Wyeth Research is the research division of Wyeth Pharmaceuticals, a part of Wyeth, a research-based pharmaceutical and healthcare products company. For more information, visit wyeth.com.

AMITH VISWANATHAN. Industry Manager, Healthcare and Life-Sciences IT, Frost & Sullivan, Boston; Frost & Sullivan, with headquarters in San Antonio, is a global growth consultancy covering a broad spectrum of industries. For more information, visit frost.com.

Rob Franco
Pittiglio Rabin Todd & McGrath

COMPANIES THAT ARE MOVING FROM THE BLOCKBUSTER MODEL to one where they are going to create the new blockbuster drug through product life-cycle management are the ones that are going to have a competitive advantage.

The PLM Environment

As the patent life of a drug comes to an end, pharmaceutical companies often roll out their PLM strategies, including a legal patent battle, new indications, and Rx-to-OTC switches, among others. Industry experts acknowledge that these strategies will not be sufficient in the future, and more integrated PLM processes need to be developed and implemented earlier in the process.

DALY. Product life-cycle management (PLM) as it applies to the pharma industry has a simple definition, but is hard to implement. PLM is the alignment of all influences for the optimization of the product. Everything has to be aligned, not only from the research and development and commercial organizations but all of a company's core functions as well. Clarity of purpose for life-cycle management also is essential. Everybody has to be able to understand where the company is going with the molecule.

FRANCO. There is a real change going on in pharmaceutical development. Traditionally, pharmaceutical companies have relied on the blockbuster model. Because of shrinking pipelines and fewer blockbusters, that model is under great pressure. Companies are finding now that blockbusters are not discovered, but made. A smaller, more modest drug can be built into a blockbuster through line extensions, including combination-line extensions and life-cycle management practices. Companies underestimate the number of line extensions of their products.

SCHNEIDER. We divide product development into two groups of activities. The first is taking new molecular entities through their initial development and market introduction for a first indication. Anything that is done to extend the application of the drug beyond the first indication is what we refer to as PLM. This generally involves three main categories: new claims, new dose forms, and new delivery systems.

PHILLIPS. Life-cycle management means plotting the course of a molecule or biotechnology product throughout its life span, from human testing all the way through its normal commercial cycle. When we look at a product's life cycle we consider the investigational stages through commercialization and market uptake, and into later commercialization phases through generic competition. Most people still look at PLM simply as a way to add years to patent protection. We think this is too limited a view of PLM. Companies have to evaluate life-cycle management right from the get-go.

RAMAN. In the life-sciences industry, organizations still look at product life-cycle management as a technology-based implementation. But life-sciences executives are beginning to realize that PLM is a strategic business approach. It applies a consistent set of business solutions for the collaborative creation, management, and dissemination of the information around products or services that are offered to the market across the extended enterprise. This involves integrating all the stakeholders in the value chain.

HISEY. When we look at the industry today, PLM efforts are not highly structured. PLM is fragmented, and generally there is no clear owner of the process within a company. PLM is far more important than individual functional resources and should be applied throughout a company in an integrated way; it should be holistic and cut across the entire value chain. Organizations need to build PLM as an institutional capability to meet the business dimensions, the technical dimensions, and the scientific dimensions of their strategies.

VISWANATHAN. Life-cycle management is a very loose term used to describe a set of systems that link various submodules for sourcing materials and inventory issues, product-data and document management, collaboration tools, cost-management measures, and certain levels of downstream information management.

FRANCO. Life-cycle management is a succession of strategies that managers use to increase sales and market share and/or extend the patent life of a product. The pharmaceutical industry is in a unique situation in that the product life cycle can be mapped and tracked quite well against its patent life cycle. There is a launch phase, followed by a growth and expansion phase, then a mature phase when there are peak sales. Then there is a precipitous drop in sales when the patent expires and the drug is open to generic competition. The real challenge for pharmaceutical companies is how to extend the life cycle of a drug beyond the initial patent exclusivity period as well as increase the overall economic value of the drug through new claims and in new therapeutic areas.

JANSEN. PLM is the capability to integrate information related to a product's definition that can be used by the extended organization. This entails having the right information available to the right individuals at the right time to support a range of decisions over the product's lifetime, with full insight as to what impact these decisions have on the entire business. Decisions are made during the R&D phase for pipeline development, at the launch phase for marketing, and for manufacturing, supply chain, and quality management issues; all these functional decisions leverage product information.

VISWANATHAN. Life-sciences, as an industry, must document thousands of pieces of information pertaining to rigorous external and internal regulatory compliance measures for every product in the pipeline. Internally, a line manager who is responsible for the production of a particular drug must ensure that certain steps have been met along the chain as far as stage-gate management and that all the appropriate approvals have been received before production begins, as per GMP requirements. These enterprise regulatory content management issues have come into vogue in the life-sciences industry during the past five years to resolve this issue. PLM efforts include

Mike Jansen
Agile Software Corp.

THE INDUSTRY CAN DO A MUCH BETTER JOB of capturing, harnessing the power of, and leveraging or reusing product information over the life of the product. Many vendors in the life-sciences arena are now adopting PLM as an integral part of information management.

Shankar Raman
UGS

Executives are driving more toward real-time visibility of their portfolios and the ability to look at products as they move through each phase in the cycle.

THE BIGGEST PROMISE THAT PRODUCT LIFE-CYCLE MANAGEMENT BRINGS TO THE TABLE IS THE ABILITY TO MAKE BETTER DECISIONS THAT AFFECT THE TOP LINE AS WELL AS THE BOTTOM LINE.

discrete elements of regulatory content management such as product data management to provide more targeted information storage and access.

Key Opportunities

PLM initiatives and strategies can open the door to a number of business opportunities and efficiencies.

PHILLIPS. The business opportunities associated with PLM are immense. But companies need to take a step back and realize that their product is a financial asset to their organization. It is a lot less expensive to extend the life of an existing product and maximize that asset than it is to develop new products with new sets of financial risks. And if companies manage the life of a product optimally from the beginning, there is a huge differential on the return from a particular molecule or biotechnology product.

HISEY. PLM provides the life-sciences industry with an opportunity to improve its performance, which will result in better drugs reaching the market more quickly and better use of assets. At the end of the day, a properly implemented and executed life-cycle management plan will translate to hundreds of millions of dollars in earnings.

RAMAN. In the discovery process, there is a tendency to use a number of different and disparate databases or silos of information. PLM is advantageous to life-sciences companies when it ties all these informational resources together, integrates the multiple silos, and then creates collaboration around information. In the commercialization processes, companies want to be able to align their supply chain toward what they are expecting in terms of reaching the market on time and on budget. PLM provides program execution for managing the different stages and gates within the process. And, on the issue of compliance, the ability to improve record management, track issues and corrective actions, and capture history is critical given the state of the pharma industry today.

JANSEN. The biggest driver, or value proposition, on everyone's mind is reducing the cycle time required to bring products to launch. But beyond the R&D, clinical, and marketing processes are the preparation and collaboration needed to get manufacturing prepared and get the supply chain ready. These functions are a huge consideration and often are overlooked until the last minute. PLM can drive value by enabling collaboration across the supply chain in preparation for launch. For a billion-dollar product, one day of lost market time can equal about $5 million, so lack of preparation translates into significant opportunity cost.

NAIGAMWALLA. The opportunity presented by life-cycle management is to increase and ultimately maximize the value of the asset. By understanding the product, by understanding external factors, and by making wise investment decisions as to where scarce resources should be allocated, companies can increase the area under the curve and extend the duration of a product's life. Life-cycle management is not a one-off deal; it is a continuous investment to get the best return on the asset.

VISWANATHAN. Many of the governmental, cultural, and liability protection issues that are troubling the industry right now have to do with its failure to streamline processes or to keep a steady trail from beginning to end. PLM, and any information management platform, has to be able to retrieve and document exactly what happened, where, for how long, and by whom to enable companies to run audits as needed in case there is an internal QA or a FDA compliance query, which could otherwise stall the development process.

When to Begin

Industry analysts and experts agree that PLM efforts cannot begin too early and are not beginning early enough at most pharmaceutical companies. But experts differ as to when discussions about PLM should begin.

JANSEN. The first question companies need to answer is where life-cycle management should start. I think it is fair to say it is somewhere in the R&D area. I contend that it

CLOSELY RELATED TO PRODUCT LIFE-CYCLE MANAGEMENT (PLM), AND AN INCREASINGLY IMPORTANT AREA OF FOCUS FOR THE INDUSTRY, IS THE CHALLENGE OF INCREASING R&D PRODUCTIVITY.

Dr. Richard Bayney
Johnson & Johnson Pharmaceutical R&D

THE ENTIRE ARENA OF INCREASING R&D PRODUCTIVITY IS ONE THAT THE INDUSTRY WILL BE CONSUMED BY for the near- and long-term as the industry strives to meet its performance goals.

The pharmaceutical industry is in an era where it is experiencing declining R&D productivity as defined by declining new molecular entity (NME) output.

Based on this definition, productivity has declined since 1996, when R&D productivity rose to its peak (see chart to the right). Since then the industry's NME R&D output has declined dramatically reaching its lowest point, with 26 NMEs being approved by the FDA in 2002. Although productivity rose in 2003 and an increase also is expected in 2004, the industry is still far from its banner year of 1996 and industry executives are, not surprisingly, concerned with the challenge of increasing their organization's R&D productivity.

According to Richard M. Bayney, Ph.D., MBA, VP of decision analysis and portfolio management at Johnson & Johnson Pharmaceutical Research & Development, there are four primary levers, or value drivers, that impact R&D productivity: reducing attrition; increasing commercial value; reducing development cycle times; and reducing development costs.

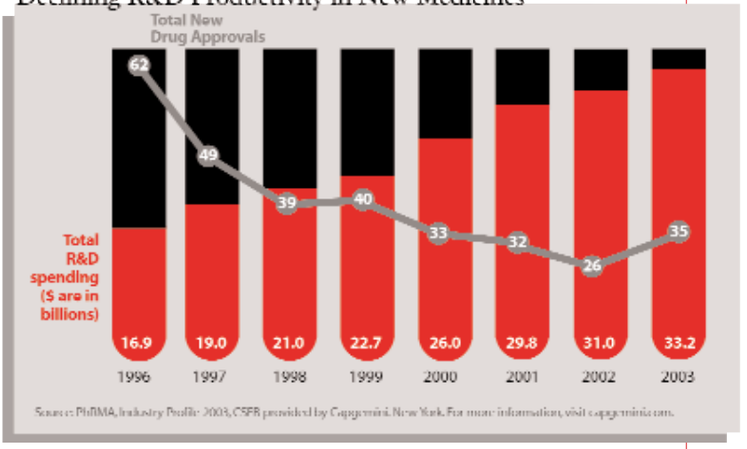
"According to the Tufts Center for the Study of Drug Development, if development times for a product could be reduced by about 19%, for example, the average cost of developing a drug would be reduced by about $100 million," Dr. Bayney says. "This alone represents a tremendous challenge to anyone in the industry."

Dr. Bayney believes the greatest lever the industry has at its disposal to increase R&D productivity is increasing the attrition of projects that are in early clinical development; this single act would in turn improve the survival of higher quality projects as they are taken forward into later phases of development.

"The only way to really reduce attrition in the more expensive phases of development is to essentially buy early and relatively cheap clinical information and establish more stringent stage-gate criteria that would allow higher quality projects in early clinical development to proceed to the later phases of development," he says. "By establishing the appropriate hurdles as to which projects in early clinical development do not proceed, we can build high quality into our late-stage clinical pipelines."

The challenge to this goal, however, is that if early development stage-gate criteria are too stringent, not enough projects will proceed into full development, so a balance is necessary, which Dr. Bayney says may be predicated, in large part, on the richness of a company's pipeline. Further, if the pipeline does not have enough compounds to allow a company to increase productivity in later clinical development, licensing and/or acquisition is an alternative strategy to help increase R&D productivity.

Declining R&D Productivity in New Medicines



Source: PhRMA, Industry Profile 2003, CSFB provided by Capgemini, New York. For more information, visit capgemini.com.

"Clearly, every company has goals in terms of the number of NMEs it would like to launch," Dr. Bayney says. "And, if a company doesn't have a robust internal pipeline, it can always consider the option to in-license products."

This trend, however, has led to an increase in the cost of acquiring licensing opportunities, he says.

"There are a limited number of opportunities available and most companies are bidding for the same assets," Dr. Bayney says. "The industry doesn't have the luxury of a plethora of available licensing opportunities, and this constraint is only going to get worse in the future."

probably doesn't start back in the research lab; rather it starts when a company is putting together a target product profile or target label, and that is often done in advance of early preclinical trial activity. That's when a company begins collecting meaningful product specific information that is needed to successfully set a product on its journey to market.

FRANCO. Most companies start looking for opportunities to expand and extend a drug's life cycle during Phase III trials, but that is really too late. By that point it might be difficult to beat competitors to market with new line extensions or product forms. The other opportunity missed is the ability to conduct line-extension evaluations in a more cost-effective manner. Some companies are starting to put together a more comprehensive life-cycle management strategy and approach in early development, even before Phase I. These companies then can take advantage of ongoing studies and augment them with pilot studies to prove or disprove some of their life-cycle candidates.

NAIGAMWALLA. PLM should begin early in the clinical-development process. That doesn't mean launching trials in five distinct indications at the same time. But while a company is developing a lead indication it should be assessing what other potential indications might be commercially viable. Once proof of concept has been determined and the company is convinced of the safety and efficacy of the product, it's time to extend efforts to other indications.

BAYNEY. At J&J, PLM efforts start in drug discovery. In the discovery phase, my colleagues have lengthy discussions about what drugs to take forward to the next phase of development, as well as about the spectrum of potential uses the drug could have based on what is known of its mechanism of action.

PHILLIPS. As part of managing an asset, pharmaceutical companies need to start developing messages and marketing positioning in Phase II. And those messages should be integrated with clinical research to ensure the research being done conforms to the objectives of that asset. Here, too, marketing can work to make sure the messaging conforms to what the research shows.

SCHNEIDER. PLM planning efforts at Wyeth are overseen by our global brand teams and typically begin during the middle of Phase III trials and certainly well before the launch of the first indication. Once in place, we may begin implementation work on subsequent indications even as we are finishing the work on the first indication.

DALY. We begin thinking about PLM before a compound goes into human trials. When we have preclinical and animal data on the compound we map out where we want to take the compound over its lifetime.

BAYNEY. Developing additional indications or formulations as part of a PLM strategy depends primarily on the level of understanding of the mechanism of action of the potential drug. In clinical development, we may wish to make concurrent investments in a secondary indication while working on the primary indication. On the other hand, if we need to establish greater clinical understanding of the molecule before making a greater resource commitment we will adopt a more sequential development plan.

FRANCO. We recommend that companies evaluate PLM opportunities on a phase-by-phase basis. At every phase of development, managers should evaluate a life-cycle plan for that product. This is really where companies can get the most benefit from life-cycle management.

Barriers to Change

Experts have identified a number of challenges that can impact a pharmaceutical company's ability to take full advantage of PLM opportunities.

DALY. We live in a modern-day Tower of Babel. We have people who specialize in different areas of pharmaceuticals and everyone speaks his or her own language. Getting people on the same page is very difficult. The challenge lies in helping people in marketing understand the scientific view point, as well as helping scientists understand the commercial impact of decisions because that's not their area of expertise. If a company can find common ground and language, success is more likely.

BAYNEY. One of the primary challenges of PLM, in the context of portfolio management, is that we can't afford to pursue every good idea that we have. A major challenge therefore, is trying to make informed judgments about which projects for which types of indications we ought to pursue.

SCHNEIDER. The biggest challenge always is trying to decide what the right targets are and which questions need to be addressed. One of the first things we address is what are the potential uses for the compound beyond the first indication, and then we look strategically at what makes the most sense in terms of the medical need and the target patient population. The second primary challenge for us at Wyeth is that PLM projects compete for resources against other projects in our portfolio, which include other life-cycle management opportunities, as well as new molecules that are coming through the pipeline. This becomes a resource allocation competition issue, which is one of the other challenges that every company faces these days. In Wyeth's case, we always seem to have more opportunities than we have dollars to spend, so that leads us to portfolio management considerations as we weigh the various choices and talk about value to patients, as well as value to the company, with the latter often in terms of return on investment.

Darius Naigamwalla
Campbell Alliance

MORE THAN IN ANY OTHER INDUSTRY, PHARMA AND BIOTECH PRODUCTS FOLLOW A PREDICTABLE LIFE CYCLE.

There is a very well-defined pathway for PLM in pharma, and that means companies need to develop life-cycle management as a core competency with proactive monitoring and investment at each stage of the product life cycle.

Amith Viswanathan
Frost & Sullivan

PLM is an aid to business. **THE PLM INDUSTRY ITSELF MUST RECOGNIZE THAT IT NEEDS TO GET IN THE LIFE-SCIENCES MARKET EARLY AND PROVIDE A FLEXIBLE ENOUGH SOLUTION THAT IT CAN SCALE WITH A NUMBER OF USERS AND WITHIN A MORE STRINGENT REGULATORY COMPLIANT ENVIRONMENT.** The vendors that can do this are the ones that will be able to penetrate the industry.

Terry Hisey
Capgemini

The proper implementation of life-cycle management can help to preserve the earnings performance of many of the major drug companies in the face of the less-than-productive R&D pipelines at this point in time. **SIGNIFICANT OPERATIONAL GAINS CAN BE REALIZED SIMPLY FROM PURSUING THESE STRATEGIES.**

FRANCO. Whenever the budgetary choice is between a line extension and a new molecular entity, the NME always wins out because the benefits are so great and because the industry is driven by a blockbuster model. Pharmaceutical companies that allocate percentages of their budget up front for life-cycle management and a percentage for NMEs are the ones that are taking advantage of the opportunities.

NAIGAMWALLA. One of the toughest challenges that pharmaceutical companies are wrestling with is putting in place high-quality resources to manage the asset throughout the 10-year to 15-year life cycle of a brand. The average tenure of a pharmaceutical company brand director is maybe two or three years and then somebody else comes in to take over.

VISWANATHAN. The need for specialists in the life-sciences industry is very high, and there is a short supply of the appropriate biologists, chemists, and computational scientists. In a heavily paper-based industry such as life sciences, lab and process documentation leaves with the scientists. This creates critical knowledge retention gaps for employers. Pharmaceutical organizations are now realizing that even at the earliest stages it is important to put in a system that can track who is doing what and replicate research for future use. This applies all the way through the chain.

PHILLIPS. A daunting challenge is to integrate all the information that product stakeholders need to make important decisions — from raw materials, to chemical engineering packaging, regulatory, and marketing. All of these areas require sound and compelling information to make the most intelligent and fruitful decisions.

Practice Makes Perfect

The experiences of progressive industry executives have resulted in the formulation of best practices for integrating PLM into a company's processes.

SCHNEIDER. We have gone through some trial-and-error phases over the years and have developed what we believe to be reasonably good practices. We begin to develop our first plans for life-cycle management during Phase III for the first indication and involve all of the key stakeholders. This includes having key R&D functions and commercial functional areas working together as a team. We receive commercial input from marketers at headquarters as well as from affiliate operations around the world. We try to synthesize the information on needs and opportunities into a single strategy, which is updated annually, in advance of budget cycles, based on evolving conditions in the marketplace or with the molecule itself. With that information in hand, we have the opportunity to weigh proposals for any given compound and its life-cycle strategies against compounds with other life-cycle strategies, or against other opportunities from our earlier development portfolio. Once we commit to something, these activities and the progress are tracked very methodically through our project management groups. Also, the direction we have taken is shared across the company. This process works quite well.

RAMAN. Pharmaceutical companies need to take a more holistic approach to PLM than they have done in the past. There has been a local optima approach, where specific func-

tions in the organization have deployed PLM technologies for their areas, such as document management or change management, in a very loose vertical integration scheme. What the industry really needs is a holistic view where, at the executive-management level, a decision is made regarding the PLM strategy and, based on that decision, projects are prioritized with regard to the areas that will create the biggest bang for the buck.

JANSEN. PLM can play a role early in the research phase by enabling collaboration among those efforts that precede human trials. But traditionally PLM starts around the point at which there is a target label being studied. There is a lot of information that comes in from studies, raw materials suppliers, production planning, forecasting of the market potential, ramp-up timing, and a lot of the information will have a significant bearing on how successful a product could and will be. There are many decisions that take place way upstream that affect the merits of the product downstream. An important part of PLM is managing all of the information and the processes by which that information is captured. By controlling these data, a company knows how its resources are allocated across the development effort, by therapeutic area, and where all its skills and resources are located. Therefore, when the company makes decisions, it understands the implications of those decisions and how to reallocate its most critical assets, its people.

HISEY. One of the best structures is when there is an individual who has enterprisewide responsibility for a firm's life-cycle management strategy and who reports to the CEO level. Another leading practice is training people across various functional organizations on the life-cycle management concept. Leading practices also include developing a business orientation among the scientific community and a scientific orientation among the business community so that people understand the implications of each area. Other best practices are incentivizing individuals based on achieving defined metrics across the organization or setting a series of goals and objectives that align the organization around the optimal activities for maximizing life-cycle management.

BAYNEY. A major trend for the future will focus on gathering early, relatively inexpensive information, which should allow us to make more informed, and hopefully better, downstream decisions when the development of projects becomes more time consuming and more expensive. This includes information from both our in-house subject matter experts as well as information from published sources. An example of this is an adaptive clinical-trial design where downstream decisions are made on the basis of the revision of a prior state of knowledge based on information gained from early clinical results. I believe that more clinical development in the future will follow this type of Bayesian logic.

JANSEN. Most life-sciences companies already have invested in software or technical systems to run enterprise resource management, customer-relationship management, human-capital management, and supply-chain management processes but the information that those tools require include crucial product details to successfully execute the processes that are intended. By creating a centralized product record where PLM feeds the appropriate data to these other executional systems, a pharmaceutical company can greatly enhance quality in an efficient, cost-effective manner. This is a key to effective PLM, regardless of industry.

Justifying the Process

As with all endeavors in business, return on investment (ROI) comes into question in the PLM arena. Whether it be for the processes and strategies or the technology required to implement the plan, life-sciences executives need to justify the PLM course of action to their employees, stakeholders, and customers.

PHILLIPS. If a company does nothing — let's say it doesn't develop a new dosimeter, or change the molecule chemically, or come up with a sustained-release form — then it's fairly easy to predict how the product is going to perform. To measure the ROI on PLM strategies, it is a matter of benchmarking the market performance against the traditional bell-curve model, one where perhaps no PLM strategies were implemented.

DALY. Measuring the ROI of life-cycle management is a fool's errand. One could spend a lot of time trying to figure it out, but I think a business case for doing product life-cycle management is so self evident that having the ability to tie hard and fast numbers to PLM is not worth the effort. Companies should just do PLM.

HISEY. Pharmaceutical companies need to understand that life-cycle management is not something that they can do, but rather something they should do. Nevertheless, companies can measure the return on the benefit they get from life-cycle management. A baseline has to be established and appropriate strategies should then be developed that are going to help improve individual areas and aggregate processes throughout the company.

SCHNEIDER. To measure ROI in our portfolio management system we try to define or quantify what the incremental impact on income or revenue would be with the life-cycle plan being implemented versus what it would be if it were not implemented. In some cases, this is purely an additive in terms of top-line revenue growth. In some cases it can be a protection or a strategy against losing market share. We try to look at the incremental difference and then determine what the timing and costs are to implement the plan. From there it is possible to generate incremental net present value and ROI valuations for the proposed PLM, allowing contrasts with competing opportunities or options. We do this fair-

Life-Cycle Management Strategies

CAPGEMINI SURVEYED PHARMACEUTICAL EXECUTIVES TO DETERMINE WHICH STRATEGIES THEY BELIEVE ARE BECOMING INCREASINGLY IMPORTANT FOR MAINTAINING THE OPTIMAL LIFESPAN OF A PRODUCT.

	(% of respondents)
In-licensing/alliances	45%
Indication expansion	31
Launch acceleration	29
New formulations	28
Combination products	28
Target population expansion	24
Prelaunch activities	22
Legal strategies	22
Change of marketing and sales strategy	21
Comarketing	19
Branded OTC Switch	14
Delivery format expansion	10
Manufacturing	10
Innovation	10
Other	10

Note: Number of respondents: 58 (Respondents could mark up to three)
Source: Capgemini, New York. For more information, visit us.capgemini.com..

ly methodically, and we do it all within the context of our overall portfolio management system.

RAMAN. ROI is certainly measurable. One of the things that most executives will say is that while one of the biggest promises of PLM is to increase top-line growth, they almost always have to justify it based on cost reduction. In the case of the pharma industry, it is difficult to measure because there is a 10-year to 15-year cycle to get a drug to market. How can a company measure something that was deployed six years back and then gauge whether the strategy brought additional NMEs or NCEs to the market? It can be a challenge to measure, but it can be done.

FRANCO. Companies struggle with ROI measurement. One of the key reasons is that companies typically have a series of metrics that measure their ROI, but those measures must be calibrated across the life cycle. The standards and goals in the clinical phases of the life cycle and at launch are going to be very different from those at the mature stage. Companies have to recognize the differences and adjust their investment strategy. For example, revenue growth and market share might be very important for a product in the early stages of its life cycle; at other stages, factors such as new prescriptions might be more telling indicators that should be considered.

BAYNEY. As a strict financial measurement, ROI is not terribly difficult to measure. But ROI should incorporate an estimation of the commercial uncertainty of the product, which, the further its launch is away from the market, is less certain. At J&J Pharma, we try to estimate the commercial value of a product with an 80% confidence level.

Looking Outside and Ahead

The pharmaceutical industry often is said to lag behind other industries, such as automotive, aerospace, consumer goods, and high-tech, in optimizing PLM. According to Capgemini, ironically, it is the pharmaceutical industry's success in sustaining extraordinary profits for many years that has discouraged the adoption of a best-practice approach to life-cycle management. As pharmaceutical company margins begin to tighten, however, experts believe the industry can learn many useful lessons from more consumer-oriented industries.

FRANCO. The pharmaceutical industry is coming to the PLM arena later than other industries because it has relied on a very stable blockbuster model. Now the industry is finding fewer blockbusters, and companies are looking at other industry models and at how other industries maximize the value of their discoveries. Industries such as the consumer-electronics industry or the computer industry are good models. Those industries have product-platform plans followed by a series of derivative line extensions, and then they plan for that platform to be replaced by a subsequent platform with new features and new price points. Those industries have done a much better job in planning how they are going to migrate customers from different platforms and products in the value chain.

PLM Solutions at Work

Invitrogen Turns to Software Solutions to Optimize Life-Cycle Management

Invitrogen Corp. recently selected Agile Software Corp.'s PLM product to optimize its product life-cycle decisions and processes.

Invitrogen managers are implementing the Agile 9 PLM solution to gain greater visibility across multiple locations, enable real-time portfolio-level decision support, and enhance its collaboration capabilities.

With Agile PLM, Invitrogen managers expect to realize significant improvements in several key areas, including global portfolio and program management, new product introductions, change control efficiencies, and research and development processes.

"We are looking for our new product introductions to dramatically drive revenue growth, so it is vital that we deliver high-value, high-quality products on schedule," says Elaine Snowhill, VP of program management at Invitrogen. "Agile provides us with the program management capabilities that we need to promote accountability for completing deliverables, executive-level visibility into our portfolio of programs, and real-time decision support that will allow us to make smarter, more timely decisions."

As the company's life-sciences portfolio and extended network of scientists have continued to grow, collaboration around Invitrogen's products has become increasingly complex. This has created new challenges to bringing groundbreaking, high-quality products to market quickly.

THE AGILE SOLUTION WILL DRIVE VALUE FOR INVITROGEN IN THREE KEY AREAS:

- **Flexibility** — Agile's PLM infrastructure gives Invitrogen increased flexibility, automates cross-enterprise process workflow with preconfigured templates for unique business areas, and enables reporting and ad hoc analyses at the project, program, and portfolio levels.
- **Standardization** — Agile PLM promotes standardization across Invitrogen's multiple sites and users by establishing a single source for the most updated product content; promoting the adoption of processes globally; enabling compliance with regulatory requirements; establishing a clear audit trail for release and change validation; enabling process measurement and continuous improvement goals; and automating secure workflow capabilities.
- **Transparency** — The Agile solutions' user-friendly, graphical, Web-based interfaces provide real-time visibility across business areas and third parties to enable greater collaboration and "virtual project teams." Agile enables reuse of product content, development methods, materials, and best practices and integrates with enterprise applications, such as ERP and MRP.

HISEY. As it relates to a structured, end-to-end life-cycle management plan, the life-sciences industry is a late adopter relative to other industries that have also experienced marketplace pressures. This represents good news for the life-sciences industry in that a lot of innovative thinking and practices have been developed in other industries that can be evaluated to determine if they are appropriate to our industry. We will catch up out of necessity because the government, consumers, and payer organizations are going to drive the industry to achieve scientific performance and business performance. This can only be achieved through life-cycle management in combination with other approaches that companies take to improve the supply chain and R&D.

VISWANATHAN. The PLM market is semi-attractive for the life-sciences industry, but it has not gotten the attention it needs, particularly from the nondiscrete manufacturing industries, such as traditional drug manufacturers and biotherapeutics producers. However, we believe that this is starting to change, as vendors are beginning to create more relevant products to combat the institutional misunderstanding of the capabilities of a PLM solution, such as an increased emphasis on collaborative information sharing platforms, built-in regulatory compliance components, and white boards for internal authorization and tracking.

PHILLIPS. Some pharmaceutical companies are implementing more traditional consumer models and taking a harder look at PLM not just as an end-phase strategy. The industry may have reached the end of the blockbuster age. Pharmaceutical industry leaders may no longer be able to rely on blockbusters as revenue drivers. They need successful life-cycle management of their products. Their jobs depend on it.

NAIGAMWALLA. Although the pharmaceutical industry is distinct, there are some similarities with and lessons to be learned from other industries. The first is the need for continued investment. The second is the need for strong branding to engender brand loyalty and to build advocates. Although these are well-defined strategies, the process is very complex within the pharmaceutical industry. For example, other industries don't require a regulatory process to launch a new version of a car or cereal.

SCHNEIDER. It is really hard to compare the pharmaceutical industry against other industries. Typically, pharmaceutical life-cycle programs span multiple years and come with a high level of uncertainty. These factors are often not the case with most other industries, where the life-cycle time frames are much shorter and can be pursued with more certainty.

HISEY. Looking to 2007, there are 19 drugs that are going to lose patent protection, representing an industry loss of more than $40 billion in revenue. In a nonblockbuster-driven model, those 19 products need to be replaced with about 60 products just to match today's revenue. This does not account for the growth projections for the industry. What this means is that the pharmaceutical industry needs to do things fundamentally differently from what it has done before, and a component of that is embracing a totally new approach to life-cycle management.

DALY. At Takeda, understanding how to opti-

Dr. Bruce Schneider
Wyeth Research

PLM ULTIMATELY GIVES A PHARMACEUTICAL COMPANY MORE INSIGHT AND KNOWLEDGE AS TO HOW A DRUG BEHAVES IN PATIENTS. If done well, a company can clarify or identify more benefits of a product to both patients and physicians, which leads to an opportunity to generate more revenue as a company expands the potential utility of a compound.

mize the value propositions for a compound is the No. 1 thing we try to do. The industry has been trying to squeeze development times, and they are probably as short as they can possibly be. Now the industry is evaluating whether it can appropriately extend commercial lifetimes or, more importantly, expand the opportunity for products during their lifetimes so that more patients can benefit.

NAIGAMWALLA. I have noticed that pharmaceutical companies are becoming more proactive in their PLM strategies because they are realizing that there are only so many blockbusters. To meet the expectations of investors and Wall Street, company executives need to maximize the value of the assets that they have, and that speaks to a greater need for PLM.

BAYNEY. As patent erosion becomes more and more of an issue for all pharmaceutical and biotech companies, it is imperative that we try to think about better ways to manage the life cycle of the product earlier. This can be achieved by a variety of mechanisms, including prospecting for expanded usage of a potential product based on its mechanism of action; investing heavily in drug-delivery platforms; and investigating drug combinations for comorbid states. I think that the role of early clinical development will soon become more pivotal than it has ever been in the history of this industry.

SCHNEIDER. Recently at Wyeth, there has been an increased emphasis on the drug-development pipeline and relatively less emphasis on life-cycle management because of the mix of our portfolio of existing products. This has evidenced itself in the mix of such projects in our portfolio and in the mix of dollars allocated to each area. But we do spend a lot of time on this, and our process for evaluating these strategies is a very intense and elaborate one. Throughout the industry, the emphasis on life-cycle management is somewhat dependent on each company's situation. ✦

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmavoice.com.