Robin Robinson

A Changing Market ENVIRONMENT Requires New PLM Strategies

If brands are to be successful beyond the launch phase, product management needs to start earlier and cross silos more frequently.

In a market environment that is increasingly value-based, the industry must begin to review its product life-cycle management (PLM) strategy and prepare for more effective ways to cope with the evolving challenges when it comes to pipeline maintenance. For example, companies need to start implementing PLM earlier than ever before. Instead of approaching PLM as a solution to patent expiry, companies need to consider the complete life cycle, and view PLM as a way to best take advantage of all stages of the product.

Today, companies that don't plan their life-cycle options early — starting at the end of Phase I/beginning of Phase II — will struggle. Our experts say starting earlier will prove to be an organizational challenge, and hence, a company's culture will become equally important and require a new emphasis on leadership development that will create the conditions necessary for product breakthroughs.

The primary focus on clinical trial management in drug development will broaden to encompass more comprehensive approaches and the entire life cycle.

Current Trends in PLM

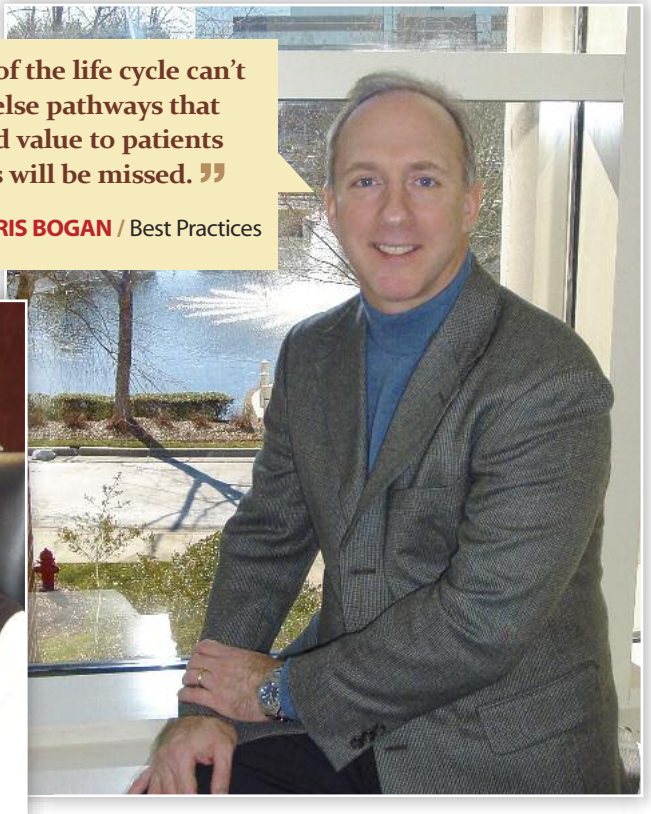
The framework of product life-cycle management has changed drastically over the past 10 years, and will continue to evolve. Strategies now focus more on collaborating with entities in and outside the company, starting management earlier in the development stage, and shifting the focus of former business models to align with earlier intervention.

In summary:

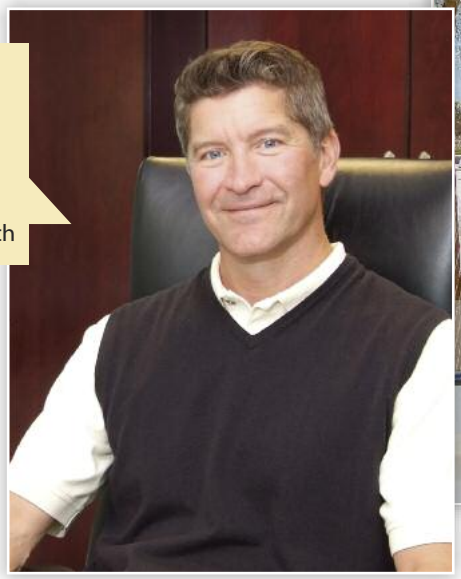
1. PLM strategies need to start earlier, go longer
2. Collaboration with internal and external partners is key to PLM
3. Complexity in the marketplace will drive adoption of PLM technology solutions

RON BURNS. PROTONMEDIA. The industry is clearly suffering from a pipeline problem. There are two strategies being employed to manage this issue. The first is the mega-merger, where a company's pipeline is part of the acquisition process. This comes with its own challenges and risks, and will probably work to some degree. The second strategy is much more intriguing, incorporating collaboration across company boundaries, and creating an ecosystem of partners in academia, the start-up community, the CRO space, etc. Since developing breakthrough products is such a challenge, my instincts tell me that in 20 years the next generation of innovative products will have come out of the second strategy. This type of collaboration will be enhanced and enabled by the availability of virtual collaboration environments as it allows teams from any geographical location to connect and build across organiza-

> "The back end of the life cycle can't be neglected, or else pathways that might have added value to patients and shareholders will be missed."
>
> **CHRIS BOGAN** / Best Practices



> "Commercial involvement and investment decisions must start much earlier in the product development phase."
>
> **ROB BAZEMORE** / Janssen Biotech



FAST FACT

RESEARCH SHOWS THAT PHARMACEUTICAL COMPANIES SPEND ABOUT 19% OF THEIR TOTAL REVENUE ON ACTIVITIES THAT FALL UNDER THE HEADING OF PHARMACEUTICAL LIFE-CYCLE MANAGEMENT.

Source: Visiongain

tional boundaries, and align strategy to execution.

CHRIS BOGAN. BEST PRACTICES. Much like change occurs in nature, PLM is changing in bursts and stops, rather than along a smooth, continuous evolutionary curve. Recent changes in the healthcare world seem destined to create interesting evolutionary bursts for PLM. For example, many companies have recently started to create mature product groups, formulate specialty products for unique markets, create late-stage fixed dose combinations, formulate prescriptions to over-the-counter products, or start generic units. Changes in biopharmaceutical and medical device business models are stimulating changes that ripple into life-cycle management. In short, the back end of the life cycle is becoming much more interesting and complex. It promises many more pathways to create value.

ROB BAZEMORE. JANSSEN BIOTECH. Commercial involvement must start much earlier in the product development phase. It has become critical to incorporate customer insights, payer dynamics, and other commercial inputs into product development and portfolio decisions earlier in the process. The clinical investment required to execute robust life-cycle management strategies with biologics is higher. A decade ago, with an approved biologic product, new indications could be obtained with relatively small clinical trials. Today, larger efficacy and safety studies are needed to obtain regulatory approval even in diseases that have lower prevalence. Life-cycle management investment decisions are also being made much earlier in the process. New molecular entities being developed today not only have funded lead indications, but may also have as many as two to three life-cycle indications actively enrolling patients before the compound is approved.

ANDREW HUNTER. KALYPSO. PLM is about managing the entire product life cycle. The pharmaceutical industry is different from many industries because of the focus on a small number of high-value products with typically the same formulation in every country, so the prod-

EXPERTS

ROB BAZEMORE. President, Janssen Biotech Inc., a company that is focused on advancing the standard of care in immunology, oncology, urology, and nephrology, and one of the Janssen Pharmaceutical companies. For more information, visit janssenbiotech.com.

CHRIS BOGAN. CEO, Best Practices LLC, a research, consulting, database, and publishing firm. For more information, visit best-in-class.com or email cbogan@best-in-class.com.

RON BURNS. CEO, ProtonMedia, which develops ProtoSphere, a virtual collaboration environment for high-performance workplaces and a virtual environment for collaborative PLM in life sciences. For more information, visit protonmedia.com.

ANDREW HUNTER. Senior Manager, Kalypso, a consulting firm that helps clients drive profitable, sustained results. For more information, visit kalypso.com.

MIKE REA. Principal, IDEA Pharma, which specializes in path-to-market strategy at Phase II, transforming the probability of commercial success for any molecule. For more information, visit ideapharma.com or email mike.rea@ideapharma.com.

Collaboration and Integration: PLM Best Practices

Since much of the profits from a drug are realized very early on in market exclusivity — and that period is ever-shrinking — it is more important than ever that pharmaceutical companies have a complete, integrated strategy in place starting in prelaunch. Collaboration and integration, although new to the pharmaceutical PLM model, will become more crucial to a product's success. Our experts outline their best practices for a carefully integrated PLM strategy.

ROB BAZEMORE
JANSSEN BIOTECH

"One best practice is the creation of cross-functional, integrated product development teams that form early in a product's development and extend well beyond the product's launch throughout its life cycle. Close collaboration between commercial, R&D, manufacturing, regulatory, and other stakeholders is essential."

CHRIS BOGAN
BEST PRACTICES

"Some hallmarks of excellence or best practices for PLM might include developing a PLM process that is standardized across the organization and incorporating the duties related to the process into job descriptions as well as embedding them as part of the performance review for brand heads and product franchise leaders. The PLM process also needs to be continuous so it maintains relevance during development, brand building, and later stages. Training is another solid practice, and companies should designate PLM experts to coach, train, and review PLM activities, and create a PLM training curriculum to develop the competence among global and country-unit marketers."

RON BURNS
PROTONMEDIA

"A very important best practice would be for large companies to reevaluate how they view learning and training in their organizations. Learning is another area that has been hit by budget cuts in recent years, but learning is not a drain where money goes. Rather, it is the key mechanism by which knowledge is transferred in a very knowledge-intensive industry. Of note when designing a solid learning program, many of the goals and objectives of collaboration teams are actually learning design problems. The learning teams and the collaboration teams have the same problem, but they often are siloed from each other from an organization perspective, and are unable to help each other. When put together, they become a strategic force within an organization to drive execution."

ANDREW HUNTER
KALYPSO

"Patent expiry is placing enormous pressure on the industry and is the main reason why PLM is so important. Cost-reduction programs, mergers, and acquisitions can only go so far in maintaining profitability. The true answer lies in bringing new medicines to patients and solving the R&D productivity challenge. The front end of the life cycle is a strong focus area for now, but PLM is about managing the entire life cycle. Educating the industry on the true definition of PLM and the potential benefits is the most critical step today. Companies taking a strategic, evolutionary approach to PLM are the most successful in generating returns on their PLM investments. We recommend a think big, start small, build incrementally approach to PLM. Developing a long-term PLM strategy and initial road map centered on solving a single, high-impact business problem will enable pharmaceutical companies to use this as the foundation on which to build a comprehensive solution."

MIKE REA
IDEA PHARMA

"A best practice is increasingly about generating several path-to-market options early on at Phase I or the beginning of Phase II at which time all of the opportunities and risks can be evaluated and assessed side-by-side as options before any one path is chosen. This approach allows companies to lay out all of the future life-cycle plans as part of each option. This is important, as it allows a company to evaluate, for example, which indication sets the price and the market access, which indication builds on that, how formulation changes along the way can take advantage of longer studies, etc. This eliminates much of the wastefulness inherent in a panic around the wholly predictable end-of-patent period. If a pharmaceutical company compared itself with Apple, and the way that company continues to innovate around a platform in an incredibly competitive space, it could learn a lot of lessons."

uct itself is the same even if there are differences in packaging and labeling. In fact, the complexity of maintaining the packaging and labeling specifications is driving the early adoption of PLM technology solutions in the pharmaceutical industry. Fortunately, the industry will be able to apply leading practices and learn from other industries.

MIKE REA. IDEA PHARMA. Life-cycle management has changed in many companies from being a solution that was bolted on at end of patent life to an idea that is considered in earlier phases of development. This is a powerful idea, as it changes the previous focus on the role of PLM to blunt or mitigate entry of generics to a new focus that enables sequences of launch. This enables companies to stop aiming at a mass-market blockbuster-type launch — where many fail — and move to one that is appropriate for a product that is finding its legs. Gleevec, for example, is a blockbuster drug precisely because it launched into a high-value, perfect-fit space before new indications were added. Companies should be asking how soon is too soon to begin thinking about where else the product could go. The answer to that is usually pretty self-evident. So, the changes in the past five years reflect the need to stock portfolios with de-risked options; to take a more domino-like approach, where success in one indication can lead to another versus the older multiple shots on goal approach, which was badly named because it usually meant multiple shots on multiple goals, which in turn created inevitable risk.

What the Future Holds

As the trend toward earlier-phase PLM strategy strengthens, the forthcoming strategies will include a continued focus on extend-

PLM Adoption Factors

According to Andrew Hunter at Kalypso, PLM technology solutions have been widely adopted by most industries, but the pharma industry continues to lag behind in its efforts. However, he predicts there are several factors that are increasing the complexity and volume of product information, which, in turn, are raising the industry's level of interest in PLM over the next five to 10 years, such as:

- More specialty and biologic products in the pipeline;
- Emergence of personalized medicine products that require companion diagnostics;
- An increase in the collaborative development of products with external partners.

Source: Kalypso. For more information, visit kalypso.com.

> "PLM technology solutions have been widely adopted by most industries, but the pharmaceutical industry continues to lag behind in adoption."
>
> **ANDREW HUNTER** / Kalypso

> "The new model of PLM strategies will include collaborations across company boundaries and create an ecosystem of outside partners."
>
> **RON BURNS** / ProtonMedia

ing life cycles, more path-to-market planning, and an emphasis on monitoring health outcomes.

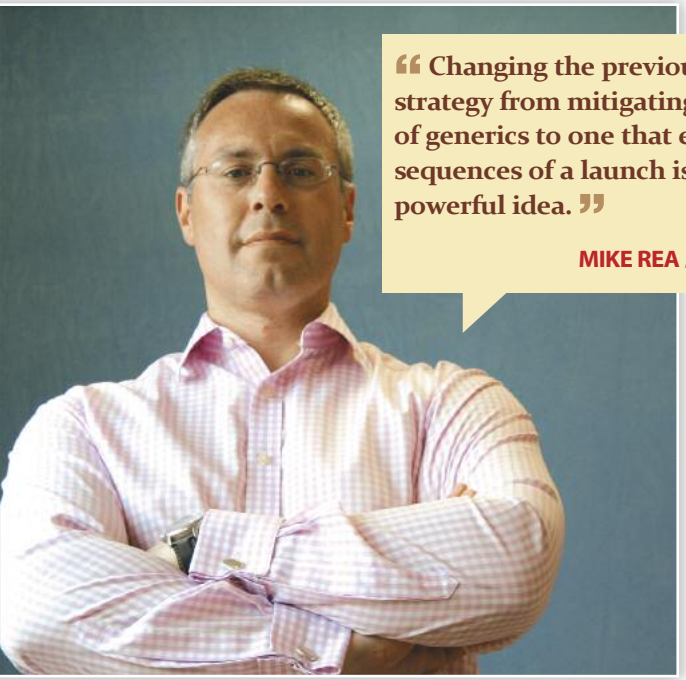
In summary:

1. Increased adoption of PLM in industry
2. Data requirements shift to outcomes and reimbursement
3. Deliberate planning will include commercial factors

MIKE REA. IDEA PHARMA. In the next five to 10 years, companies will become even more aware of mitigating the risk that they have traditionally ignored — commercial risk. Until now, the industry has prioritized technical and regulatory probability of success, in many cases to the detriment of the commercial proposition — producing the statistic that only one in five products returns its investment. Planning life cycle actively based on commercial parameters as well as clinical parameters can mean that as success follows success, there is a deliberate plan, rather than haphazard accumulation of indications. So, more and more companies are now planning a path-to-market strategy with a view to first launch, subsequent launch, and beyond, with cumulative evidence and changes in formulation/regimen, etc., over time.

ANDREW HUNTER. KALYPSO. PLM technology solutions have been widely adopted by most industries, but the pharmaceutical industry continues to lag behind. However, this is changing as companies begin to understand the potential benefits, and we expect there to be increased adoption of PLM technologies in the next five to 10 years. Life-cycle management for most pharmaceutical companies today is all about marketed products and how to either extend the patent life or find new indications to expand the commercial potential of these products. This is understandable with so many blockbuster medicines close to patent expiry, but the fact is that each product spends 50% or more of its total patent life in the research and development phase.

ROB BAZEMORE. JANSSEN BIOTECH. Looking forward, in the next five to 10 years, data requirements needed at the time of approval and launch of a product or for new life-cycle indications will continue to expand. Although regulatory authorities may require the same efficacy and safety data, customers and payers will demand outcomes data, comparative data, and other information to determine reimbursement and comparative pricing. Also, companies will increase investment in services to maintain and support the use of brands and more attention and resources will be dedicated



> **"Changing the previous PLM strategy from mitigating the entry of generics to one that enables sequences of a launch is a powerful idea."**
>
> **MIKE REA** / IDEA Pharma

to introducing solutions for patients, not just products. Finally, as biologic markets have become more attractive, and crowded, the cycle times over which a product enjoys exclusive or differentiated positioning will shorten.

PLM Identifies High-Risk Periods

While risk is inherent all along the product life cyle, there are certain points that may be more vulnerable to risk and challenges than others. From regulatory hurdles, communication disconnects, and losing focus on the PLM, these minefields must be managed carefully with a strategy that has been conceptualized well in advance and with a steadfast focus throughout the life cycle.

In summary:

1. The front, middle, and back end of PLM require equal focus

2. Patent protection and new indications create hurdles

3. Decisions need to be made early

ROB BAZEMORE. JANSSEN BIOTECH. For biologics, key risks lie in several areas, including patent protection on new products brought to market and how long that protection extends. The regulatory approval path for new indications, particularly in high unmet need areas and rare diseases, is another hurdle to be overcome. The continuing lack of incentives to invest in innovation also comes into play, as well as uncertainty about future pricing and the reimbursement landscape.

CHRIS BOGAN. BEST PRACTICES. There are three life-cycle points that create some risk of neglect or missed opportunity. First, there is a risk that early PLM is just about indications or brainstorming without substantive planning and market analysis. Second, there is a risk during brand growth that PLM is lost or forgotten from the brand plan among all the tactical activities of growth in a competitive market. Third, there is a risk that the back end is neglected and that pathways that might have added value to patients and shareholders are missed or forgotten.

RON BURNS. PROTONMEDIA. I think the biggest risk right now is the disconnect between well-articulated strategies at the senior level and the culture that is developing to implement that strategy. As the mega-merger model has taken hold of a significant portion of the industry, it is clear that layoffs and downsizing will be needed. This creates a culture of fear within an organization. So instead of navigating to the goals of the organization, employees navigate according to Maslow's hierarchy of needs and work on survival. The life-sciences industry's HR departments used to have leadership development programs to manage issues such as these, but HR functions have also been downsized. Life-sciences companies will need to put the human back into the human resources department because many of its most vexing problems, including PLM, are soft and human.

MIKE REA. IDEA PHARMA. The room to maneuver is lost the further along the life cycle the product goes; eventually the product becomes limited to a change in presentation or dose. The biggest risk is that characterization of the molecule and its range of effect, its potential for efficacy in a range of conditions, and dosages are not evaluated early enough. The industry is increasingly being directed by value and perceptions of value. The earlier transparent ever-greening approaches and extensions were always poorly perceived by payers and will be less tolerable as we go forward. If life-cycle management becomes about adding indications, formulations, regimens, combinations, etc., to the product, the trajectory for growth within the patent window will become increasingly limited as time goes on. Decisions that need to be made around the IP for a product can end up making billions of dollars of difference, but they need to be made creatively and in time to execute.

ANDREW HUNTER. KALYPSO. The industry has relied on a small number of blockbuster medicines and it is struggling to develop replacements as patents expire and revenue disappears. R&D budgets have been growing for years yet are now being reduced, so companies have to bring innovative new medicines to the market faster and with fewer resources. The biggest challenge for the industry is without question at the front end of the product life cycle. It takes several years to develop a new product, so companies need tools to ensure efficient collaboration and to enable sharing of product information to minimize R&D cycle times and get new medicines to patients faster. PLM technology solutions have the potential to do this better than existing tools, but it will also require a change to processes and mindsets as product information becomes a company asset and not owned by any single function. PV

Three PLM Trends

Best Practices expects there to be three dramatic changes in the way PLM is conducted in the very near future. When done well, these activities will add hundreds of millions or even billions of dollars of value to a blockbuster franchise, says Chris Bogan, CEO of Best Practices.

Mr. Bogan predicts these three transformations in the coming decade:

1. More emphasis will be given at the early product development stage to the full life cycle to accurately gauge a product's lifetime potential. This will stimulate better and more thoughtful early PLM planning.

2. PLM skills will be developed both in the global strategic marketing organization and at the country-level brand unit. This will stimulate better training and greater competence in PLM.

3. Back-end PLM will become much more interesting and crucial than in past generations. Mature products may one day become the domain of fast-track talent, rather than a backwater for brand marketers. Strategic PLM activities that can win top talent could include planning for life extensions, readying retail products to grow in places like China and India, or creating fixed-dose combinations to create back-end franchises.

Source: Best Practices.
For more information, visit best-in-class.com.

A Sound Investment Strategy — American College of Physicians Custom Advertising Programs

CME and Promotional Special Advertising Inserts

Enclose your promotional advertisement, educational monograph, or educational CD-ROM as a ride-along with *Annals of Internal Medicine*, *ACP Hospitalist*, and *ACP Internist*.

Belly Band and Cover Tip Programs

Place your message across the covers of *ACP Internist* and *ACP Hospitalist* with these programs. Both programs can be secured on an issue-by-issue basis and placed on ACP member subscriptions or sent to your targeted list.

All ride-alongs are subject to Publisher's approval.

ACP
American College of Physicians
INTERNAL MEDICINE | *Doctors for Adults*

Contact:
Kevin Bolum, Director, Advertising Sales
at kbolum@acponline.org or 215-351-2440
Kenny Watkins at kwatkins@watkinsrepgroup.com
or 973-785-4839

ADS1004-6