

Pharma **VOICE**

THE FORUM FOR THE INDUSTRY EXECUTIVE

YEAR in **PREVIEW**



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What's Ahead for 2012

Our readers identified the top trends and game changers they expect to define the various industry sectors in the coming year.



JOHN BLAKELEY
Executive VP and Chief Commercial Officer

ERT, a clinical research service provider that assesses the safety of newly developed drugs by major pharmaceutical companies. For more information, visit ert.com.

I strongly believe that the life-sciences industry has to accelerate the change in business model, which gets away from the traditional and moves strongly toward a new era.

The need to control every aspect of the drug development process is not as strong as was previously thought. Recognition that third-party partner

organizations are a valuable variable cost asset will bring strong change to the process of developing new drugs.

The strategy from my point of view is clear. The life-sciences industry needs to decide where to draw the line around intellectual property and everything beyond should be outsourced.

The benefit of strong strategic alliances means variable cost models for pharmaceutical companies and forces CROs as well as other third-party vendors to seek ever-more creative and cost-effective ways to achieve the end result.

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JAY CARTER, R.PH.
Senior VP, Director of Strategy Services

AbelsonTaylor Inc., an independently owned full-service healthcare advertising agency. For more information, visit abelsontaylor.com or email jcarter@abelsontaylor.com.

2012 is the year of the cliff. Many multibillion dollar brands will experience a loss of exclusivity, affecting not only their respective pharma companies, but also competitive players in those major markets, by offering attractive generic options for healthcare providers and their patients. We've known it's been coming for some time, and organ-

izations will finally put their well-honed strategies to the test to address this change.

Not to be glib, but effective approaches need to be implemented. These approaches will be as different as the myriad of pharma companies affected. Each has different strategic challenges and opportunities. What's more, this is not a zero-sum game; companies going through the year of the cliff can "win" in a variety of different ways. The one commonality they all face is an unmet customer need: high-quality healthcare at an affordable cost.

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TIM DAVIS
CEO

Exco InTouch, a provider of mobile communication solutions for patient recruitment, retention, compliance, ePRO, eDiary, and post-marketing studies. For more information, visit excointouch.com.

In line with E&Y's latest report on Pharma 3.0 there will be a requirement to not just identify the drug with the highest potential revenue, but also to develop the drug with the most effective health outcome for the patient. This is not a new area for clinical research, but it is becoming increasingly more important with increased rigor demanded by governments, regulatory bodies, and patient groups alike.

To assess health outcomes there will be increased activity in monitoring and collecting of data from the patient while at home. This will rely more heavily on self-reported data from the patient and real-time reporting from medical devices. The Pfizer REMOTE study has demonstrated that the industry can find new and innovative ways of working to support more efficient clinical research.

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NEIL DE CRESCENZO
Senior VP and General Manager

Oracle Health Sciences, Global Business Unit, a deliverer of comprehensive, end-to-end suite of software applications for clinical development and healthcare. For more information, visit oracle.com/healthsciences.





In 2012, life-sciences organizations will continue to navigate the sunset of patents for blockbuster drugs, face an increasingly complex regulatory climate, and prepare for the roll out of major provisions of healthcare reform.

In this environment, improved agility and operational efficiency across the enterprise are essential, including in the research and development pipeline. Life-sciences organizations, in the year ahead, will be steadfastly focused on finding new ways to accelerate and improve the productivity of their research and development (R&D) pipeline to improve their ability to bring new therapies to market faster and more affordably.

As important, life-sciences organizations will be focused on advancing the realm of personalized medicine. In this environment, they will seek, in particular, to make strides in enabling the secondary use of health information, which is essential in advancing into a new era of targeted therapies.

To advance both improved R&D productivity and enablement of personalized medicine, life-sciences organizations must embrace collaboration, social networking, mobile technologies and analytics delivered through whatever IT delivery mechanism the customer prefers, such as the cloud or on premise. The announcements we made on October 6, launching the Oracle Social Network and Oracle Public Cloud, are examples of how major companies are stepping up to support this evolving need.

To improve R&D productivity, many life-sciences organizations are establishing virtualized clinical development environments, which require collaboration with many partners, including universities, CROs, and other biotech or pharmaceutical companies. The technology organizations use to support this new age of virtualized clinical development must, in turn, evolve as well. Today's organizations require IT solutions that enable them to seamlessly connect with internal and external partners and capitalize on synergies.

Collaboration with healthcare providers is essential for the secondary use of health information. To facilitate this collaboration, life-sciences organizations and their healthcare partners require solutions that enable the aggregation, normalization, and anonymization of health information and powerful analytics that drive new insight.

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FRANCES L. DEGRAZIO

VP, Marketing and Strategic Business Development

West Pharmaceutical Services Inc., a global provider of innovative solutions for injectable drug administration. For more information, visit westpharma.com.

For 2012, the pharmaceutical industry will need to adjust R&D and business models to deal with the growing importance of specialty pharmaceuticals, including sensitive biopharmaceuticals, and the growth of generics. Differentiation will be key for the generic market, and unique container closure and delivery systems are often an excellent way to set generics apart from their brand counterparts.

Improving efficiency for specialty drugs is critical in the development and manufacturing process, so the ability to minimize risk in development and show flexibility in manufacturing and supply chain is needed due to the fact that these products are lower in number of units produced. On the other hand,

generic drugs are typically offered at a larger volume and at much lower pricing, so the industry will need to consider not only efficiency, but also how to provide high-quality equivalency at a lower price. Effective packaging selection early in the development process can be key for generic manufacturers who need to facilitate efficient regulatory review while still ensuring high quality and suitability for their product.

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DENISE (DEEDEE) DEMAN

Founder, Chairman, and CEO

Bench International, a global, retained, executive recruiting and consulting firm providing senior talent to life science institutions. For more information, visit bench-international.com.



The life-sciences industry would be well-served by going back to the old-school basics — focusing on the patient. I'm witnessing an environment now that's tantamount to why Rome fell. Many companies are too focused on short-term objectives instead of taking the long view centered on serving patients, consumers, and their families. I believe it is critical for the industry to return to, "Do well and right by human beings and the money will follow." By remaining keenly focused on the real target — improving the lives of patients — this sector will prevail and flourish with dignity.

Going back to the basics and focusing on a patient-centered approach is easier said than done. It often requires leaders to make unpopular choices and painful decisions. And it certainly requires much more than tossing around words like "transformation" and "innovation." The more they are spoken, the less they are accomplished. The act of living these words is when they take on real momentum.

Life-sciences companies need visionary, courageous, and passionate leaders who are willing to learn from the mistakes of the past, so as not to make them in the present and future. These are the kinds of leaders who employees strive to follow, even in the worst of times. They lead by example and insist on the same from others — from the C-suite to the manufacturing floor. They foster healthy debate and are intolerant of excuses. They know that no drugs or products were ever created via tacit agreement. Breaking the current systemic malady of command and control isn't easy, but I believe it's the only way life-science companies will be able to return to a more patient-centered focus.

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HIEN DEYOUNG

VP of Human Resources

Acucela Inc., leverages promising science in visual cycle modulation to develop new methods for treating blinding eye diseases that affect tens of millions of people worldwide. For more information, visit acucela.com.

Attracting, cultivating, and retaining the best talent remain the desires of most companies across industry. In today's competitive business environment, the path to success lies more in a company's employee base than ever before.



The best and most successful companies realize these notions and go about the process well. So, the question becomes: how to do it well? We believe that doing it well means adopting a philosophy that promotes the idea that each person's contribution can and does strengthen the unique fabric of a company and culture.

What the life-sciences industry has going for it is simple: we wake up every day with one mission in mind develop safe and effective therapies for the patients around the world. For us, that means developing answers for blinding eye diseases. So, we are intent on attracting those who share in this passion. In addition, we promote a culture that

seeks to ensure that everyone who needs to be at the table is present, regardless of rank, politics, etc. I would also argue that we need to look for the right elements, in our respective companies, that produce engaged employees. What would happen if we start looking at the results the employee produces and a dialogue ensues from that perspective?

My experience tells me that an engaged employee feels empowered, has a sense of ownership, and is able to make strong, informed, and efficient decisions.

As growing biotechnology and pharmaceutical companies continue to thrive — yes, there are companies doing so despite the challenging economy — we must remember that it's not about just hiring more people, but about hiring the right people and then giving them the tools, support, and culture necessary to contribute to the company's future success.

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RICK KEEFER
President and CEO

Publicis Touchpoint Solutions, a provider of multichannel message delivery solutions to the life-sciences industry. For more information, visit touchpointsolutions.com or rick.keefer@touchpointsolutions.com.

Cross-channel sales and marketing is an essential step for the industry to move into the new life-sciences business model. This approach is only effective when functional areas and franchise silos are broken down to fully optimize preference- and behavioral-based approaches. A powerful backend database and ongoing analysis is also needed to provide the optimal ROI.

Digital is now ubiquitous and rapidly changing. We believe that most field sales teams will soon be iPad-enabled. Innovative digital channels, such as

live video detailing, also provide intriguing and highly effective ways to reach HCPs that can augment more traditional channels.

As an industry, we can do so much more to impact patient compliance and improve health outcomes.

Highly effective adherence and retention programs are increasingly appealing as they provide a win-win for patients, caregivers, HCPs, payers, and the program sponsor.

Much of our industry's promotional messaging has been product features and benefits focused. As health outcomes become increasingly important, message points will concentrate even more on what this means to the patient and how it impacts health outcomes.

MATT KIBBY
Global Operations Lead

BBK Worldwide, a global provider in the field of patient recruitment. For more information, visit bbkworldwide.com.



In focusing on the top trends that will impact global pharma operations in the next three to five years, mergers and acquisitions will certainly continue to drive sponsor efforts to bolster drug development pipelines.

A related and growing trend will be the collaboration between major pharmaceutical sponsors and smaller entities in the co-development of new compounds and expanded patenting of existing compounds. The ever-entrenched roll of global CROs in the major pharma business model is the prime example of this trend. But research assistance can come from many varying contracted vendors that also assist with a spectrum of services from staffing to supplies, storage, distribution, and communications and public relations.

Smaller research-focused entities are helping some smaller sponsors focus on high margin, viable, and high profile clinical categories, such as oncology and virology. Meanwhile, some top echelon pharma companies are sprinting to the other side of the spectrum. They're making major pushes to diversify into consumer healthcare product fields to supplement research enterprises with steady cash flow from established brands, again, some acquired through mergers and acquisitions.

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JEFF KOZLOFF
Co-founder, President, and CEO

Verilogue, uses technology to capture and analyze live, in-office physician-patient dialogue used by the healthcare industry to further enhance its understanding of the numerous diseases that face society today. For more information, visit verilogue.com.



As company growth percentages continue to slow, large pharma organizations are continuously downsizing and reorganizing to stay competitive. This has created tremendous inefficiencies at the micro and macro level. Internally, morale is negatively impacted and uncertainty over job security and budget cuts dampens productivity. This malaise also effects external partners and new investment capital, as the entire industry contracts. Cutting-edge innovation is still lauded on paper, but the long-term discipline needed to embrace innovation is challenged by every quarterly earnings call.

The industry needs to move beyond the molecule and include more value-added services. Life-sciences companies need to embrace a selling model that places the customer's agenda and needs over their own. Successful companies are embracing customer acumen principles and training reps to be more customer- vs. product-centric.

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NANCY LURKER
CEO

PDI Inc., a healthcare commercialization company providing insight-driven promotional services. For more information, visit pdi-inc.com.



Life-sciences companies, whether private or public, are particularly tasked to develop new commercial models and streamline operations to offset the revenue losses from blockbusters going off patent and the longer lead times required to bring new molecular entities to market as a result of increased regulations.

The fact that new drugs in the pipeline will serve the needs of specialized conditions also requires new efficiencies and new models to achieve profit objectives. And of course, the great unknown is healthcare reform.

In this time of information overload, it is critical that we find a way to reach our customers with material they need and want. We must break through the clutter and engage them with our products' value propositions.

Traditional physician access via personal detail continues to decline; consumers are faced with too many choices in seeking information. Therefore, we must think outside the box to achieve an interaction where the physician and consumer will form a connection, regain trust, and re-engage with us.

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TIM O'ROURKE, PH.D.
Chief Research Officer

Healogix, a global healthcare marketing research and consulting firm. For more information, visit healogix.com.

This year the increasing cost of healthcare outpaced income growth. This will only increase the building pressure to show that every healthcare dollar is well spent.

As an industry we need to stand up for the value our products provide. We need to get the message out that dollar-for-dollar medication, with proper prescribing and compliance, still provides the biggest bang-for-the-buck in healthcare.

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JOHN M. VANN
Executive VP, Corporate Development

Chiltern, a full-service, global CRO with extensive experience in the management of Phase I-IV clinical trials across a broad range of therapeutic areas and contract staffing solutions. For more information, visit chiltern.com.

Containing costs while advancing quality and delivery remain constant objectives year after year because technology and innovation continue to drive new benchmarks of performance for both pharma/biotech companies and CROs. The challenge is to manage and control

implementation.

The continuous review and assessment of current technologies in use and review of performance metrics leads to continuous process improve-

ment. Data to support changes in course and direction with regard to process and retooling of systems based on these data allow for greater responsiveness to market demand for greater oversight and control as well as quality and delivery.

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STEPHEN WRAY
President and CEO

Cadient Group, a digital healthcare marketing agency serving a diverse range of industry markets and stakeholders, including pharmaceuticals, biotechnology, medical devices, hospital/healthcare systems, institutions, and associations. For more information, visit cadient.com.



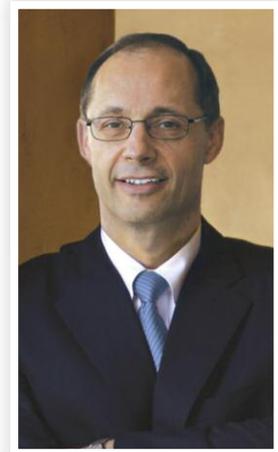
The pharmaceutical industry will further integrate mobile into promotions and everyday office practices and tools. It is long overdue. Mobile has already revolutionized the industry from the outside in, but mobile will continue to transform the healthcare industry from the inside out, when the industry harnesses mobile's true potential in 2012.

The industry will continue to reinvent and restructure itself. Large pharmaceutical companies will reinvent themselves as specialty business units. Specialty bio and pharmaceutical companies will continue to recreate themselves as R&D and commercialization organizations. Digital will be the great equalizer among all, no matter how the company or drug is rebranded, reinvented, or reorganized.

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JOSEF VON RICKENBACH
Chairman and CEO

Parexel, a global bio/pharmaceutical services organization that helps clients expedite time-to-market through our development and launch services. For more information, visit parexel.com.



The reformation of healthcare around the world is an important trend that will impact the industry over the next five years. Costs are being driven skyward by many demographic dynamics such as longer life expectancies and the healthcare needs of baby boomers. The biopharmaceutical industry needs to re-define itself within the context of the changing healthcare environment.

The prices of biologics are high, and there is a transition away from blockbuster to niche-buster drugs. It will take a lot more to move the clinical needle significantly while reducing costs and the same approach to development won't work. It is in the best interest of pharmaceutical industry leaders to accept a new role tied to the larger healthcare pie. ^{PV}



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