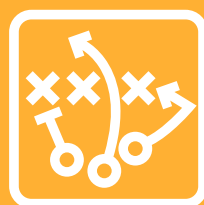


2013 LIFE SCIENCES TRENDS

Know who you are, define the strategy, and align your operations and actions.

The challenges and opportunities facing the life sciences industry have changed very little in the last five years: drug pipelines and R&D spend continue to shrink, growth has shifted overseas, generics continue to increase competitive pressure, and the regulatory environment continues to evolve. However, it is those companies who are able to define who they are and align their business around their core strengths that will emerge as leaders.



CORPORATE STRATEGY

Mega-mergers are out, spin-offs and partnering are in. Is your company prepared for the results?



SUPPLY CHAIN

Does your supply chain have the agility to adapt to the emerging global marketplace AND increasing concerns about theft, counterfeiting, and drug safety?



QUALITY

Companies should take the opportunity of an uncertain regulatory future to improve their core quality systems and processes.



EMERGING MARKETS

Significant opportunities in emerging markets include challenges with infrastructure, local government control, and pricing pressure.

HIGHLIGHTED TRENDS



CORPORATE STRATEGY

Mergers and acquisitions are not going to slow down in 2013 for the industry; spinoffs are also on the rise as companies continue to refine their portfolio of products and define who they are as a business. However, the era of the mega-merger has been left behind; instead, more targeted, precise acquisitions will take place. Over the last year the industry has seen some big spin-offs: Abbott Laboratories and its spin-off AbbVie; Pfizer and the animal health business Zoetis, and Pfizer's sale of its Nutritional business to Nestle; expect to see more mergers, acquisitions, and divestitures as life sciences companies refine and execute their strategies.

Corporate Identity

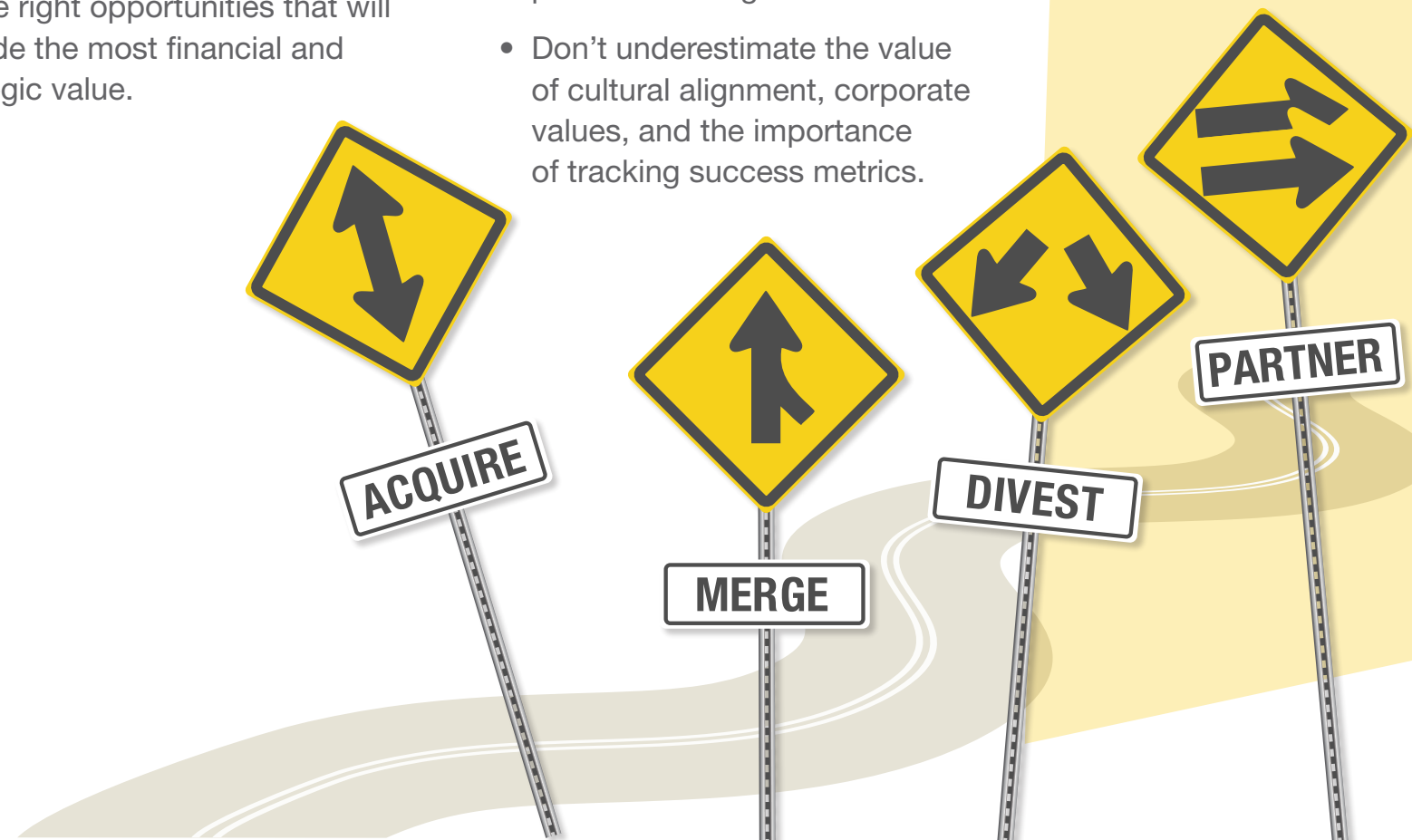
Companies will continue to define whether they will provide a diversified portfolio of products, addressing markets from cradle to grave, or maintain a core group of products, addressing a specific sub-segment and spinning-off non-core business to drive greater shareholder value and more efficiently run businesses. Strategic partnerships will be a key part of both these strategies and will require that companies focus on the right opportunities that will provide the most financial and strategic value.

Align Strategy with Action

- When considering partners or acquisition targets consider the value they provide in expanding the core therapeutic product portfolio, or the opportunity to enter into new markets.
- Align the integration strategy or partnership agreements with the original acquisition or partnership strategy. Achieving the quantifiable benefits originally desired will depend on this alignment.
- Don't underestimate the value of cultural alignment, corporate values, and the importance of tracking success metrics.

MEASURING SUCCESS

- Shareholder value should increase through acquisition, partnerships, or divestiture of assets.
- Define, measure, and refine the desired outcomes of each deal through negotiations and execution.
- Frequently revisit success metrics during integration to ensure expected outcome.



SUPPLY CHAIN

In 2012, pharmaceutical industry media coverage was riddled with incidents of drug theft, counterfeiting, and adulterated product, which has led to a new challenge for companies: ensuring patients have a high level of confidence in the integrity of pharmaceutical products. At the same time, companies are recognizing the vast opportunities for growth in emerging markets like Russia, China, and Brazil. These challenges and opportunities call for a supply chain that is both agile AND compliant, one that is aligned to their business strategy, products, and distribution channels.

Security and Regulation Require Action

Public perception of drug safety is putting increased pressure on lawmakers to establish regulations that require tighter controls on packaging and distribution chains to ensure the integrity of the products delivered to patients. Is this enough to make serialization a reality across the industry, and if it is are companies ready to implement a robust serialization solution?

While serialization continues to buzz and trend in industry forums, long-time followers know they have seen it before, only to be disappointed when legislation was sacrificed due to economic pressures. This time the tone seems different, as the industry starts to see that serialization in some form will be a reality and is no longer a matter of if, but when. The challenge for companies is where to invest, since the regulations within the U.S. and abroad are neither unified nor complete. Rather than wait and see, companies should start with what the industry does know, and initiate serialization pilots within their supply chains – now, not later.

Emerging Markets Require Agility

While companies recognize the opportunity for future growth in markets such as Russia, China, and Brazil, the reality is they will need an agile supply chain to support these markets. Existing supply chain networks and practices won't all effectively support these emerging markets. Companies will need to evaluate their supply chain design across all the markets they serve and make implicit trade-offs between customer service, inventory, and cost. The key is to figure out what capabilities will be important to your company moving forward.

MEASURING SUCCESS

- Does your supply chain have the agility to manage new markets with unique requirements?
- Do you have the right technology to support these markets that is integrated with your core supply chain technology?
- Is your supply chain design aligned with your business strategy, products, and distribution channels?



★ QUALITY

In December 2012, the FDA issued 12 warning letters related to GMP or quality systems issues at pharmaceutical, biotech, and medical device companies. In this economic environment, where there is continuous pressure on containing costs and improving the top-line, there is little margin for error. The negative press, impact to production, and overall cost of remediation from a warning letter or 483 are counter-productive to cost containment and operational excellence. However, a state of remediation can present opportunities for operational improvement that should not be missed.

Operational Efficiency and Quality Systems

Companies in the throes of remediation have an opportunity to leverage what they learn and enhance their quality systems in a way that meets overall corporate objectives. A remediation initiative should not be any different than any other strategic initiative. It should:

- Take the time to outline the business objectives beyond compliance.
- Define a comprehensive methodology to redesign the quality systems and integrated processes that align to your objectives.
- Define a governance structure that ensures progress to plan and delivery of stated objectives.

Companies that take the opportunity to make operational efficiency and quality systems work together will differentiate and drive value across the business, even when remediating.

Key Metrics and Realistic Targets

Measure your company's success by defining key operational metrics. Align these metrics with realistic targets that allow the organization to continuously improve over time. Setting unrealistic expectations with the organization will lead to frustration and disengagement. However, the flip side – setting realistic expectations, metrics, and timelines – will drive ownership and result in a sense of accomplishment within the organization.

MEASURING SUCCESS

- Identify your organization's current quality management maturity.
- Analyze your organization's quality systems in detail, identifying opportunities, and develop an optimization plan to address the opportunities identified.
- Create a platform for change that further supports a culture of quality and efficiency.
- Define key operational metrics that align to your quality systems across the organization.



HIGHLIGHTED TRENDS

EMERGING MARKETS

As populations grow and the need for better healthcare increases in emerging economies, the industry has started to find ways to enter these markets. It has been predicted that 25% of industry sales will come from emerging markets by 2015. There are companies that have already realized double digit growth in these new markets in 2012, while others have struggled to enter the market. Some companies are buying their way into new markets, while others are heavily investing in local R&D. No matter how your organization defines emerging markets, each face similar broad-range challenges.

Pricing Pressures

Even though these countries are eagerly seeking advanced healthcare, there is tremendous pricing pressure. Unique, innovative products coupled with new pricing strategies will be instrumental to driving growth in these markets.

Infrastructure

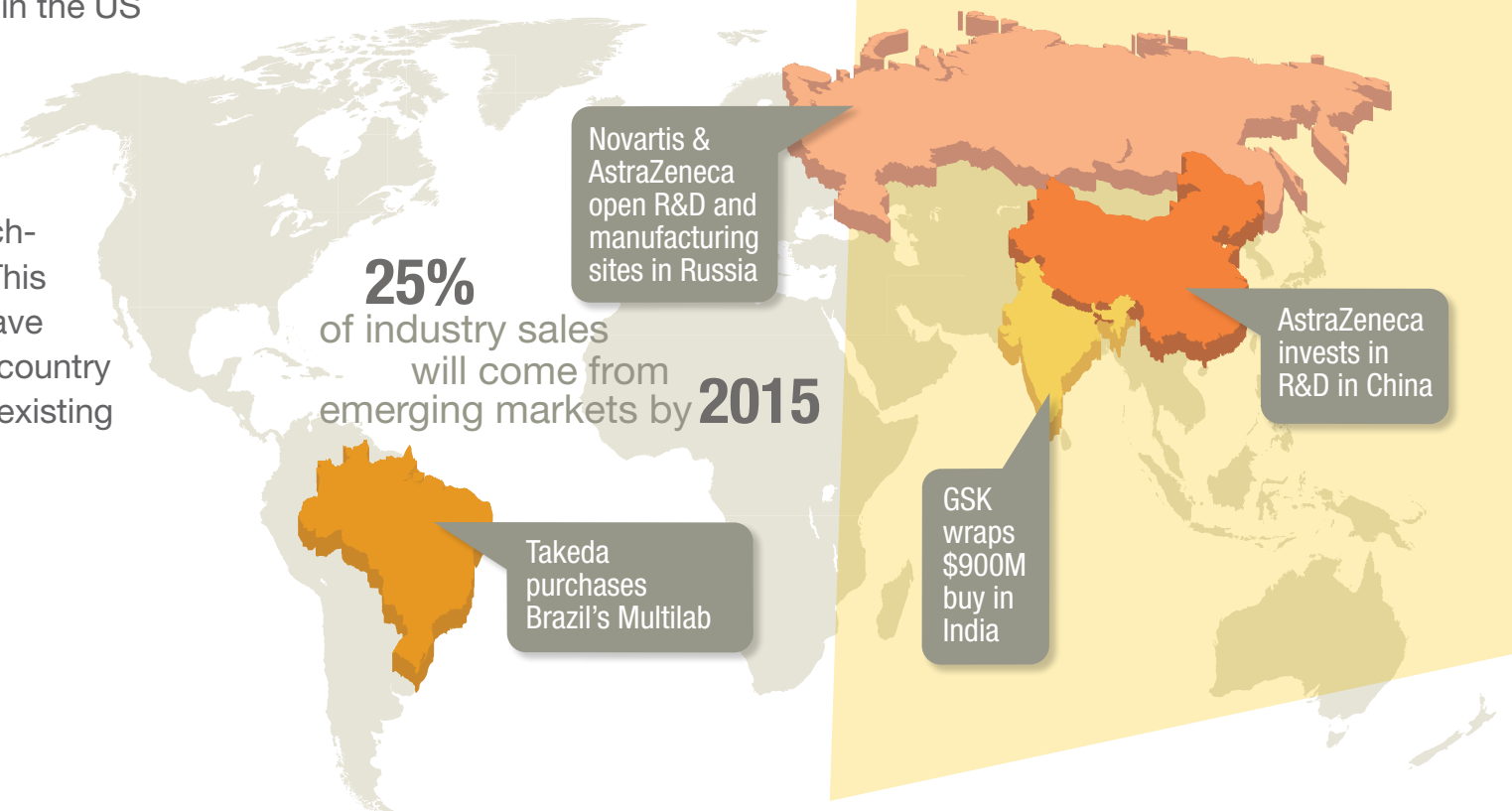
While these countries' economies are rapidly growing and have large populations, the physical infrastructure does not exist as it does in the US or Europe. Therefore just getting the products to the patients creates unique challenges that existing processes or technology cannot support. This also creates a need to have 'tribal knowledge' of the country and how to navigate the existing infrastructure.

Government and Regulation

Governments such as China and Russia look to take an active role in the approval and distribution of healthcare products in their countries. This means stricter requirements on the importation of products, or in Russia's case the inability to import products, and changing regulations regarding patent leniency for generics.

MEASURING SUCCESS

- Understand the market and how it aligns to your core competencies to define a strategy for growth.
- Be ready to change the way you operate in these dynamic markets; agility will be key to success.
- Learn from your competitors' success and failures, and realign your strategy.





About the Author

Janel Firestein leads Clarkston Consulting's Life Sciences practice and has been helping senior executives in pharmaceutical, medical device, and biotechnology firms address their business challenges for the past decade. During her tenure with Clarkston Consulting, she has become a recognized expert delivering business results in the areas of regulatory compliance, business process improvement, change management, product development, quality systems, and strategy.

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