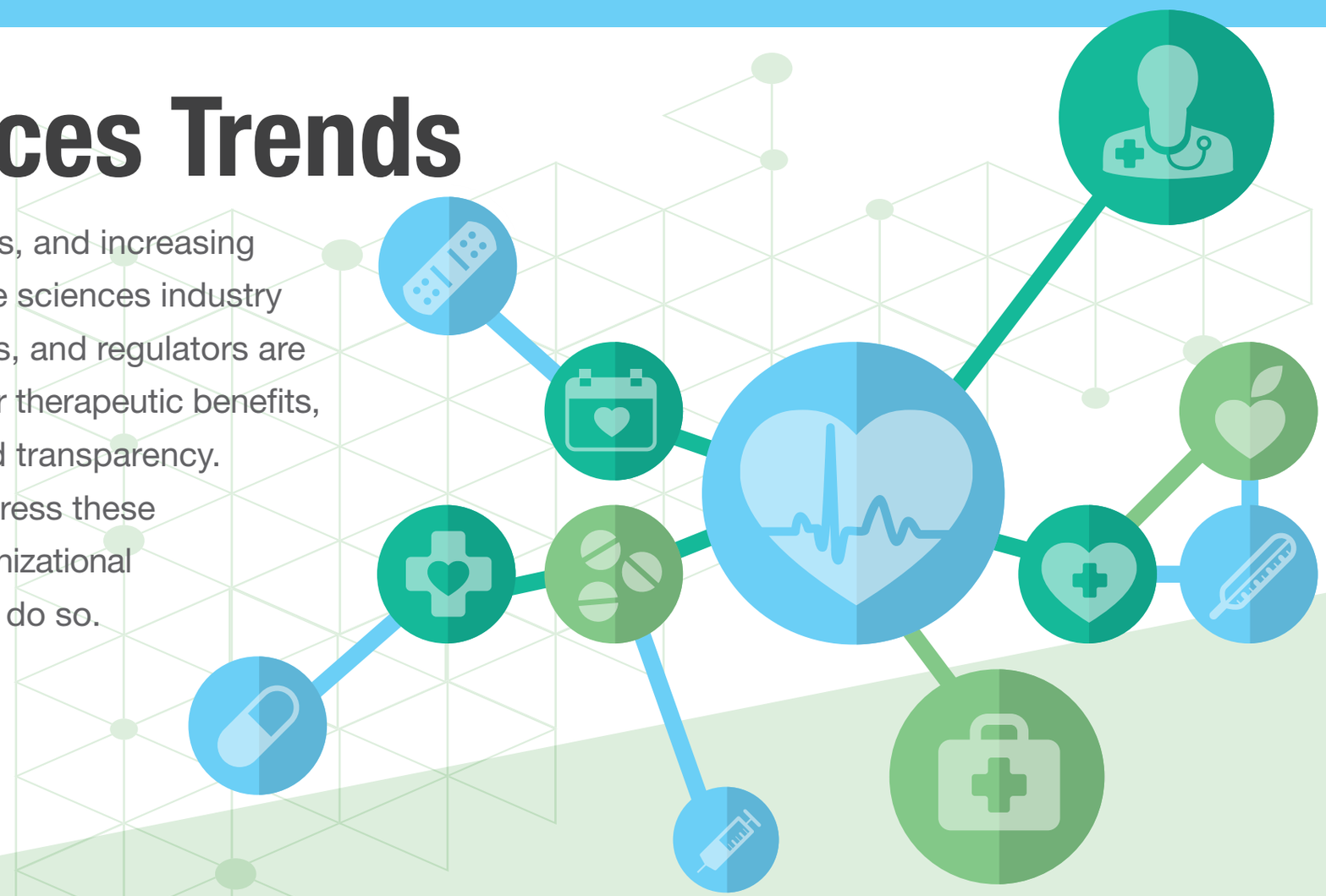
2014 Life Sciences Trends

Healthcare reforms, shifting market demands, and increasing regulatory pressures are transforming the life sciences industry on a global scale. Patients, providers, payers, and regulators are demanding a higher quality of care and better therapeutic benefits, combined with reduced costs and enhanced transparency. Leading life science companies need to address these challenges, considering ways to improve organizational efficiency and encourage innovation as they do so.



Quality and Supply Chain

With regulatory pressures increasing, how will your company ensure the quality and security of your products throughout the global supply chain?

Healthcare Reform

Healthcare reform is shifting globally, pushing organizations to provide high quality care at lower costs. How will your company respond to the collective demands of regulators, payers, providers, and patients?

Innovation and R&D

R&D investment is waning among U.S. companies, as cutting costs has become a priority. How will your company continue to innovate while also maintaining operational efficiency?

Quality and Supply Chain

In 2014, companies in the life sciences industry will continue to feel pressures to secure their supply chain and ensure the quality of their products. To the relief of many in the industry, Congress passed the Drug Quality and Security Act in November 2013, preempting the impending California E-Pedigree deadline. Will this shift the priorities of the pharmaceutical industry, or just provide leeway for implementations that are underway?

Pressure from Trading Partners

In 2015, wholesale distributors, dispensers, and repackagers must develop verification methods to determine whether a product is a valid, suspect or illegitimate. If an organization possesses a suspect or illegitimate product, it is their responsibility to notify trading partners in order to prevent further circulation. In addition, in the event of a recall or investigation, authorized parties in the drug supply chain must respond to requests for the transaction history of the pharmaceutical product from federal or state officials within 48 hours. Paper systems can support these efforts, but when considering the sheer volumes of product that pass through a wholesale distributor alone, it will be difficult to manage. Distributors, dispensers, and repackagers may require trading partners to share information electronically in order to drive efficiency and ensure compliance.

Aligning Operations with Plans for Growth

Industry mergers and acquisitions are not slowing down, but the era of the mega-merger has passed. Life science companies will continue to make targeted and precise acquisitions where there is alignment with the corporate strategy. As they transform their strategy, business leaders need to assess whether traditional operating capabilities will support their company's new direction. In some instances, less mature organizations may find that the operations and the systems landscape of acquired entities do not align with their own, even though they are aligned therapeutically. These organizations will have to decide who the best owner of the acquired entity will be. More progressive companies are building integration playbooks and developing genuine competencies around mergers, acquisitions, and divestitures, which support their strategic vision and facilitate aggressive financial and operational integration.

Increased FDA Scrutiny in India & China

In 2013, the FDA took action against companies operating in India for non-compliance with Good Manufacturing Practices. Companies like Wockhardt, Fresenius Kabi, and RPG Life Sciences received warning letters, and Ranbaxy had products from a fourth plant banned for import by the FDA. Although actions taken by the FDA in India made headlines, the implementation of quality systems, data integrity, and the validation of manufacturing processes are additional issues gaining global concern. For instance, with the recent approval of visas for new FDA inspectors in China, there will be added scrutiny, particularly examining problems in imported products over the last few years – including the tainted Heparin that resulted in dozens of deaths in 2008. With India serving as a major supplier of APIs and generics sold in the US, and China's healthcare spend growing by an average of 14.6 percent annually,[1] manufacturers need to instill comprehensive manufacturing audit plans at their suppliers, and ensure mitigation plans are in place to address possible supply disruptions.

Navigating this Trend

- *Collaborate with your trading partners, discussing how you will develop verification methods, share information, and prepare for serialization requirements.*
- *As you develop your strategy for the coming years, ensure that your company's operations and supply chain are aligned for future growth.*
- *Be prepared for potential supply chain interruptions due to quality or regulatory issues abroad.*

Healthcare Reform

For the past five years, the industry has anticipated the full impact of the Affordable Care Act (ACA), and the effects borne in 2013 were only the beginning. Payers are gaining influence over the therapies prescribed by doctors, patients are becoming more informed, and information and data consumption is evolving with the perpetual rise of social media. Together, these influences are changing how companies operate in this new era of healthcare.

Connecting with Providers and Patients

Increasingly, patients and physicians are evaluating therapies, side effects, and their overall value using informational websites and social media. Life sciences companies have an opportunity to leverage their expertise to not only educate physicians and patients about medical conditions, lifestyle choices, and healthcare options, but to also demonstrate the efficacy and benefits of their medications. Based on our recent research with Babson College, physicians shy away from new medications that have a limited number of clinical trials, only prescribing those that are thoroughly tested and proven more effective. This may actually promote the notion of sharing clinical trial data in ways that are relatable to patients and physicians, and that compare their results to those of other therapies.

Increasing Payer Influence

The rising influence of payers globally, and the need to drive down healthcare costs, are increasing pressure on the industry to make changes. With aging populations increasing in developed countries like Japan, universal coverage goals looming in China, and impending austerity measures in Europe, countries are looking to lower costs or find generic alternatives. In addition to pricing pressures, payers are requiring that companies prove the value of their therapies, not only through efficacy and adherence, but also quality of life standards. Clinical trials will need to clearly demonstrate that new therapies have significant benefits over existing ones in order to justify price increases and formulary acceptance.

Affordable Care Act

In November 2013, a study reported that insurance enrollment shortfalls may damper U.S. prescription drug sales projections by 30 percent.[2] In order to ensure low cost healthcare, there must be a balance between young, healthy individuals and older, sicker ones. The initial promise of extended healthcare coverage, which would drive increased drug utilization and reimbursement, now seems less likely in light of the ACA's current and foreseeable challenges. To mitigate these hurdles, life sciences companies will need to find ways to drive efficiency, whether by reducing their operating costs, reforecasting R&D and operations to align with changing demand, or examining additional ways to meet pricing demands.

Navigating this Trend

- *Expand clinical trials to include testing against current medications.*
- *Leverage informational websites and social media to better engage with patients and physicians.*
- *Make it a goal to educate and forge relationships with leading physicians, particularly those that serve comparable patient populations.*
- *Effectively leverage medical conferences, journals, and reputable online communities to educate physicians about the benefits of therapies.*

Innovation and R&D

As many industry companies continue to limit their R&D investments, pharmaceutical pipelines are starting to suffer. Additionally, due to pressures to maintain sales in the pharmaceutical industry, the World Health Organization states that there is "an inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of providers and the public to select and use drugs in the most rational way," particularly when these companies are the primary source of information regarding a therapy's efficacy.[3] This raises the question: what is the future of medicine?

Placing Big Bets on the Future

Finding a balance between advanced therapies and new drug development for major diseases will be critical for the population, but does it align with the strategies of life science companies? As more drug patents expire, and generic filings increase, companies will continue to look for innovative, high-value treatments instead of tackling major disease therapies requiring a larger investment with shorter patent terms. Companies who work closely with the FDA can develop commercialization pathways for innovations in regenerative medicine, 3D printing, and diagnostics and personalized medicine – which would potentially introduce new treatments for debilitating or deadly diseases with decreased side effects and increased effectiveness. Nevertheless, how will the government better incentivize companies to remain focused on major diseases and broader treatments?

Efficiency and R&D: Reality or a Pipe Dream?

The high cost of R&D often drives up the price tag for new drug therapies. However, by reducing R&D spend, do companies stifle innovation or drive efficiency in the clinical trial process that will actually bring down costs and encourage innovation? The industry will need to find a balance between the two in order to effectively meet increasing global demand. Collaboration with regulators will become more critical, particularly as debates surrounding patient privacy and safety, harmonizing electronic data systems, and leveraging new models for protocol design continue. Additionally, companies should consider data points that payers require as they design studies, which will improve the probability of securing a spot on their formularies. While there is no finite solution to the challenges facing the industry this year, collaboration and transparency will help ensure the success of all parties involved.

Transparency in Clinical Trial Data

Global consumers have long been suspicious of the data provided by life science companies, and these companies are under more pressure than ever to increase the transparency of the clinical trial results they provide. Will greater data transparency improve public trust along with the confidence that providers and payers have in the results? Companies such as Pfizer and GlaxoSmithKline have already committed to greater transparency, and Roche is planning to do so this month with the early release of clinical trial results from their schizophrenia drug bitopertin. This will be a learning process for many companies, particularly when considering how much data to share, in which format to share it, and how to maintain the privacy of clinical trial participants. Companies will need to develop policies and procedures that address these issues, but that don't impede operational effectiveness and time to market, or increase R&D costs.

Navigating this Trend

- *Carefully consider placing bets on medical advancements for the future, while continuing to invest in broader treatments that meet today's market demands.*
- *Leverage electronic systems and data analysis to drive R&D efficiency.*
- *Examine how to best share clinical trial data to promote transparency while also maintaining the privacy of patients.*
- *Balance the demands of payers, physicians, patients, and regulators, being conscious of how this may affect R&D costs.*

Continue the Discussion

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.

For more information,
contact Janel Firestein:
jfirestein@clarkstonconsulting.com
Access Janel's blog here.

Trends in the Life Sciences

- 2014 Biotech Trends Report
  Regulatory pressures are adding layers of complexity to business decisions, pharma companies are increasingly leaning on biotechs to supplement their R&D functions, and global market dynamics are shifting. Together, these factors will challenge the ability of biotechs to bring new and innovative therapies to market.
- 2014 Contract Manufacturing Trends Report
  With pricing pressures, pipeline challenges, and emerging markets reshaping the way pharmaceutical companies operate, contract manufacturers will need to transform the way they operate, as well.
- 2014 Generics Industry Trends Report
  With several key issues and opportunities arising that will directly impact patient access and affordability, the coming year will be pivotal for the generics industry.
- 2014 Medical Device Trends Report
  In today's rapidly changing business climate, understanding the regulatory and demographic environment of the medical device industry is only part of the challenge.

References

1 The Economist Intelligence Unit. *Investing in China: An assessment of the economic, political and healthcare outlook in China*. 2013.

2 Bloomberg. "Obamacare Failure May Shave 30% From U.S. Drug Sales." November 19, 2013.

3 World Health Organization. "Trade, Foreign Policy, Diplomacy and Health: Pharmaceutical Industry." 2014.

CLARKSTON

Headquarters
2655 Meridian Parkway
Durham, NC 27713
Phone: 800-652-4274

www.clarkstonconsulting.com

About Clarkston Consulting

Clarkston Consulting is a different kind of management and technology consulting firm. We deliver a unique experience for market leaders within the Consumer Products and Life Sciences industries. Considering professionalism, expertise, and value as prerequisites, we take service a step further through our unyielding commitment to the success of people as individuals, both our clients and our employees. By combining integrity, adaptability, and a whatever-it-takes attitude, we have achieved an extremely high rate of referral and repeat business and a 10-year average client satisfaction rating of 97%.