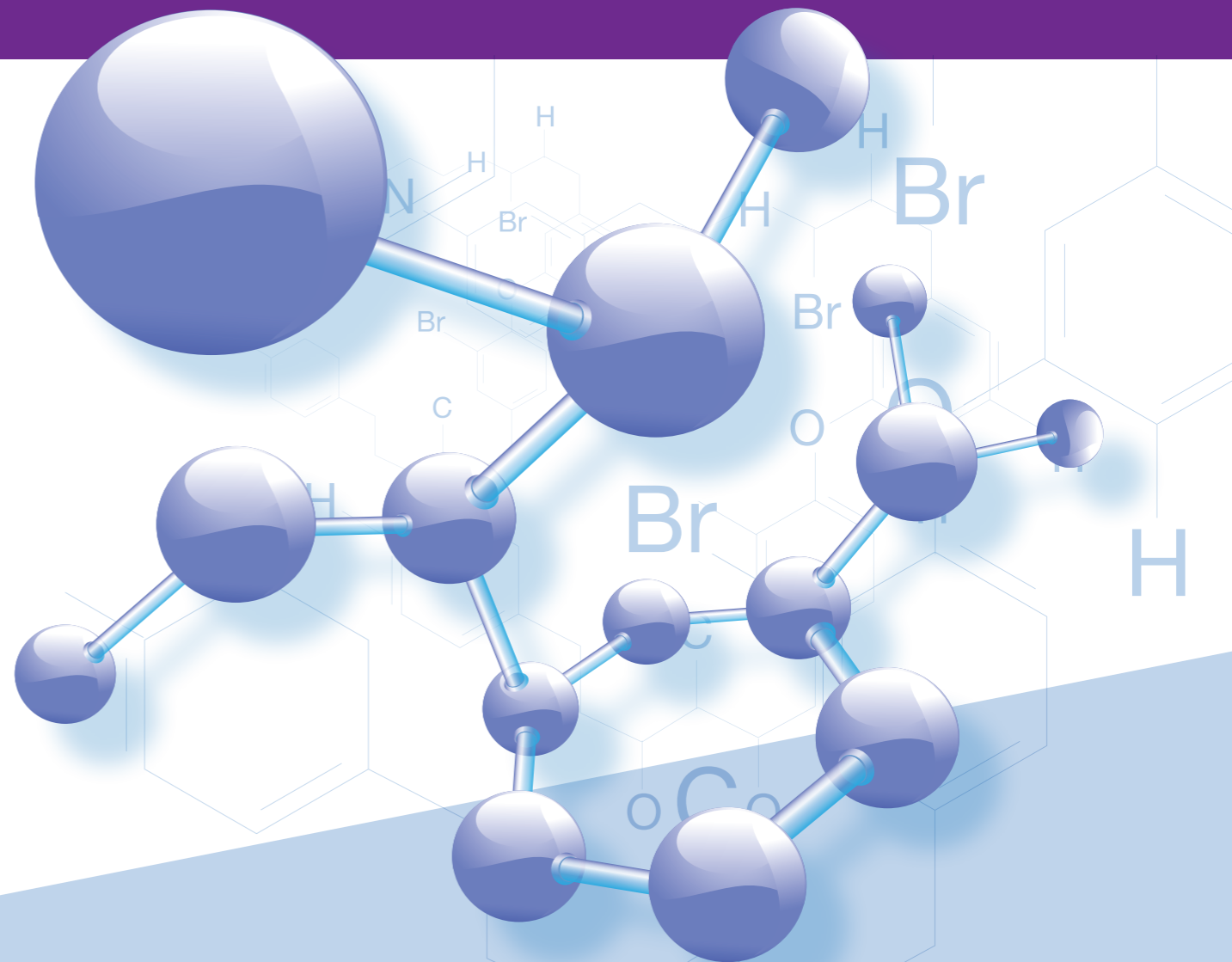


2014 Biotech Trends

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. The success of today's biotechs will depend on their approach when addressing these factors, which could ultimately affect the vitality of the life sciences industry.



Regulatory Impacts

Regulatory changes have always been a challenge for life sciences organizations. As we look at 2014, what regulatory forces will have a significant impact on biotechs?



Reimbursement

Continued investment is contingent upon the realistic evaluation of a therapy's market value opportunity. How much does reimbursement risk factor into the equation?



Partnerships & Acquisitions

Biotechs are looking for capital and capabilities, and Big Pharma seeks innovative technologies to enhance their pipelines. How is the partnering landscape changing and what opportunities may arise?



Emerging Markets

Emerging markets like India and China continue to entice investors and multinationals. Interesting partnership opportunities are matched by IP and trust concerns – so, it is it worth the risk?

Regulatory Impacts



Across the life sciences industry, evolving regulatory and compliance requirements are necessary and expected, though their implications are not always foreseeable. Along with the various global and domestic regulations, and grey areas involving regenerative therapies and personalized technologies, there are particular regulatory forces that biotechs need to consider. While the impact may be greater if commercialization is the strategy, these regulations will largely affect how therapies are marketed to potential partners, payers, and consumers.

Innovation Act

The Innovation Act bill (H.R. 3309) may impact how biotechs defend their patents. Intended to help reduce frivolous, lengthy and costly patent disputes, the Innovation Act raises many concerns among biotechs that start-ups and innovators will not be adequately protected. The Biotech Industry Organization (BIO), the largest biotechnology trade association, published its concerns about the act,¹ and also identified amendments² that could help address those concerns. Biotechs should stay abreast of the legislation, preparing for the long-term effects it may have on IP protection and innovation in the industry.

Drug Quality and Security Act

In the U.S. and internationally, there are growing concerns around the safety of the medical supply chain, which has led to increased legislation. In the U.S., the Drug Quality and Security Act was recently signed into law, and provides clear guidance for all products distributed in the U.S.; paper

or electronic lot-level traceability is required by 2015, and unit-level serialization is required by late 2017. Other countries and regions like the European Union, China and South Korea, have similar serialization requirements taking effect between 2015 and 2017, as well. As biotechs begin the commercialization process, they must incorporate these serialization requirements, and should consider how their partners are doing so, also.

Affordable Care Act (ACA)

As a result of the ACA, millions of previously uninsured individuals will be registering for health insurance as 2014 begins. This massive influx of patients into the healthcare system will create ripple effects, with physician bandwidth being one in particular. Biotechs have the opportunity to build communities that provide information and support to healthcare professionals, as well as patients. Big Pharma companies are already exploring ways to fill this need, [MerckEngage](#) and [Sanofi's The DX](#) being two such examples.³ By focusing on the physician and patient communities served by their therapies, which often fall into the specialty or orphan categories,

biotechs have the opportunity to connect on an even more personal – and valuable – level.

The ACA will also create challenges that may be more acutely felt by biotechs than their Big Pharma counterparts. Discussed further in the next section, reimbursement challenges will only intensify under the ACA, as Accountable Care Organizations push companies to prove the overall value of their therapies.

Navigating this Trend

- The demand for secure and authentic medicines is increasing, and regulatory agencies worldwide are requiring unit level serialization and traceability over the coming years. Are your systems capable of supporting these requirements? What are your partners doing to prepare, and what are their expectations of you?
- How are you planning to address opportunities that stem from the Affordable Care Act, particularly increasing awareness of your products and creating greater value for your target patient population?

Reimbursement



As a driving regulatory force, the Affordable Care Act is escalating the power of payers and fueling the importance of formulary positioning. Under the ACA, payers and Accountable Care Organizations (ACO) are becoming increasingly interested in the overall value of a therapy. As a result, the need to demonstrate efficacy, ongoing therapy adherence, and improved quality of life will be even more critical for therapies with higher costs. Many quality measures have been, and will continue to be, developed for each therapeutic area. These measures will help biotechs identify the types of information they need to capture, analyze, and present in order to prove their value and gain an adequate share in the market.

Fighting for Formularies

Formularies are an increasingly crowded place, and securing optimal positioning will prove to be more and more difficult. With many biotech therapies being understandably expensive—requiring notably large investments to typically serve smaller patient populations—demonstrating effectiveness and improved quality of life will be essential. Efficacy will no longer be enough to gain a formulary spot, and once secured, biotechs will have to defend their position. This will require ongoing data collection surrounding therapy adherence and patient activities. Additionally, with the intensity of the rebate market, products that are past patent exclusivity, or that don't significantly differentiate themselves, will likely suffer.⁴

Proving Their Value

As biotechs and investors look to invest in a technology's clinical trials, the potential market value of the technology should only be part of the investment decision equation. Reimbursement value is increasingly driving the market, ultimately determining how the value opportunity must be evaluated

and adjusted. Certainly, out-licensing partners and investors will put greater emphasis on reimbursement value, but biotechs should also use this as an important component in their own business decisions, whether deciding if or how much to invest, to commercialize or sell, and when to do so.

To better position technologies, biotechs should enhance their trials by not only tracking effectiveness and safety, but also increasing their emphasis on quality of life measures; this will help build a stronger business case for their products and will provide data to make more informed decisions. In addition, building relationships with payers, working to collaborate throughout the drug development process, will help biotechs set realistic market expectations and improve investment strategy decisions.

Navigating this Trend

- Gaining an optimal position on formularies has never been more challenging. Aside from heavy rebates or aggressive pricing, how will you ensure success?
- How are you positioning your technologies to demonstrate their value? Are you prepared to collect data through clinical trials and beyond, in order to verify efficacy and quality of life improvements?



Partnerships & Acquisitions

Logically, the growth of partnerships and outright acquisitions between Big Pharma and biotechs over the past several years makes sense: biotechs need capital and capabilities, while Big Pharma companies need steady pipelines. Realizing this trend will continue, the market dynamic is shifting, potentially dealing biotechs a more equal, if not better, hand to play.

Pharmas Mitigate Risk

Large pharmaceutical companies are spending approximately \$5 billion to bring one new medicine to market, often accepting the investment burden for the those that succeed, as well as for the roughly 95% that fail.⁵ Because of this, Big Pharma has increased their interest in licensing promising biotech technologies and acquiring biotech firms to help offset their R&D investment risk. In addition, large pharma companies also appear to be reducing their own R&D capabilities. Merck and Eisai announced reductions to their R&D departments in late 2013, and others such as Pfizer and Novartis have been doing the same over that past several years.

To date, biotechs have assumed that they are at a disadvantage when negotiating; after all, there are only so many Big Pharma players that may be interested in a given technology, while there are dozens, if not hundreds of biotechs vying for their investment. However, given their continuous need for pipeline growth and an increased reduction in R&D capabilities, Big Pharma will become progressively more dependent on biotechs to fill the gap.

Biotechs Transform the Paradigm

Large pharma companies, however, are not the only interested parties. Large biotechs such as Biogen Idec have created venture arms to help steer innovation in their own pipelines. And some aggressive smaller biotechs are also getting involved, one such example being Salix Pharmaceuticals, who recently announced its intention to acquire Santarus. Salix is financing nearly \$2B of the \$2.6B deal. As biotechs gain confidence in their technologies, and strive for greater market share in their therapeutic areas, they are less inclined to share market opportunities with Big Pharma. They would rather step in, and invest in other biotechs that will help them achieve their goals.

Navigating this Trend

- Interest in biotech innovation is growing, and may be nudging the marketplace towards a seller's market. Are you able to define a strong negotiating position and maximize your business opportunities?
- As partnerships and acquisitions continue to evolve and include peer biotechs, are you examining every option to identify the best strategy for your products and your company?



Emerging Markets



Emerging markets undoubtedly offer a tremendous amount of opportunity for biotechs. India and China, in particular, with their large population sizes and growing demand for quality healthcare products, offer significant potential for growth and expansion. To enter and sustain in these markets, however, there are many challenges and risks to consider.

Intellectual Property & Innovation

One of the primary concerns when entering emerging markets surrounds intellectual property (IP) protection. The challenge is difficult: a large percentage of the population in developing countries cannot afford high medical costs so their governments are inclined to support legislation, or the lack thereof, that keeps costs low. Unfortunately, the precedents set by the regulatory bodies in these countries can often deter multi-nationals and investors. Over the past year, for example, India has created an environment that not only curtails innovation, but encourages compulsory licensing, causing some companies to announce a general withdrawal from the market. How companies and other countries react to this type of legislation will shape how, and whether, biotechs should enter similar markets.

Potential for Partnerships

In China, a growing number of western pharmaceutical companies are forming partnerships with Chinese biotechs. A strategic move on the part of pharma companies, their goal is to not only supplement their pipelines, but to also natively penetrate the Chinese market. For biotechs in search of Big Pharma partners, other biotechs are potential competitors, and this type of partnership increases competition among global firms. On the other hand, for biotechs looking to acquire or partner, Chinese biotechs may present a dynamic opportunity.

However, there is some cause for concern. First, the precedent that India has set may surface in China and other markets. In addition, with the recent news of alleged bribes and corruption on the part of several Big Pharma companies, an environment of speculation and distrust may be building between western bio-pharma companies and regulatory agencies in China. The repercussions of these allegations will need to be monitored through 2014.

Navigating this Trend

- What is your strategy for entering emerging markets, and how will you ensure the IP protection in the process?
- In addition to the potential of new markets, how might partnerships with biotechs in strategic countries expand your capabilities and position, both internationally and domestically?



Continue the Discussion



About the Authors

Traigh Groover is a Partner at Clarkston Consulting with more than 20 years of experience

working with executives and leaders in the Life Sciences and Consumer Products industries. His specific expertise is in delivering business-enabling solutions, including operational and system strategies, ERP and Quality Systems implementations, organizational design and regulatory compliance initiatives.

Traigh also leads the biotech sub-vertical, which focuses not only on the industry's challenges, but how Clarkston can help build opportunities and innovative solutions for our clients. The biotech sub-vertical team supported the development of this report through their extensive research, vision, and key industry relationships.



Regulatory Impacts

- Case Study: *Piloting Serialization*
- Insights Paper: *Biosimilars are Coming. Are You Ready?*
- Solution Overview: *Serialization & Traceability*



Reimbursement

- Case Study: *Sales Reporting and Analytics Solution*
- Insights Paper: *Sales, Marketing, & Influence Optimization: Integrating and Interpreting Demand*
- VIEWpoint: *Driving Bottom Line Results with Effective Data Governance and MDM*



Partnerships & Acquisitions

- Insights Paper: *Build an Effective Merger, Acquisition and Divestiture Execution Capability*
- Latest Insight: *Crowdfunding: Breathing New Life into Biotech?*



Emerging Markets

- VIEWpoint: *Optimizing Financial Planning and Consolidation for Global Expansion*

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