Audit Evolved
The next generation of life sciences audit
Running a life sciences business has never been more challenging. Life sciences (LS) companies face pricing pressures as health care reform puts a laser focus on patient outcomes and measurable results. And many leading companies are peering over the edge of the patent cliff into a revenue abyss, forcing them to search for new growth paths that don’t rely on blockbuster drugs.

Yet, other forces are spurring the industry to grow. As our population ages—and chronic diseases proliferate—the need for health care continues to rise. Plus, many new companies in the emerging health technology sector are looking to the power of digital technology to create innovative products and services.

Is this complex mix of market forces a major threat or an opportunity? At Deloitte, we see it as part of the evolution of life sciences—and we are evolving with it.

**Deloitte**

Deloitte Touche Tohmatsu Limited (DTTL), with its network of member firms, is one of the largest professional services organizations in the world, with more than 240,000 professionals in 150 countries, including more than 78,000 professionals in the US. DTTL is a leader in life sciences and health care (LSHC), serving more than 90% of the Fortune 500 LSHC companies and 80% of the Fortune Global 500 LSHC companies. As such, Deloitte is uniquely qualified to help you navigate today’s life sciences marketplace, providing exemplary professional services and delivering the next generation of audit for life sciences.

**Deloitte’s Life Sciences practice**

- Nearly 13,000 life sciences and health care professionals in 90 countries, including more than 5,500 in the US
- 2,800+ professionals specifically focused on life sciences in the US
Disrupting the norm

The powerful market forces in life sciences are influencing how companies compete and grow. Here are six key trends that appear to be shaping the industry.

**Putting patients first.** Of all the major trends, the shift toward patient-centric care models may have the biggest near-term impact, potentially affecting the life sciences value chain from R&D through treatment delivery. The industry should consider improving how it engages with patients—whether to encourage compliance for new therapies or to support therapies and initiatives that are already in place. It also should consider improving its public image. Although trust in life sciences companies appears to be rising, it still appears lower than for other health care stakeholders. Addressing this head-on is one way to build patient confidence and gain permission to engage with them—which can open the door to new market opportunities.

**Merger mania.** Merger and acquisition (M&A) activity in life sciences is high as many established companies acquire innovative startups and other promising sources of breakthrough intellectual property. An objective? To maintain or grow their businesses in the face of the patent cliff, replenishing product pipelines and replacing lost revenue with valuable niche offerings that can help compensate for the decline of blockbuster drugs.

**Pushback on pricing.** Success in today’s life sciences marketplace likely requires a careful balance of innovation and cost reduction. As health care reform increases the focus on outcomes, value, and relative effectiveness, continued scrutiny and pressure around pricing can be expected. Also, when seeking approval and reimbursement for innovative drugs, companies can expect extensive contract negotiations and new pricing mechanisms, such as outcomes-based agreements and risk sharing.

**Pursuit of efficiency and excellence.** Business leaders in life sciences are often under pressure to reduce costs and improve quality. This will likely require improvements across a wide range of areas, from research and manufacturing to finance, safety, selling, and general and administrative expenses. For improved results, it might make sense to consider increasing integration across R&D, manufacturing, and commercial organizations.

**Making global growth a priority.** Although global growth has been up and down over the past few years, life sciences companies should consider looking for new opportunities in markets such as Latin America and Africa that have significant access constraints and unmet needs. These markets will likely remain key sources of growth in the future.

**Health tech on the rise.** Digital technology is transforming many aspects of our lives, and health care is no exception. In the life sciences market, numerous new entrants are emerging to harness the power of technology—filling the space between existing offerings and developing new products and services that attempt to replace or enhance what existing companies are doing.
At Deloitte, audit is more than an obligation for our clients. It’s an opportunity. In addition to providing assurance services and enhancing trust, we add value by bringing an outside-in perspective and delivering meaningful insights for clients to consider.

Our commitment to quality, proven innovation, and unrivaled diversity of thought makes a Deloitte audit a powerful lens that can help clients better understand risk and improve business performance—helping to make companies stronger and benefiting investors, capital markets, and the economy as a whole.

Advances in technology are driving dramatic change in many aspects of business, including audit. Deloitte is leading this transformation by redefining what’s possible and developing smarter ways to conduct audits that deliver tangible benefits for life sciences companies.

**Quality leaders**
Audit quality remains our highest priority and is at the core of everything we do, from strategy to delivery to innovation.

**Transformed execution**
Along with developing next-generation applications and advanced analytics, we are transforming our methods and approaches to enhance execution of the audit and deliver higher quality consistently.

*Our commitment to quality and exemplary execution means that we customize audits to the unique risks and requirements of the life sciences industry and provide relevant insights for clients to consider.*
Audit innovation

Deloitte is developing the next generation of audit applications—those that use workflow automation, artificial intelligence, and other cutting-edge innovations—to reduce the amount of manual data collection and processing, leading to audits that are more transparent and offer more insight.

**Argus:** Electronic document interrogation and analysis.
Use cognitive technologies—advanced machine learning and natural language processing—to quickly process and extract key information from electronic documents to analyze an entire population of documents.

**Deloitte Online and Deloitte Connect:** Online collaboration, information sharing, and progress tracking.
Communicate and collaborate seamlessly with your Deloitte audit team via a secure online collaboration site that has been designed with your unique engagement requirements in mind.

**Disclosure Analytics:** Automated analysis of SEC filing disclosures.
Access real-time, online SEC filing disclosures and accounting policies, enabling instantaneous peer comparisons and updates on emerging disclosures and industry trends.

**Icount:** Mobile-enabled inventory counts.
Use mobile devices on-site to perform physical inventory observations and transmit results in real time, enabling the audit team to instantly monitor and review all location counts via a web-based application.

Audit analytics

Deloitte’s analytics and visualization tools can be tailored to a specific industry and business, delivering insights that can be highly relevant and actionable.

- **Deloitte Signal:** Comprehensive risk analytics
- **Deloitte Analytics Library:** Industry-specific data analytics and visualizations
- **Deloitte Optix:** Advanced data analysis of journal entries
- **Statistical Techniques for Analytical Review (STAR):** Predictive analytics with regression modeling

Deloitte Wins ‘Audit Innovation of the Year’ at 2015 International Accounting Bulletin Awards

Find out more at deloitte.com/us/audit.
Addressing the tough accounting questions

In addition to shaping business strategy and industry direction, the complex market forces and trends in life sciences raise some uniquely challenging accounting questions.

How and when to recognize revenue?
This is likely the industry’s single biggest accounting challenge, due to the complex nature of how life sciences products are priced, distributed, and sold. In life sciences, revenue recognition often relies heavily on estimates and assumptions about returns and other potential revenue adjustments, including discounts, rebates, and incentives. These estimates are often made with limited visibility to detailed sales and customer data, particularly for cutting-edge products that lack a historical precedent. In addition, as alliances become more prevalent, there are a growing number of issues about how and when revenue is allocated among various parties.

How to classify acquisitions and divestitures?
M&A is another challenging accounting area in life sciences. A key issue is whether an acquisition should be classified as acquiring a business or acquiring an asset (such as intellectual property), since the accounting for each of those cases is very different. Also, acquisitions often result in complex business structures with complex accounting requirements. Divestitures raise similar issues.

Should financial statements be consolidated?
Many of today’s life sciences companies are establishing a variety of arrangements with other parties to support the research, development, or sale of their intellectual property or products. This can lead to taking on other parties’ risks and rewards in unconventional ways, which raises the issue of consolidation. After more than four decades with little change, the accounting guidance on consolidation has been evolving rapidly in recent years, making this an area that preparers and auditors carefully consider.

Which contingencies need to be accounted for?
ASC 450 defines a contingency as an “existing condition, situation, or set of circumstances involving uncertainty...that will ultimately be resolved when...future events occur or fail to occur.” In life sciences, contingencies are common for a wide range of issues, from product liability and patent litigation to regulatory approvals, environmental concerns, and regulatory compliance.
Life sciences and the future

It takes broad perspective and deep industry experience to effectively navigate through today’s complex and constantly evolving life sciences landscape. As one of the world’s largest professional services organizations—and a market leader in life sciences—Deloitte can help.

Our knowledge and experience span the entire life sciences and health care ecosystem—from manufacturers and providers to payers and government agencies. And we apply a cross-functional approach to everything we do.

We offer professional services in four key business areas—audit, advisory, consulting, and tax—making DTTL and its network of member firms a professional services organization that can seamlessly deliver a full set of services and capabilities to help your company tackle its biggest, most complex challenges.

**Forward thinking**

Deloitte’s commitment to clients includes access to timely, insightful thought leadership on the latest industry topics. Some of our thought leadership includes:

- Life Sciences Accounting and Financial Reporting Update—including Interpretive Guidance
- 2017 US Life Sciences Industry Outlook
- Measuring the Return from Pharmaceutical Innovation 2016
- Upcoming Dbriefs Webcasts

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Look Again™

Where others see obligation, we see opportunity. An audit is not just an obligation; it’s an opportunity to see further and deeper into your business. As one of the country’s top professional services organizations, Deloitte has the knowledge and experience to help your business in the rapidly evolving life sciences marketplace.

To learn more, contact us or visit us at deloitte.com/us/audit.

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