Are you ready for the empowered consumer?

How Internal Audit can help life sciences companies change with the times
Introduction

The traditional business model of life sciences companies is under unprecedented stress. Demographics and technology are converging to drive a once-in-a-lifetime transformation: as more people than ever before are receiving care and chronic illnesses in an aging population threaten to reach pandemic proportions, consumers have access to devices and data that give them ever-increasing control over their care.

Across the board, there is an urgent focus on coordinated, lower-cost care with improved outcomes. Taming escalating costs is essential: in the US, health care costs are expected to reach 23% of GDP, up from 17% in 2012, while 13% of adults in the UK and 6% of adults in France face serious challenges in paying their medical bills. At the same time, countries around the world are expanding access to health care, and a growing middle class in the emerging markets is demanding more – and better – care.

Given the volatility of the landscape and the velocity of innovation and information, it’s more important than ever for organizations to gain visibility into everything they do. At this inflection point for the industry, organizations that know their supply chain, understand the efficacy of their products and the health outcomes that result from their use, and know their partners and influencers will be best placed for success.

Internal Audit (IA) will play an essential role in helping companies gain the visibility they need to succeed. With its ability to look across the enterprise, IA can help spot emerging issues, help sharpen the organization’s focus on compliance, drive efficiencies and add value to the business – all while continuing to provide the baseline assurance the organization requires. In particular, IA can serve the organization by developing audits that focus on the risks that matter.

1 “NHE Fact Sheet,” Centers for Medicare & Medicaid Services website, September 2014.
Impact of a changing environment

Seizing the opportunity presented by the evolution of patient-centric technology, nontraditional competitors with new business models have entered the fray including telecommunications companies working to empower patients in managing their own care, IT companies bringing the power of analytics to help improve patient outcomes, and large retail chains offering health care options to customers.

Through social media and “mHealth” — smart mobile applications and devices, including wearable devices – patient self-management is moving closer to a daily reality. These apps and devices allow for remote monitoring and rapid access to clinicians when questions arise. A recent telehealth trial in the UK showed the promise of new technology: it reported a 15% reduction in doctor’s office visits, a 20% reduction in emergency admissions, a 14% reduction in the need for planned admissions and a striking 45% reduction in mortality rates. More than 20,000 smartphone apps are already available, with more on the way, and more than 45 million wearable devices are scheduled to ship in 2015, rising to an estimated 126 million units in 2019. And around the world, social media sites are connecting patients and providers in new ways.

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Navigating the new landscape

Six broad sector issues are increasing pressure on the top and bottom line: Each issue affects the others, and each organization will develop a unique mix of audits to address its particular situation.

Research, discovery and clinical trials

With stalling demand in mature markets, price pressures in emerging economies and the “cliff” of expired patents a recent, painful memory, effective research, discovery and clinical trials have never been more important. Price pressures are driving the need for providers to find ever more efficient ways of developing drugs while drug research and development (R&D) has become harder than ever; even while only one candidate in thousands will reach market approval, it remains impossible to identify with certainty which candidates in clinical trials will succeed. Targeted therapeutics show immense promise, but with their use limited by definition, organizations must spread the R&D cost over a much smaller population. At the same time, payers are increasing their scrutiny. They are looking for services that are broad and holistic and that span the entire cycle of care. They are also evaluating the costs of specialty drugs carefully.

In response, companies are decentralizing their R&D functions and collaborating with others to increase productivity through not only traditional licensing transactions but also “pre-competitive” collaborations that focus on common efficiency issues such as clinical trial enrollment. They are also using big data analytics to improve their R&D portfolio decisions with an eye toward clinical effectiveness.

Operations management

Top-line pressures are driving the need for increased efficiencies across the value chain. Payers are seeking more discounts or rebates from drug providers; cost containment is a top priority, and value for money is a close second, if the focus on stricter coverage criteria is any indication.

Leading organizations have responded by sharpening their operations management. They are using shared services centers and outsourcing to reduce costs and gain efficiencies in R&D, manufacturing, supply chain, commercial operations and support.

Global growth

Life sciences companies are focusing on global growth; they are looking to expand their presence and product offerings in emerging markets. As the middle class grows in developing countries, they are expanding access to health care to meet the demands of their increasingly affluent citizens. And as life expectancy continues to increase across the globe, the aging populations in emerging economies represent a growing market – and a potentially lucrative opportunity.

Organizations are looking to grow in emerging markets through organic growth; alliances with companies that already have a significant presence in the market; joint ventures, often with local companies; and outright acquisitions. They are also working to determine the appropriate mix of products, both branded and generic, to address the needs of these markets, and refining their business models accordingly.

Commercial operations

Organizations are also taking a thorough look at their commercial operations. In part, this is due to the growing influence of payers in the life sciences ecosystem: they are partnering with providers to add value to the patient experience, and they are increasingly unwilling to allow their pharmaceutical partners to focus only on pharma-centric approaches.

Incentives are changing as the marketplace begins to emphasize health outcomes. Value-based payment models are gaining currency, and across the landscape there are emerging examples of care integration for complex illnesses and complex needs. Along the same lines, leading organizations are making evidence-based decisions on which tests are needed in each patient’s case.

Those decisions focus on “real world” evidence of cost and effectiveness, as companies adjust their commercial model to the new reality. Organizations are also working to improve the way they work with physicians, with an eye toward increased efficiency, and they are exploring “beyond the pill” business models to add value and fuel growth.

Increased compliance risk

But moving into these new markets presents an increased compliance risk, as do evolving regulations in developed and developing countries. Enhanced scrutiny from regulators is a given; the life sciences industry is the most targeted sector for US Foreign Corrupt Practices Act (FCPA) enforcement, and actions by non-US agencies are also on the rise, thanks to legislation such as the UK Bribery Act. Across all industries, while fraud risks are rising, standards are not; controls are frequently inadequate and deal due diligence can be lacking. Regulators have responded by targeting the executives of multinational companies.

As organizations expand their operations on a global scale, they are increasingly likely to face audits from the US Food and Drug Administration (FDA) to verify compliance with Title 21 of the US Code of Federal Regulations (21 CFR) and similar directives. To cope, companies are placing a premium on the accuracy of vendor information, communications and verification. They are also investing in resources and tools to help them manage adherence to global, regional and local laws and regulations, including sanction lists, embargo lists and export regulations.

Capital allocation

To make growth happen, organizations must be willing to invest; at the same time, they must meet shareholder expectations for dividends and share buybacks, especially given the increasing prominence of activist investors. The right mix of capital allocation is vital. Organizations are aggressively evaluating their portfolios of both products and businesses and considering divestitures of businesses that lack the appropriate scale or do not represent a strategic fit. They are seeking to improve their capital efficiency, reassessing capital structures, including debt, and exploring strategies to make the best use of cash “trapped” offshore.
A strong internal audit function can help the organization thrive in this challenging risk landscape by integrating risk and compliance seamlessly into the rhythm of the business.

By aligning its audit plans to key business issues and initiatives, IA can leverage its deep assurance knowledge to provide the Board and management visibility into these risks and other pressing concerns. Internal Audit is uniquely placed to offer these insights because of its enterprise-wide view, which allows IA to connect the dots across the entire organization. Leading organizations are taking advantage of IA’s strengths by treating the function as a trusted strategic advisor. Keeping its feet firmly planted in the assurance functions that represent its core competency, IA is adding value to life sciences organizations by focusing on the risks that matter.

The audits that address these risks require a solid understanding of the organization’s internal audit standards and approach; an understanding of the organization’s strategic objectives and business activities; robust, up-to-date technical IT knowledge; strong analytical skills; and the ability to communicate clearly and concisely. The appropriate mix of resources will vary based on the organization and its IA bench strength.

Some types of risks (e.g., procure-to-pay, vendor management) are common to every organization. But companies in the life sciences sector also face very specific risks based on the industry’s unique business and regulatory landscape. Here are some audits designed to address sector risks that are top of mind and could result in significant negative impact for your organization.

### Key questions to consider

- Is good clinical practice (GCP) maintained?
- Are patient recruitment targets achieved?
- Are good documentation practices followed for patient records?
- Is safety reporting (adverse events) done appropriately?
- Have the contract research organizations (CROs) been paid as per the services rendered?
- Are there any protocol violations? If yes, what are the remedial measures taken?

### Potential scope and objectives:

- Evaluate compliance across the clinical trial ecosystem
- Measure the overall cost of research and development and clinical trials
- Capture specification (OOS) events from laboratory testing in good laboratory practices (GLP) environments
- Review the use of quality risk management that can facilitate regulatory compliance to a substantial degree and also improve quality of communication between industry and regulators
- Measure process capability
- Review procedures for continuous quality verification
- Evaluate packaging and labeling compliance

### Research, discovery and clinical trials

**Potential scope and objectives:**

- Evaluate compliance across the clinical trial ecosystem
- Measure the overall cost of research and development and clinical trials
- Capture specification (OOS) events from laboratory testing in good laboratory practices (GLP) environments

**Key questions to consider**

- Are the raw materials tested appropriately?
- Are the suppliers evaluated and qualified?
- Are processes aligned with 21 CFR?
- Are past due corrective and preventive actions (CAPA) and deviations properly identified and monitored?
- Do the facility and its many departments (organizational units) operate in a state of control as defined by the good manufacturing practice (GMP) regulations?
- Does the quality assurance (QA) department or unit routinely review production records to make sure that procedures were followed and properly documented?
- Are all written QA procedures current and approved?
Intellectual property (IP) protection
Potential scope and objectives:
- Evaluate assets analysis and IP identification
- Perform IP management gap analysis
- Perform an IP royalty audit
- Identify IP function process improvement

Key questions to consider
- Does the organization have a full list of all trade secrets and intellectual properties with risk exposure in new emerging markets?
- What are the current IP management policies, processes, systems, tools and team structure?
- Is there an audit provision in the contracts/agreements with the joint venture investor, partnership, research and development alliance, vendor, distributor or licensee?
- How is the dispute or litigation to be managed in overseas countries with varied jurisdictions?
- How does the organization manage the legal and reputation risk?

Mergers and acquisitions (M&A)
Potential scope and objectives:
- Evaluate the strategic risk of the M&A to the organization
- Assess the valuation, internal controls and synergies in due diligence
- Review the deal approval and close process
- Assess the post-deal integration

Key questions to consider
- Is there a predefined business case with the projected benefits and costs to assess the M&A impact to the organization?
- Do the buyer company and the engaged deal service provider have a solid methodology, tools and team to perform financial and operational due diligence and synergy validation?
- Does the buyer company have the effective governance and related processes to manage the deal approval and close?
- How does the organization or the deal service provider plan to manage the post-deal integration covering governance, organization, people, process and systems?
- Is there a well-defined benefit realization plan to measure the value of M&A?

Global growth

Operations
Potential scope and objectives:
- Review the marketing strategy return on investment
- Evaluate the impact of patent cliff (scenario analysis)
- Review the competitive landscape for new drugs and generics
- Analyze technologies used to enhance marketing strategy
- Evaluate partnerships and collaborations

Key questions to consider
- Is there a well defined benefit realization plan to measure the value of M&A?
- Is the company keeping pace with emerging technologies to enhance marketing capabilities?
- Is the company leveraging existing technologies to the maximum extent possible to reduce costs and drive better KPIs?
- Are customer needs (centricity) taken into full account when developing the commercial strategy?
- Are multiple channels for collaboration being considered to maximize returns on investment and research, e.g., joint ventures?
- Are regulatory changes anticipated and built into strategic plans?
- Are the company’s capabilities (e.g., talent, technology) keeping pace with the rapidly changing industry?
- Are the performance management expectations consistent with the operational goals of the organization?

Cybersecurity
Potential scope and objectives:
- Review management’s cybersecurity program, including the strategy, governance and operating models in place to protect its critical assets as well as respond to and contain cyber threats

Key questions to consider
- Does the organization periodically evaluate cyber risk governance and perform an annual cyber risk assessment?
- Is there a threat mitigation program in place?
- Does the organization have an inventory of its highest value assets and has the organization evaluated the use of highly sensitive data across the organization?
- Does the organization understand how its critical assets could be accessed or disrupted?
- Is there the necessary expertise to build an effective cybersecurity program and respond appropriately to cyberattacks?
- Is the cybersecurity program robust enough to adapt and anticipate new types of cyber threats?
- Does the cybersecurity team conduct periodic drills to prepare for cyber incidents and are the necessary procedures in place for incident response?
- Does the cybersecurity team have effective metrics in place to report on threat management and mitigation?
- Are any information security reviews performed on suppliers and is there a formal process to follow up and close identified risks?
Potential scope and objectives:
- Assess the risk/reward calculation
- Review information on which capital allocation decisions are based
- Conduct volatility tests of markets where capital is being allocated
- Evaluate the model that is used to support business decisions for uncertainty and risk
- Evaluate the tools that are used to plan and assess capital needs
- Assess the risk criteria used to allocate capital (e.g., volatile and emerging markets)

Key questions to consider
- Do profits exceed capital costs?
- Is the organization making the right investments?
- How long will the advantages last?
- Is the right portfolio of development and business initiatives being built?
- Are partnering structures that allow for ongoing collaborations being created?
- Is scenario planning considering real options for capital allocation being performed?
- Is the organization properly calibrating risk vs. reward?
- Is capital allocated as effectively and efficiently as possible across geographies and business units?

Capital allocation

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Key questions to consider
- Are plants conforming to GxP compliance requirements?
- Are quality management systems mature enough to meet compliance requirements?
- Are CAPA systems focused on mitigating product deviation issues?
- Are data integrity protocols managed to meet the compliance norms?
- Do IT systems support the predicate rule conformance requirements?

Increased compliance

Potential scope and objectives:
- Conduct plant good quality practice (GxP) compliance assessments
- Perform process audit validations
- Assess the quality management systems
- Assess continuous compliance readiness
- Review IT systems to validate and determine compliance

Key questions to consider
- Are plants conforming to GxP compliance requirements?
- Are quality management systems mature enough to meet compliance requirements?
- Are CAPA systems focused on mitigating product deviation issues?
- Are data integrity protocols managed to meet the compliance norms?
- Do IT systems support the predicate rule conformance requirements?

Conclusion

The traditional life sciences business model is facing a crisis of sustainability. The combination of rapidly growing demand and disruptive technology is forcing organizations to develop new, untried and untested approaches. In this environment, IA will play a more important part than ever before, not only in its accustomed assurance role but also as a proactive function that helps the organization assess and organize the risks arising in today’s turbulent risk landscape.

IA can become a trusted advisor to the organization by leveraging its view across the organization and its knowledge of the industry while building on its core competencies. In earning a seat at the table, IA can help the organization survive and thrive in the new life sciences environment.

“Internal Audit has a key role to play in helping organizations across the sector understand and act on the risks and opportunities inherent in the ever-changing life sciences landscape.”

Michael J. O’Leary, EY Global IA Leader
Want to learn more?

Insights on governance, risk and compliance is an ongoing series of thought leadership reports focused on IT and other business risks and the many related challenges and opportunities. These timely and topical publications are designed to help you understand the issues and provide you with valuable insights about our perspective. Please visit our Insights on governance, risk and compliance series at www.ey.com/GRCinsights.

If there’s no reward without risk, can risk be a good thing?

Risk is a much more risky proposition than it used to be. New risks emerge every day as markets get disrupted, political instability interrupts supply chains and new technology pushes boundaries across the risk landscape. Yet, while many organizations see risk as a negative, good risk management can actually help companies go faster.

For EY Advisory, a better working world means solving big, complex industry issues and capitalizing on opportunities to deliver outcomes that help grow, optimize and protect our clients’ businesses. We’ve shaped a global ecosystem of consultants, industry professionals and alliance partners with one focus in mind – you.

We help you make incremental strategic decisions around risk management to help your business strategy stay on course. We help you look at risk from all angles and across every part of the organization, including cybersecurity, supply chain, internal audit and risk assurance.

Our global connectivity and understanding of your issue inspire us to ask better questions. We then co-create more innovative answers that enable you to develop a top-down, risk-based approach to transforming your risk management environment. Together, we help you deliver better outcomes and long-lasting results, from strategy to execution.

We believe that when organizations manage risk better, the world works better.

So, if there’s no reward without risk, can risk be a good thing? Ask EY.

The better the question. The better the answer. The better the world works.
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About EY’s Advisory Services

In a world of unprecedented change, EY Advisory believes a better working world means solving big, complex industry issues and capitalizing on opportunities to help deliver outcomes that grow, optimize and protect clients’ businesses.

Through a collaborative, industry-focused approach, EY Advisory combines a wealth of consulting capabilities – strategy, customer, finance, IT, supply chain, people and organizational change, program management and risk – with a complete understanding of a client’s most complex issues and opportunities, such as digital disruption, innovation, analytics, cybersecurity, risk and transformation. EY Advisory’s high-performance teams also draw on the breadth of EY’s Assurance, Tax and Transaction Advisory service professionals, as well as the organization’s industry centers of excellence, to help clients deliver sustainable results.

True to EY’s 150-year heritage in finance and risk, EY Advisory thinks about risk management when working on performance improvement, and performance improvement is top of mind when providing risk management services. EY Advisory also infuses analytics, cybersecurity and digital into every service offering.

EY Advisory’s global connectivity, diversity and collaborative culture inspires its consultants to ask better questions. EY consultants develop trusted relationships with clients across the C-suite, functions and business unit leadership levels, from Fortune 100 multinationals to leading disruptive innovators. Together, EY works with clients to co-create more innovative answers that help their businesses work better.

The better the question. The better the answer. The better the world works.

With 40,000 consultants and industry professionals across more than 150 countries, we work with you to help address your most complex industry issues, from strategy to execution. To find out more about how our Risk Advisory services could help your organization, speak to your local EY professional or a member of our global team, or view: ey.com/advisory

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