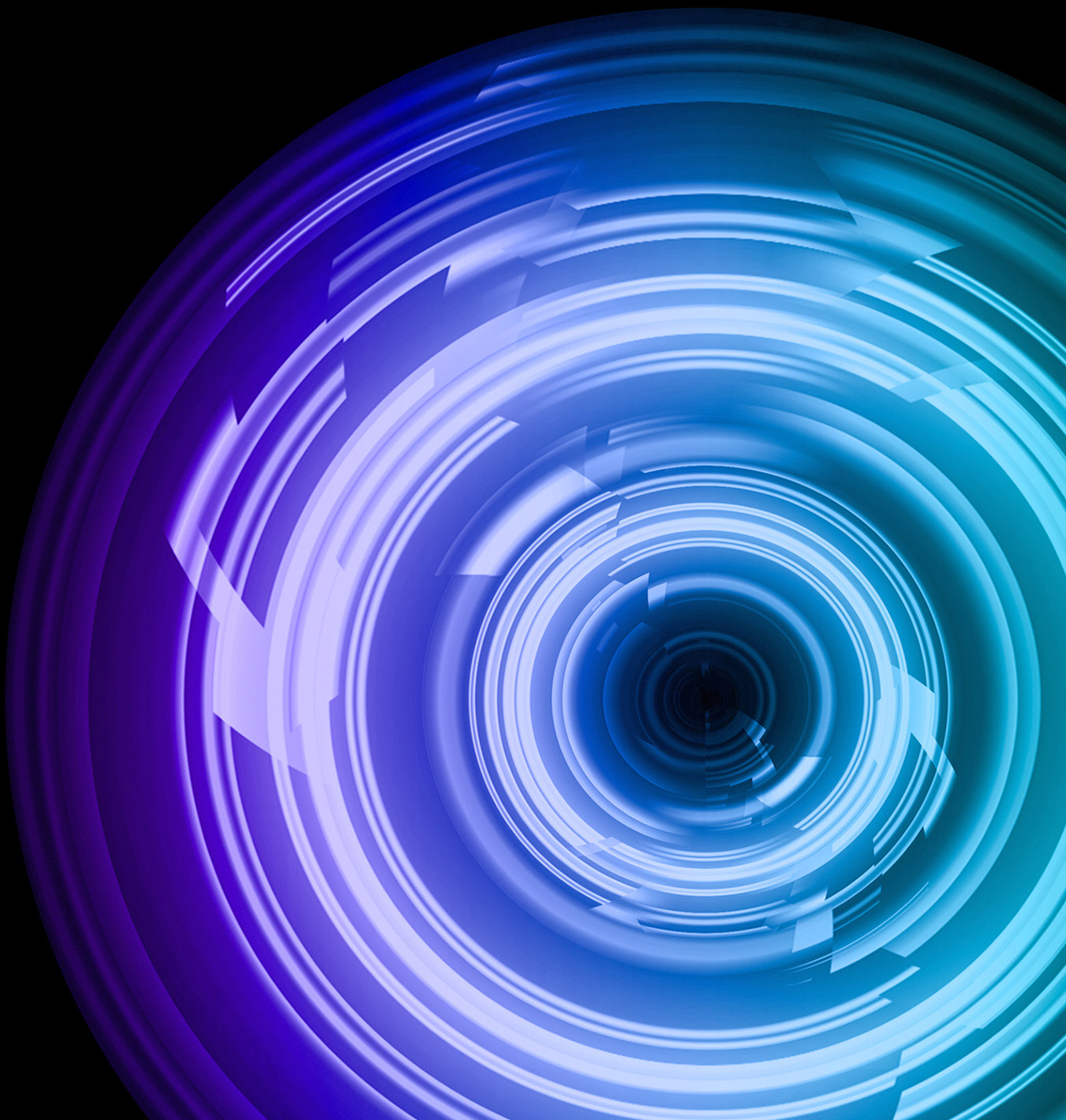# Deloitte.

# New opportunities for compliance in life sciences and health care

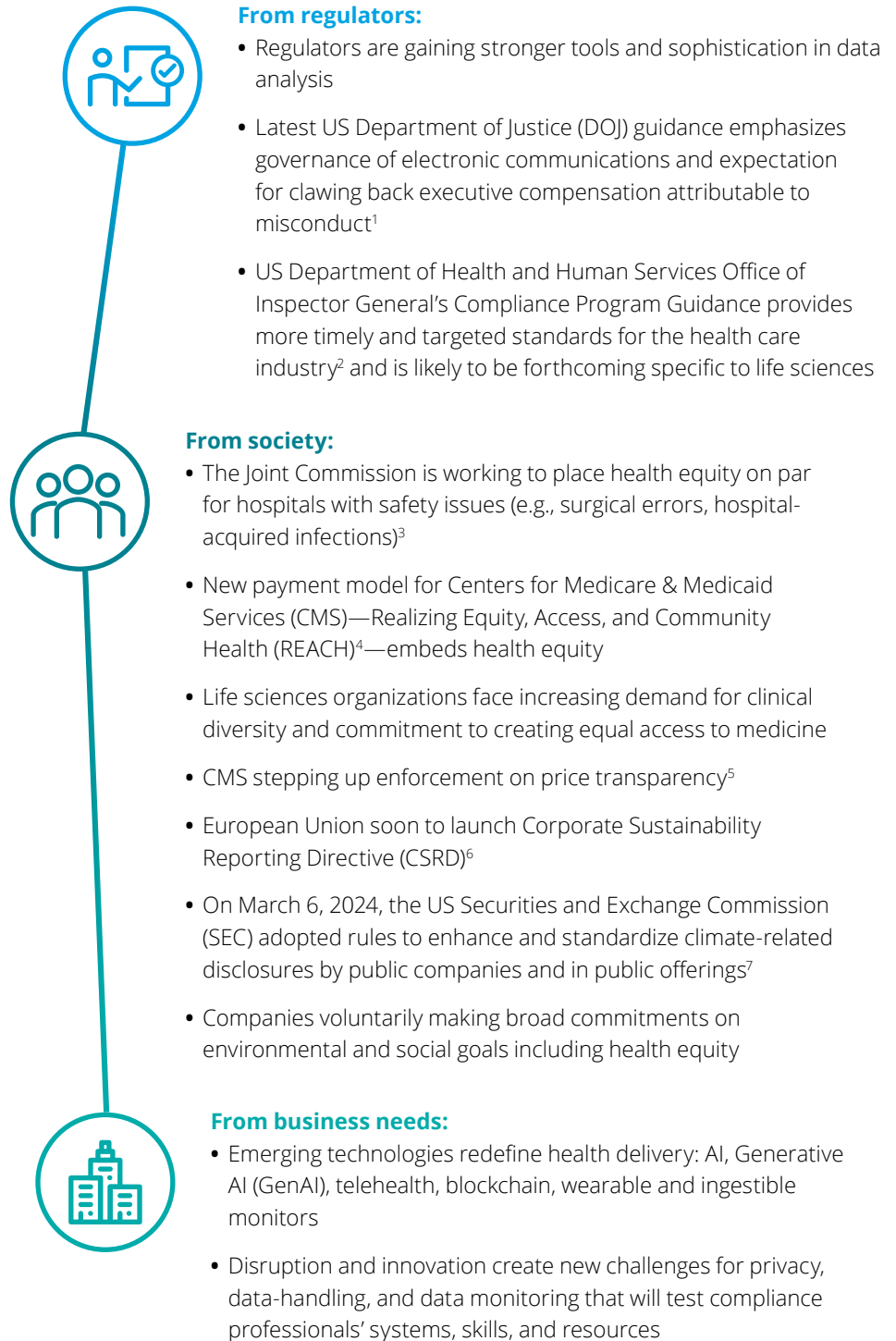**How organizations can meet growing demands—and go beyond**

Life sciences and health care organizations need to establish and maintain trust to operate—and compliance is essential to that trust. As the environment for these industries grows increasingly pressured in 2024 and beyond, it's no longer enough to follow the rules, check the boxes, and investigate any failings:

- Regulators demand more, as their surveillance tightens and their tools for monitoring compliance improve.

- Society demands more, expecting life sciences and health care organizations to enable health equity, protect information privacy and security, achieve sustainability, and reflect diversity and inclusion, all on behalf of a growing range of stakeholders.

- And business needs demand more, with intense competition, pressure on resources, increased use of disruptive technology, and ever-greater needs for insight and analysis.

In the United States and globally, compliance and regulatory professionals see challenges mounting in the years ahead (figure 1). While some life sciences and health care organizations have elevated their compliance and regulatory functions, many have not yet organized to meet new demands. Compliance should shift its focus from hindsight to foresight and, even more important, insight—deploying its data and tools to identify process improvements, control efficiencies, and new opportunities.

**Figure 1: Demands on compliance programs are growing**

**From regulators:**

- Regulators are gaining stronger tools and sophistication in data analysis

- Latest US Department of Justice (DOJ) guidance emphasizes governance of electronic communications and expectation for clawing back executive compensation attributable to misconduct[1]

- US Department of Health and Human Services Office of Inspector General's Compliance Program Guidance provides more timely and targeted standards for the health care industry[2] and is likely to be forthcoming specific to life sciences

**From society:**

- The Joint Commission is working to place health equity on par for hospitals with safety issues (e.g., surgical errors, hospital-acquired infections)[3]

- New payment model for Centers for Medicare & Medicaid Services (CMS)—Realizing Equity, Access, and Community Health (REACH)[4]—embeds health equity

- Life sciences organizations face increasing demand for clinical diversity and commitment to creating equal access to medicine

- CMS stepping up enforcement on price transparency[5]

- European Union soon to launch Corporate Sustainability Reporting Directive (CSRD)[6]

- On March 6, 2024, the US Securities and Exchange Commission (SEC) adopted rules to enhance and standardize climate-related disclosures by public companies and in public offerings[7]

- Companies voluntarily making broad commitments on environmental and social goals including health equity

**From business needs:**

- Emerging technologies redefine health delivery: AI, Generative AI (GenAI), telehealth, blockchain, wearable and ingestible monitors

- Disruption and innovation create new challenges for privacy, data-handling, and data monitoring that will test compliance professionals' systems, skills, and resources

Source: Deloitte analysis

To evolve compliance programs to effectively meet today's demands and prepare for tomorrow, life sciences and health care organizations should strive to overcome numerous hurdles, including:

- Disparate and inconsistent policies, processes, and systems that increase compliance burden without improving compliance.

- Resource constraints resulting from organizational contraction, time and talent consumed by routine regulatory tasks, rule enforcement, and lack of digital tools and capabilities to meet new challenges.

- The brand of compliance professionals as watchdogs, enforcers, or cleanup crews, rather than as active partners in ensuring that the business grows while maintaining the highest standards of ethics, integrity, and trust.

- Lack of consistent accountability and ownership for compliant outcomes throughout the business, which may view risk management as an afterthought and compliance as a safety net, rather than a key component of business decision-making.

Transformation isn't easy. But many life sciences and health care organizations that have tackled these challenges with intention to report strong returns for their efforts. Robust and agile compliance teams are stronger partners to the business, can better manage compliance costs, can focus on the most pertinent risks and issues, and are able to free up resources for higher-order tasks. Clearer processes and better interfaces make company commitments and standards clear, thereby making behaviors and decisions rooted in ethics more natural. Enhanced analytical tools enable compliance and regulatory professionals to drive insights to support the business as a whole. Elevating the role of compliance can create a more attractive career path to attract, develop, and retain new professionals.

Most important, empowering the compliance function within the business can drive more compliant outcomes—and thus maintain the trust with regulators, patients, providers, communities, and other stakeholders that life sciences and health care organizations need to survive and thrive.

**CASE STUDY**

## Building a digital-first solution for compliance service delivery

An integrated health care company wanted to streamline compliance services and improve stakeholder experience with a digital-first solution enabled by data-driven insights and automation. Deloitte helped develop the vision for a self-service digital compliance hub, supported by a compliance shared service operation with communities of expertise, where stakeholders initiate compliance inquiries, access compliance policies and standards, get questions answered, and retrieve data and insights. To build the hub's foundation, Deloitte is integrating compliance use cases into the enterprise's digital platform.

## What does a modernized compliance program look like?

To prepare for all that is to come, compliance programs should be:

*Encompassing*—Heavily regulated industries like life sciences and health care face pressures from all sides: regulators, patients, providers, and competitors. Organizations in these industries are deeply familiar with regulation and have long embraced a culture of compliance. New demands, however, require extending that culture. Regulators and stakeholders demand evidence that firms are meeting their commitments across the spectrum of interests. Taking those commitments beyond words and into action—and demonstrating that they've been met—creates new missions for compliance professionals.



**CASE STUDY**

## Monitoring outreach to health care professionals

A global pharmaceutical firm wanted to enhance training, monitoring, and auditing of its associates' meetings with health care professionals. Deloitte provides ongoing service to train associates and to conduct compliance checks before, during, and after events and meetings. Consistent, streamlined monitoring helps the firm increase efficiency and reduce risk, and continuous data analysis provides additional insights into process performance and compliance metrics.

*Embedded*—To meet demands old and new, organizations should ensure that every stakeholder interaction reflects the highest ethical standards. Compliance professionals cannot achieve that goal alone; every employee must embody both the letter and the spirit of regulations and practices to understand and model integrity and an ethical ethos.

Successful compliance programs will lead a shift from rules-based systems to a culture grounded in values—one where compliance is routine and ethical discussions are part of every decision. To make compliance routine, compliance professionals should ensure that rules are clear, consistent, readily available, and easily understood. To go further, compliance professionals should create a relationship of trust with business partners that allows compliance to be at the table from the point of concept and strategy to execution.

*Agile*—Neither regulatory demands nor public expectations remain static. Compliance professionals operate in a dynamic global environment, navigating a labyrinth of requirements while charged with upholding their organization's values and meeting rapidly evolving business needs. Compliance systems must be flexible to accommodate the risks, rules, and standards that are just emerging. This flexibility calls for new ways of working and a new workforce to meet a diverse set of challenges.

Compliance officers will need to draw upon skills ranging from industry expertise to business operations to data science—and more. Chief compliance officers (CCOs) will be challenged to create rewarding career paths for talented workers who have the skills to succeed in a wide range of roles—but also the ethical foundation and protective instincts to make compliance their mission.

*Technologically savvy*—Some compliance operations have been slow to embrace technology, relying too often on personnel-intensive manual processes. Compliance should look to apply technology creatively to meet growing burdens with limited resources. With fewer people-intensive processes, compliance professionals can focus on more strategic, value-creating efforts such as issue remediation and escalation, root cause analysis, investigations, and overall business advisory.

Streamlining the compliance workflow is just a first step. Digitally enabled interfaces can improve employees' ability to align to compliance requirements, helping embed compliance in the organization's routine and culture. Digital tools can use existing and new data to drive better decisions, advancing compliance's ability to advise the business on efficient ways to align to regulatory needs. Artificial intelligence (AI) offers promising avenues for both employee engagement and data analytics for current and future compliance needs. Digital tools can work tirelessly 24/7 across a full range of data and quickly create tailored outputs that highlight and illustrate trends or generate meaningful insights. Compliance teams that employ advanced analytics can see where trouble is likely to appear tomorrow—and work to keep it at bay.

## The promise—and perils—of Generative AI

Generative AI (GenAI) is reshaping the health care landscape; its transformative power extends across domains. That power can be used to not only enhance productivity and reduce costs but also streamline compliance processes and help improve outcomes. However, with this strong capability comes significant ethical questions, growing regulatory requirements, and a need for strong governance and monitoring. For compliance professionals, GenAI is both an appealing opportunity and a source for concern.

GenAI has the potential to accelerate the realization of compliance as a nimble business partner that drives tangible value. Compliance functions that have been early adopters have leveraged AI for regulatory scanning and decomposition, regulatory analysis, mitigation remediations, policy enhancement, and much more.

But the power of GenAI does come with risk. GenAI invokes questions of ethical use, privacy and IP infringement, and bias to name a few. Compliance organizations will need to partner across their organizations in an effort to make the use of GenAI responsible, accountable, safe and secure, and in alignment with regulatory standards.

Compliance should be part of cross-functional governance teams that evaluate the potential design and implementation of GenAI across the organization. Acknowledging and addressing the risks upfront, compliance can play a key role in GenAI achieving its promise in a trustworthy, transparent, and equitable way.

*Strategic*—Historically, compliance professionals have been regarded as reactive protectors, not forward-thinking advisers. In these highly regulated industries, compliance and regulatory professionals have unique opportunities to change that perception and demonstrate they are strategic business partners. By going beyond risk mitigation, compliance can team with the business to enable growth, process improvements, efficiencies, and differentiated market opportunities.

Achieving that role requires changing expectations for compliance professionals, from watchdogs and enforcers to enablers of value creation. In these ways, compliance can help provide roadmaps—rather than speed bumps— for expanding the business.

**CASE STUDY**
## Unifying digital compliance platforms

A global pharmaceutical company was confronted with multiple complex and disparate systems for compliance, leading to higher costs, poor communication, and ineffective reporting capabilities. Deloitte evaluated multiple platform options against a diagnosis of the current state and an evaluation of future needs. Implementation reduced 21 unique systems to nine and has provided consistent end-to-end workflow management, enhanced information-sharing and reporting capabilities, scalable systems, and improved user experience.

## How can compliance programs evolve?

Compliance organizations can be classified on a spectrum from basic—fulfilling traditional rule-based functions—to value-creating with compliance as an integral contributor to business innovation and growth (figure 2). To move up the maturity curve, transition requires changes in technology, approach, staffing, and roles. It also requires a robust process of careful change management.

How can life sciences and health care organizations that want to ascend that spectrum modernize their compliance functions? Following a staged approach can help. Steps include:

- *Determine* the desired goals, objectives, and expected outcomes in modernizing the compliance and risk management functions.

- *Gain buy-in* from the C-suite and the board for moving toward a new, enhanced approach by articulating the value it will bring.

- *Assess* the current functions—people, process, technology—against the desired modernized program.

- *Set priorities* for both functional capabilities and organizational risk areas that need attention, including anticipated changes in the organization, the industry, and the market.

- *Update* the purpose and role of compliance and risk management to reflect the desired future state, ensuring that it aligns to the organization's overall strategy.

- *Implement* the new strategy.

- *Measure* the results and apply lessons learned to continuously evolve and improve the function.

**Figure 2: Moving compliance from basic to value-creating**

|  | Basic compliance | Modernizing compliance | Value-creating compliance |
|---|---|---|---|
| **Role** | Align to regulatory requirements and fulfill basic compliance | Develop clear compliance vision to embed across entire organization | Use compliance insights to create new value in the business |
| **Message** | Follow the rules | Make ethical decisions, go beyond the rules | Embed compliance in every employee's relationship with every stakeholder |
| **Technology** | Bespoke, fragmented | Automated, embedded processes to reduce burden, empower employees | Broad use of process automation and predictive analytics |
| **Staff** | Follows defined operating model, identified roles, responsibilities | With less manual work, more focus on strategic insights from compliance analytics | Thinks strategically, provides roadmaps for growth instead of speed bumps |

Source: Deloitte's standard maturity assessment levels

### CASE STUDY
## Transforming revenue cycle compliance

A health care system's program for revenue cycle compliance was inefficient, narrowly focused on provider billing, and often reactive with minimal education and process improvement support. Deloitte implemented a program that leverages data to continuously identify risk areas, trends, and patterns and enable a continuous risk-based auditing, monitoring, and education program, supported by a global delivery center of industry specialists. By deploying standardized audit approaches, pre- and post-audit communications, data-driven reporting, and post-audit education for providers and coders, billing compliance risks are reduced while the stakeholder experience with compliance is greatly strengthened. In addition to auditing and monitoring, Deloitte provides ongoing assistance for helpline issues, investigations, new provider onboarding, and education on regulatory changes.

**New opportunities for compliance in life sciences and health care**

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# Endnotes

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3.  The Joint Commission, "Health care equity," accessed April 4, 2024.

4.  Centers for Medicare & Medicaid Services (CMS), "ACO REACH," accessed April 4, 2024.

5.  CMS, "CY 2024 Hospital Outpatient Prospective Payment System (OPPS) policy changes: Hospital price transparency (CMS-1786-FC)," November 2, 2023.

6.  European Commission, "Corporate sustainability reporting," accessed April 4, 2024.

7.  US Securities and Exchange Commission (SEC), "SEC adopts rules to enhance and standardize climate-related disclosures for investors," press release 2024-31, March 6, 2024.

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