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2025 Life sciences regulatory outlook

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Technical transformation

In 2025, regulatory and compliance functions within life sciences and health care organizations are poised for significant technical transformation. The adoption of advanced technologies, such as artificial intelligence (AI) and Generative AI (GenAI), can redefine how these organizations manage compliance. AI and GenAI can enhance productivity by automating routine regulatory tasks, enabling near real-time data analysis, and providing predictive insights that help identify and mitigate compliance risks before they materialize. These technologies can streamline compliance processes, help reduce the burden on human resources, and allow compliance professionals to focus on strategic, value-creating activities such as issue remediation, root cause analysis, and overall business advisory.

Moreover, the integration of digital tools and platforms can facilitate enhanced data handling, monitoring, and reporting capabilities. The compliance function can go through the transformation of being proactive versus reactive and shift to ongoing monitoring from legacy paper-based processes in some cases. Compliance teams can leverage these tools to create more transparent, accountable, and secure systems that align with evolving regulatory standards. The use of advanced analytics can enable compliance professionals to foresee potential issues and address them proactively, thereby maintaining the trust of regulators, patients, providers, and other stakeholders. As organizations embrace these technological advancements, they will also need to strengthen governance and monitoring frameworks to help address ethical concerns, privacy issues, and potential biases associated with AI and other emerging technologies. This transformation can enhance compliance efficiency and also help embed a culture of integrity and ethical decision-making throughout the organization.

AI and automation: Future ways of working

Continuous monitoring

In the dynamic life sciences sector, effective compliance and risk management are essential. The rapid integration of digital technologies and innovative business models necessitates that compliance teams adapt swiftly. Traditional data collection methods are inadequate, highlighting the need for continuous monitoring to facilitate timely oversight of compliance risks.

Continuous monitoring involves maintaining ongoing awareness of potential risks within an organization. This proactive approach can enable early detection and mitigation of issues, potentially preventing minor concerns from escalating.

The transformation of business models and digital advancements in life sciences has increased pressure on compliance teams. Traditional monitoring techniques often fall short, leading to data overload and missed risks. Continuous monitoring enables a shift from reactive to proactive compliance, enhancing agility and responsiveness.

Without continuous monitoring, organizations risk missing critical compliance issues, which may lead to regulatory noncompliance; penalties; and damage to reputation, efficiency, and financial stability. Traditional methods may also lack the agility needed to respond to new business models, increasing the potential for oversight.

GenAI model validation and ongoing monitoring

The advent of GenAI has marked a pivotal transformation for many organizations. It offers efficiencies, insights, and enhanced customer engagement but also introduces new and heightened risks—some of which can be mitigated through model validation and continuous monitoring. GenAI presents new and amplified risks that can adversely affect an organization if not properly managed. Some of these risks include privacy breaches, hallucinations, data leakage, prompt injection, toxicity, unintended bias, adversarial attacks, and IP infringement.

If these risks are not mitigated, they can lead to significant enterprise consequences such as financial loss, reputational damage, poor strategic decisions, operational disruptions, and regulatory violations. GenAI model validation and monitoring are crucial in helping mitigate these risks.

The following are some ways to monitor and manage emerging risks:

- Data assessment involves evaluating data sources, quality, integrity, and relevance by examining tokenization, analyzing data chunking, and assessing data acquisition and sufficiency (e.g., error analysis, learning-curve analysis, and out-of-sample testing).
- Conceptual soundness involves assessing the model's design, framework, and architecture. It evaluates the existence and quality of guardrails, assesses prompt construction, and reviews GenAI leaderboards and benchmarks.
- Performance testing involves evaluating the model's performance and quantifying various risks through testing. This includes analyzing hallucinations using consistency scoring and assessing the prompt injection rate. It also involves calculating accuracy (i.e., bilingual evaluation understudy, or BLEU) and retrieval augmented generation (RAG) evaluation metrics.
- Implementation testing and controls involves evaluating IT implementation processes and user acceptance testing (UAT), which includes evaluating the size, range, and appropriateness of GenAI UAT, along with GenAI-specific IT implementation processes and controls.
- Ongoing monitoring reviews the scope of the ongoing monitoring plan and test results. It assesses the selection of monitoring metrics and evaluates the scope, frequency of reviews, key performance indicators (KPIs), and thresholds for performance metrics.

GenAI regulations

The use of AI and GenAI in the life sciences industry has the potential to revolutionize work production and drive significant business transformation. Governments and health authorities across various regions, including the European Union (EU), United Kingdom (UK), United States (US), China, Japan, and India, have expressed a commitment to ensuring AI adoption is human-centric; trustworthy; and protective of health, safety, and fundamental rights. Despite these common goals, the approaches to AI regulation differ significantly across these regions. For instance, the EU has adopted a horizontal legislation approach with the EU AI Act, which applies to all AI systems and emphasizes a risk-based framework. The EU AI Act officially came into force in August 2024, marking the establishment of a comprehensive regulatory framework for AI across industries, including life sciences.[1] EU is approaching the AI Act horizontally and approaching industry-specific regulations vertically. It is the most detailed legislation. China, on the other hand, focuses on a vertical approach with regulations tailored to specific AI technologies. In the US, the approach to AI regulatory framework has been in flux. The new US administration has rescinded the previous AI executive order and, on January 23, 2025, replaced it with the executive order "Removing Barriers to American Leadership in Artificial Intelligence," which aims to position the US as the global leader in AI. It also established an advisory council on science and technology, focusing on several innovative technologies, including AI.

In 2024, landmark bills in the EU and California set the tone for emerging AI regulations. Collaborative efforts, such as the G7's Hiroshima AI Process and the G20's commitment to international AI governance, aim to harmonize regulatory frameworks and promote international cooperation but are not binding. A unified regulatory environment could benefit life sciences organizations by enabling them to plan and enhance their products and processes using AI, ultimately benefiting consumers with innovative life sciences products and services that can help improve health and quality of life.

Numerous countries may roll out new AI regulations in 2025. Among them are the UK and EU. While the initial approach centered on adapting existing frameworks to accommodate new technologies, there is now a growing recognition among some lawmakers in favor of establishing dedicated AI legislation, with the stated goal of balancing innovation and the safety of AI. Enacted global regulatory frameworks often aim to ensure that AI is safe and secure, with effective governance and appropriate oversight, such that it does not undermine the legal rights of the users and patients.

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Social media

Fair market value (FMV) for digital opinion leaders

Internet influencers, also known as digital opinion leaders (DOLs), may be compensated by pharmaceutical and medical device organizations for sharing their expertise. This practice has been common in the life sciences industry, with DOLs being the latest group of health care professionals to educate audiences.

Unlike traditional media, the internet enables DOLs to reach vast audiences quickly. High-profile DOLs with more than a million followers can attract the demographics and engagement organizations desire. Compensation for DOLs often depends on follower tiers and social media metrics, including engagement rates, which measure likes, comments, views, and shares.

Earned media exposure, or the ability to drive conversations beyond their own posts, also influences DOL compensation. Life sciences organizations of different sizes consider working with DOLs, with multinational corporations and those targeting rare diseases recognizing their value.

Engaging DOLs in this regulated industry requires compliance team input. Determining FMV for DOL content involves complex calculations, but a thorough analysis of metrics can justify compensation and support the organization's engagement strategy.

Third-party due diligence

Anti-bribery and anti-corruption (ABAC) in action

In 2024, the life sciences sector saw a decline in M&A activities due to the absence of blockbuster deals, high global interest rates, and increased anti-trust enforcement. Despite this, medtech M&A rebounded, driven by significant investments in cardiovascular assets. Predictions for 2025 include continued big pharma M&A to offset revenue losses from patent expirations, increased medtech consolidation, and a rise in diagnostics and neurology M&A. Overall, the sector anticipates a bullish outlook for 2025 with strategic growth in key therapeutic areas. As these M&As take place, organizations will have to keep risk management and due diligence at the forefront.

Organizations in the life sciences industry often operate with limited budgets for third-party risk management, benefiting significantly from integrated platforms that foster a risk-based approach. These platforms serve as central hubs for risk identification, enhancing risk categorization and due diligence through technology. They provide near real-time insights for quicker issue remediation and facilitate continuous improvement through feedback loops. Automating basic screenings for lower-risk third parties can reduce costs, enabling teams to focus on higher-risk audits, which is crucial in a highly regulated sector.

A robust ABAC program should align with business activities to effectively detect and prevent fraud. This requires access to diverse data sets from finance, procurement, and regulatory compliance. Integrated data structures, such as data lakes, help identify synergies across functions to optimize operations. Data-driven risk-scoring models prioritize third parties based on risk and assist compliance teams to detect price manipulation, control weaknesses, and potential fraud. This is vital for preserving the integrity of clinical trials, product safety, and patient trust.

Tech enablement improves program quality and coverage throughout the third-party life cycle, starting with automated screening. Advanced technologies like AI and machine learning enhance due diligence by integrating data sources for real-time insights, which is crucial for fast issue resolution. Approaches to ABAC and third-party due diligence (TPDD) programs use risk-tiered procedures. Rapid third-party risk assessments entail basic checks for lower risks and detailed steps, like shareholder identification for higher risks. Documenting these procedures within a comprehensive ABAC framework supports improvement and compliance, which is essential for safeguarding public health. Robust risk management underpins the development and distribution of new therapies and devices.

Chemicals of concern

Chemicals of concern (CoCs) are substances found in pharmaceuticals, medical devices, consumer products, and food that pose significant health and environmental risks. Examples of these chemicals include per- and polyfluoroalkyl substances (PFAS), titanium dioxide (TiO_2), benzene, and nitrosamines. Regulatory bodies such as the European Medicines Agency, US Food and Drug Administration, European Chemicals Agency, and US Environmental Protection Agency are actively evaluating and implementing regulations to manage these substances. The implications of these regulations are substantial, potentially leading to loss in revenue, lawsuits, and the removal of essential medicines from the market. CoCs are prevalent in everyday items like dry shampoo, makeup, and nonstick pans, which has led to heightened consumer awareness and regulatory scrutiny. This increased scrutiny can be seen in a variety of regulatory actions across the globe. For example, global regulators setting nitrosamine limits in pharmaceuticals, European regulators setting restrictions on the use of TiO_2 in foods, and the enforcement of reporting requirements, maximum contaminant levels, and restrictions on the use of PFAS in various products drawing concern from both executives and consumers. In 2025, we anticipate a continued rise in the restriction of common ingredients.

The risks associated with CoCs can be categorized into patient safety, market access, business continuity, and brand reputation. Safety concerns stem from the toxicity and widespread presence of these chemicals, prompting stringent regulations that significantly affect vulnerable populations. Market and business risks include potential supply chain disruptions and product recalls, which necessitate robust risk mitigation strategies. Additionally, reputation and trust are paramount as growing patient-consumer awareness and advocacy can have an impact on brand loyalty
and financial performance. To navigate these challenges, organizations are implementing proactive measures within their supply chain controls and ABAC/TPDD procedures. They are also investing in AI and machine learning to enhance risk identification, categorization, and mitigation throughout their product development pipelines. Automating basic screening processes can reduce costs and allow a focus on higher-risk areas, while a digital ecosystem is essential for managing CoCs, integrating data, and streamlining regulatory responses.

Effective risk mitigation also requires collaboration with external stakeholders and cross-functional internal teams. As regulations continue to evolve, proactive measures and digital innovation will be important in maintaining brand reputation and consumer trust.

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Medtech's drive to compliance and innovation

The Deloitte Center for Health Solutions conducted a survey in the summer of 2024 involving 85 medtech leaders to assess the benefits they derived from AI and GenAI.[2] The findings reveal that 42% of executives acknowledged AI's impact on product development, while 35% noted improvements in IT and cybersecurity. Furthermore, GenAI is projected to help medtech organizations achieve cost efficiencies ranging from 6% to 12% of total revenue over the next few years, potentially translating into substantial savings.[3] For organizations with revenue between $20 billion and $26 billion, this could mean a cost reduction amounting to $1.2 billion to $3.2 billion.[4]

To harness AI's potential while remaining in alignment with regulatory standards, medtech organizations should focus on three main areas: establishing ground rules for AI deployment, shaping internal governance systems, and promoting transparency and accountability. This involves documenting AI algorithms, ensuring data privacy, and maintaining model transparency. Additionally, organizations should train their employees to become fluent in AI applications, confirming they are aware of both the opportunities and limitations posed by this technology and to be able to validate the AI's output. Enhancing workflows to integrate AI efficiently can also help in aligning with regulatory requirements and improving operational efficiency. As medtech organizations embrace AI, they are encouraged to develop a strategic blueprint that aligns AI initiatives with both business objectives and regulations. Medtech organizations should have global regulatory intelligence capabilities to stay abreast of the changing regulatory environment by region and country as they differ, and some things might be allowed in one part of the world but not in others. Identifying high-value opportunities that comply with the regulatory framework is important, as is establishing teams or centers of excellence to govern AI investments. By fostering responsible AI usage, setting clear guidelines, and ensuring transparency in AI processes, medtech organizations can be positioned to mitigate risks and build trust among stakeholders. Ultimately, these measures can not only strengthen compliance but also pave the way for sustainable innovation within the industry.

Understanding the 340B drug pricing program

The 340B Drug Pricing Program, established by the Veterans Health Care Act of 1992, is a federal program in the United States that mandates drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices.[5] The intent of the program is to enable these entities, which often serve vulnerable and underserved populations, to stretch limited federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. By reducing the cost of pharmaceuticals, the 340B program aims to improve access to medications and health services for those who need them most.

The 340B program has faced numerous challenges from various stakeholders, including health care providers, pharmaceutical manufacturers, and policymakers. The program has experienced exponential growth over the years: Sales through the 340B channel are estimated to exceed $124 billion and are growing faster than non-340B channels. [6] Critics argue that the rapid expansion has led to some entities potentially exploiting the program's benefits, diverting resources away from the intended low-income patients.

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Pharmaceutical manufacturers have called for reform within the 340B program. They argue that the program's current structure allows for significant financial gains by covered entities without necessarily translating into increased patient care or reduced drug prices for patients. Manufacturers contend that the lack of stringent oversight and clear guidelines has led to abuses, such as hospitals and clinics generating substantial revenue from the resale of discounted drugs to insured patients, rather than using the savings to support indigent care.[7]

Drug manufacturers are actively pushing for changes to the 340B program, including proposing rebate models, engaging in audits, and initiating legal action, all aimed at reducing perceived abuse of the program. In-house 340B teams are working closely with legal and policy colleagues to educate the Health Resources and Services Administration (HRSA), Congress, and the public on the perceived challenges of the program. At the same time, parties from the provider side of the program seek to educate and advance alternative perspectives. Regardless of point of view, it is certain that the program will continue to be challenged. With multiple rebate-related suits from manufacturers against the HRSA and multiple audit-related suits from covered entities against the HRSA, outcomes of these cases will change the landscape whether or not the HRSA acts.

Manufacturers are advocating for several key changes to the 340B program to address these concerns. They propose enhanced transparency and accountability measures such as requiring covered entities to report how savings from the program are used and ensuring that the benefits directly support patient care. Additionally, manufacturers suggest implementing stricter eligibility criteria for participating entities and improving the auditing process to prevent misuse. These reforms, they argue, would help restore the program's original intent and ensure that it continues to serve the needs of vulnerable populations effectively.[8]

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Thank you to the following contributors:

Michael Crowthers, Russell Rose, Clifford Goss, Oliver Steck, Malka Fraiman, Kush Varma, Mark Pearson, Dimple Thomas, Mark Paternostro, Allison May, Mayura Gill, Jillian Patane, Clarissa Crane, Jenisha Malhotra

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