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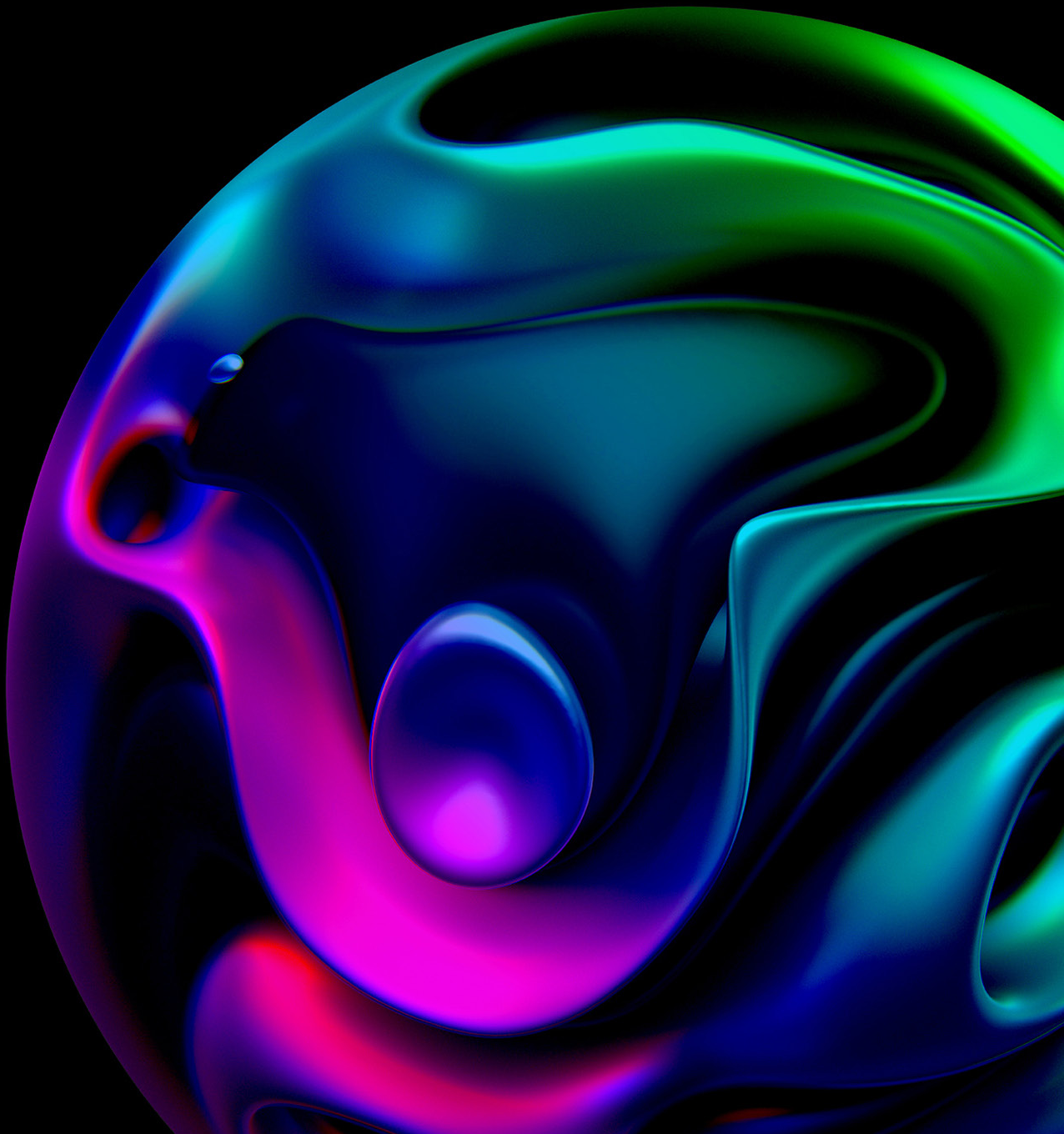
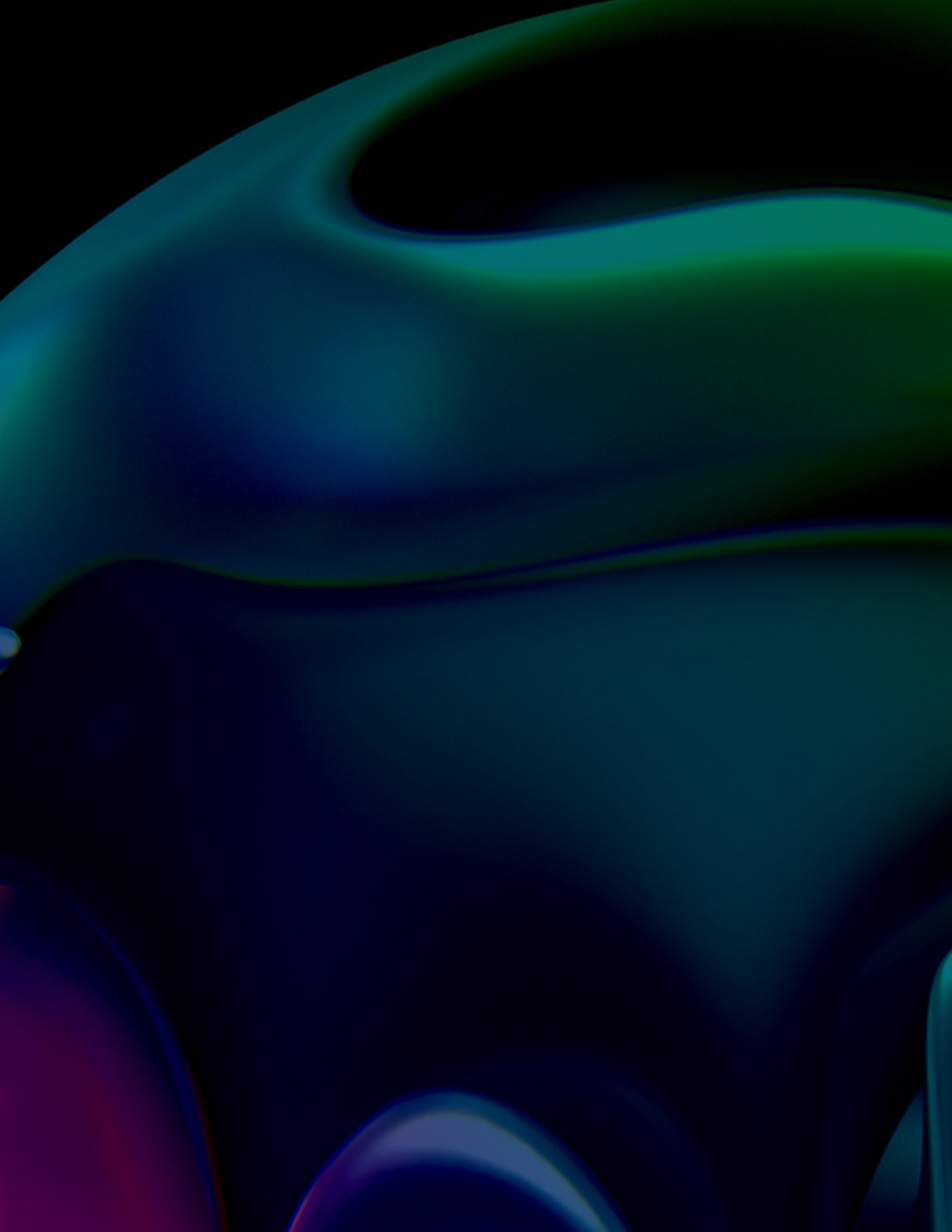
A global look at generative AI regulations in life sciences





Use of artificial intelligence (AI) and generative AI (GenAI) in the life sciences industry, if used boldly, can revolutionize work production and be "a catalyst to a radical business transformation."[1]

As discussed in a recent Deloitte article,[2] "Can life sciences companies unlock the full value of GenAI?," the use of a string-of-pearls strategy—stringing multiple use cases and other digital tools together (rather than using individual GenAI use cases)—could transform entire processes.

While GenAI has much promise, the global AI regulatory environment could pose challenges for the life sciences industry. A global collaborative and clarity of the regulatory environment can help accelerate the AI journey and adoption across regions. We recognize that a global set of regulations is not feasible. However, it is our belief is that the potential role of global guardrails based on countries' regulatory approaches will provide regulatory clarity and could be beneficial. A string-of-pearls approach can only be utilized effectively if the multiple technologies and geographies are aligned to a harmonized regulatory environment.

Deloitte's Global Regulatory Intelligence Team (GRIT) explored the regulatory environment of AI in six geographical jurisdictions as well as other international standards development organizations such as the International Organization for Standardization (ISO).

While at the global level there are a high number of "overall" cross-industry AI standards available[3] under development, ISO Technical Committee (ISO/TC) 215 was tasked to set up a road map to steer the creation of AI life sciences–specific standards at the ISO level. Resolution 2019-106 of ISO/TC 215 created a road map to future directions in developing standards for AI health applications and provided a set of 28 recommendations. The more technical staff will utilize International Electrotechnical Commission (IEC) standards through the SNAIG (Software Network and Artificial Intelligence advisory Group) TC 62[4] on AI and connected topics.

Across the six geographies observed—European Union (EU), United Kingdom (UK), United States (US), China, Japan, and India—governments and health authorities have stated they strive for AI uptake to be human-centric and trustworthy, and to facilitate protection of health, safety, fundamental rights, democracy and rule of law, and the environment from harmful effects. However, despite common stated goals, a variety of approaches to AI regulations were found:

- The EU focuses on a horizontal legislation with standardization per sector. The EU AI Act may be one of the stricter frameworks globally. The EU approach is to regulate AI as a single broad field (rather than as separate technologies or sectors).[5] On December 9, 2023, the European Council and the European Parliament reached a provisional agreement on AI harmonized rules of the AI Act, which aims to ensure the safe use of AI and respect fundamental rights and EU values. The legislative initiative utilizes a "risk-based" approach: the higher the risk, the stricter the rules. The new provisional agreement includes four main elements: rules on high-risk AI systems, governance with enforcement powers at the EU level, an extensive list of prohibitions, and requirement of high-risk AI systems to conduct a fundamental rights impact assessment.[6]

  One of the unique provisions of the EU AI Act is related to its applicability to other countries outside of the EU. The act applies to any provider placing either an AI system or service in the European Union, regardless of the provider's global location. The EU AI Act also applies to users of AI systems located in the EU. Additionally, the EU AI act applies to providers and users located in a "third country where the output produced by the system is used in the EU."[7]

- The UK government is currently taking a pro-innovative and sector-focused approach to regulating AI, defining the core characteristics of AI to establish the scope of its regulatory framework to guide sectors. Enforcement would be on a nonstatutory basis and implemented by existing regulators.

- In the US, there is no comprehensive federal legislation on AI; however, the White House and regulatory agencies have acted within their existing authorities. The US Food and Drug Administration[8] issued several discussion papers and guidance documents regarding the use of AI in drug development and medical devices. On October 30, 2023, President Biden issued an executive order (EO)[9] to direct the federal government to plan its own use of AI as well as begin plans to regulate and oversee the use of AI in the private sector. This EO emphasizes the intent of the administration to work with global allies such as the Group of Seven (G7, which includes Canada, France, Germany, Italy, Japan, UK, and US) to establish an international framework that will be the foundation of the development of AI use cases. This EO may speed up US regulatory framework development. The Federal Trade Commission (FTC) is also involved in AI regulations in the US and is mainly focused on consumer protection and the risks of AI associated with consumer data that's collected and processed.[10] Section 5 of the FTC Act prohibits "unfair or deceptive acts or practices in or affecting commerce,"[11] and further described as "a broad and flexible provision under which the FTC actively prosecutes companies that deploy AI in a harmful or deceptive manner."[12]
- Like the US, Japan currently has no overarching AI regulation, and it's employing its "soft law" governance. General guidelines are released from several ministries to help industries (companies) develop and utilize AI solutions aligned with a basic philosophy (e.g., "Social Principles of Human-Centric AI" published by the Japanese government).[13]
- Compared to other countries, China initiated the focus on AI later. Its policy toward AI and data is evolving from "internet+ (*plus*)" to "data x (*multiply*)),"[14] and has taken a more vertical approach to address singular AI issues (compared to the EU horizontal approach, which applies standards across a wide range of AI applications): "China combines national-level, provincial, and local regulations with an emphasis on upholding state power and cultural values."[15] The regulatory authorities are continuously introducing AI-related laws and regulations, which are tailored to the development of existing technologies. The "New Generation Artificial Intelligence Development Plan,"[16] which was introduced in 2017, aims to make China a global leader in AI by 2030.
- The Indian government has vacillated between a nonregulatory approach, which fosters innovation, and a more cautious one, which emphasizes mitigating user harm.[17] An approach of minimal regulation stems from the view of being innovative-forward, while the risks associated with AI require some guiding frameworks. India has aspirations to be the global AI hub, which makes some regulatory framework necessary. In April 2013, the Indian government declared that it would not regulate AI, but two months later the Digital India Act would serve to regulate AI.[18]

At the 18th G20 Summit in New Delhi, which took place September 9–10, 2023, a G20 Leaders' Declaration was adopted in which leaders committed to "work together to promote international cooperation and further discussions on international governance for AI."[19] On October 30, 2023, leaders of the G7 announced international guiding principles (known as the Hiroshima AI Process[20]) and a code of conduct for companies developing advanced AI systems aimed at fostering international cooperation in the realm of AI.[21] The ministers intend to collaborate with prominent international organizations and actors, among them the Global Partnership on Artificial Intelligence (GPAI),[22] which met in India in December 2023 to start the process. Once those guiding principles are established, there may be a shift in approach of jurisdictions toward similar AI regulations and guiding principles. On December 6, 2023, G7 leaders issued a statement on many global challenges, AI regulation being one of them, following their virtual meeting: "We renew our commitment to advancing international discussions on inclusive artificial intelligence (AI) governance and interoperability between AI governance frameworks, while we recognize that approaches and policy instruments to achieve the common vision and goal of trustworthy AI may vary across G7 members, to achieve our common vision and goal of safe, secure, and trustworthy AI, in line with our shared democratic values."[23]

Because many life sciences companies are operating globally and would need to adhere to a range of regulations across jurisdictions , moving forward with a string-of-pearls strategy may require clarity and standardization of those regulations. Clarity of the trajectory of the global regulatory AI environment and framework could be beneficial to global life sciences companies in their ability to plan for the future in terms of products, systems, and process enhancements using AI. It could ultimately enable life sciences companies to either maintain or enhance their competitive edge. It may also benefit consumers as enhancements using AI can bring to the market innovative new life sciences products and services that can improve consumers' lives and health.

Endnotes

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