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China Life Sciences & Health Care Industry

Recent regulatory initiatives and impact

2023

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Overview: Accelerated centralized anti-corruption rectification in China

Since 5 January 2023, when China's Central Commission for Discipline Inspection (CCDI) published a resolution saying it would fight a tough and protracted war against bribery and corruption, deeper "special rectification work" on corruption has begun in several sectors of the economy including healthcare, social security and elderly care services. A few months later, 14 Government departments including the National Health Commission (NHC) issued the *Notice on the Key Points for Correcting Unhealthy Practices in the Field of Pharmaceutical Purchase and Sales and Medical Services in 2023*, which strengthens investigations of all forms of bribery committed by pharmaceutical companies, distributors, sales representatives, hospitals, and other participants in pharmaceutical and medical services. Nation-wide rectification work under the Notice has four phases with various highlights in each phase:

Phase I :
By July 2023
Self Review

- Educational learning and mobilization for self-correction in all hospitals

Phase II :
August 2023 ~ May 2024
Centralized Inspection

- Investigation of key issues and typical cases followed by disciplinary actions

Phase III :
June 2024
Summarization and Rectification

- Preparation and revision of applicable laws and regulations

Phase IV :
Till 2027
National ABAC Campaign

- Medical sector included in China's 5-year ABAC campaign

This rectification work has now been in progress for several months and its key features are now clear:

Ambition and focus
This is a nation-wide campaign that comprehensively covers up- and downstream industrial chains, including hospitals, pharmaceutical and medical device companies, distribution channels, contract outsourced services (CXOs), and healthcare organizations (HCOs). The Government also shows a strong commitment to addressing corruption issues, particularly in key positions of power within the life sciences and healthcare industry.

Alliances and coordination
Inspections are being carried out by provinces using various methodologies and procedures for different focuses and areas. Cross-provincial and cross-governmental department inspection measures have had a strong deterrent effect.

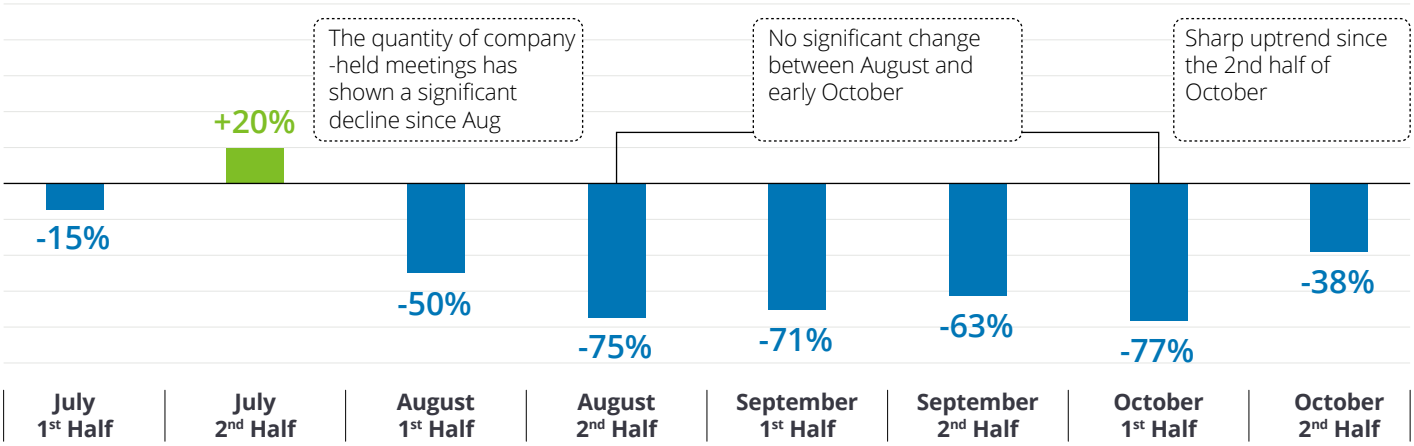
Long-term impact
Each phase of rectification work has a different specialty, with the central Government having launched a five-year anti-bribery and anti-corruption plan that will extend the impact on the pharmaceutical and medical services sectors until 2027.

Market responses

In August, outpatient volume decreased by a slight 8%, medical consumption fell by 16%, and there was a 12% decline in surgical procedures, indicating a drop in national clinical volume since the start of the rectification period.

The volume of marketing events, a typical promotion activity for pharmaceutical and medical device companies, fluctuated between July and October.

Fluctuations in marketing event activity



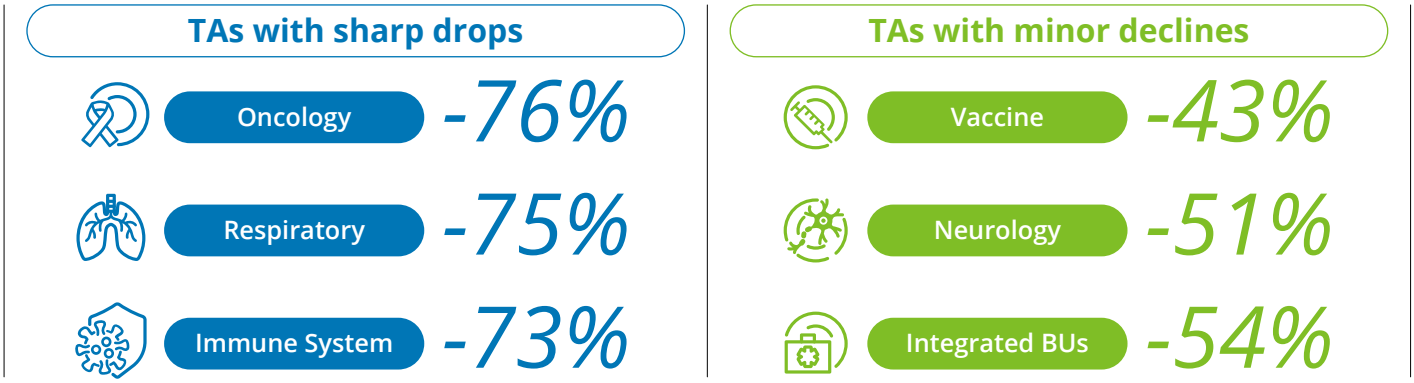
Source: Deloitte Analysis

There are other notable trends in industry marketing.

Varied flexibility and demand in therapy areas

Oncology witnessed the most substantial declines in meetings held by companies and clinical medicine consumption.

Changes in marketing events by therapeutic area

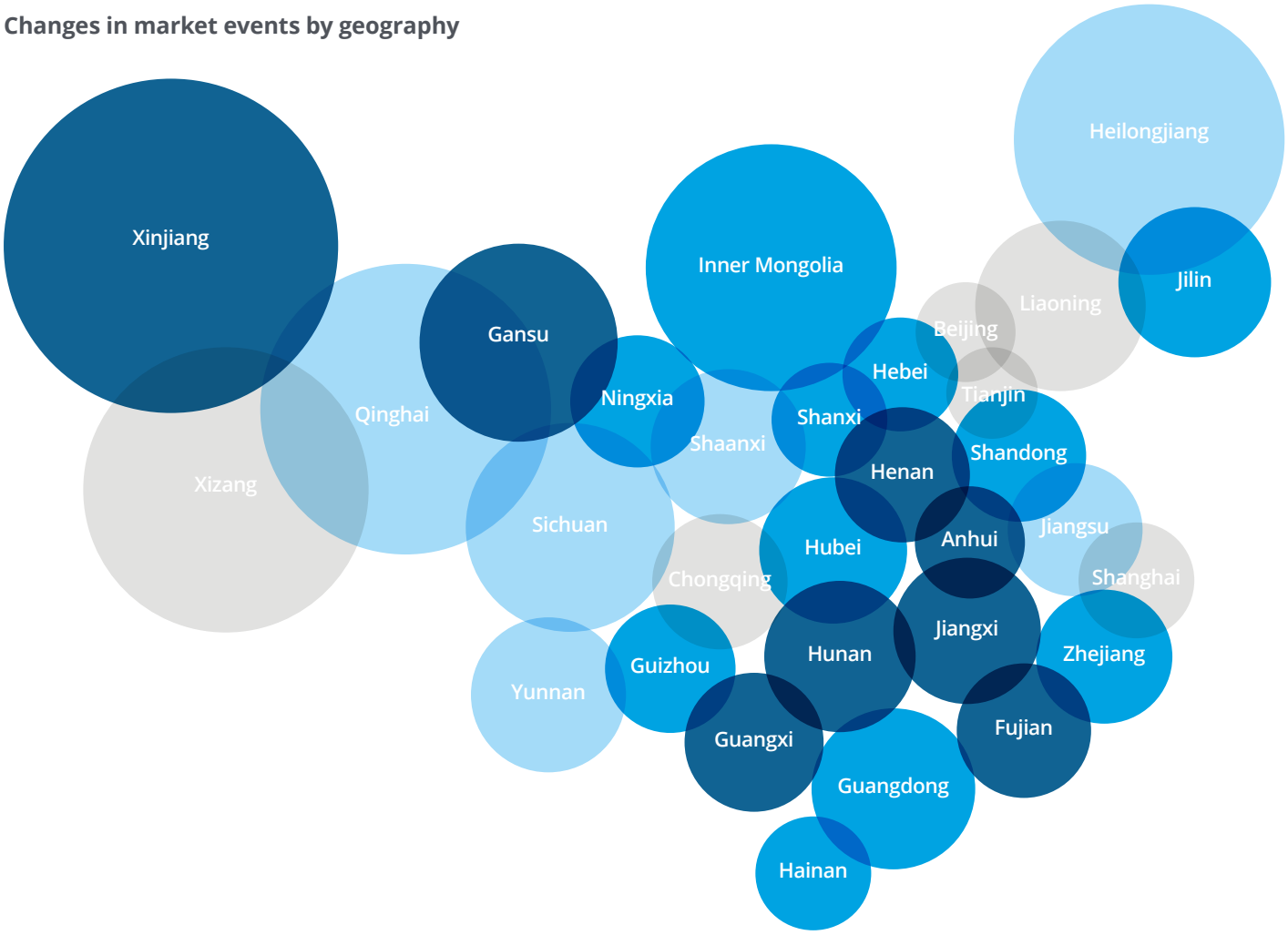


Source: Deloitte Analysis

The volume of events has varied from region to region

Although there were high rates of decline in all regions in August and September, the Northwest, Northeast and Northern regions saw slightly stronger recoveries than in other regions.

Changes in market events by geography



Reduction Ratio Range

- >70%
- 65%-70%
- 60%-65%
- <60%

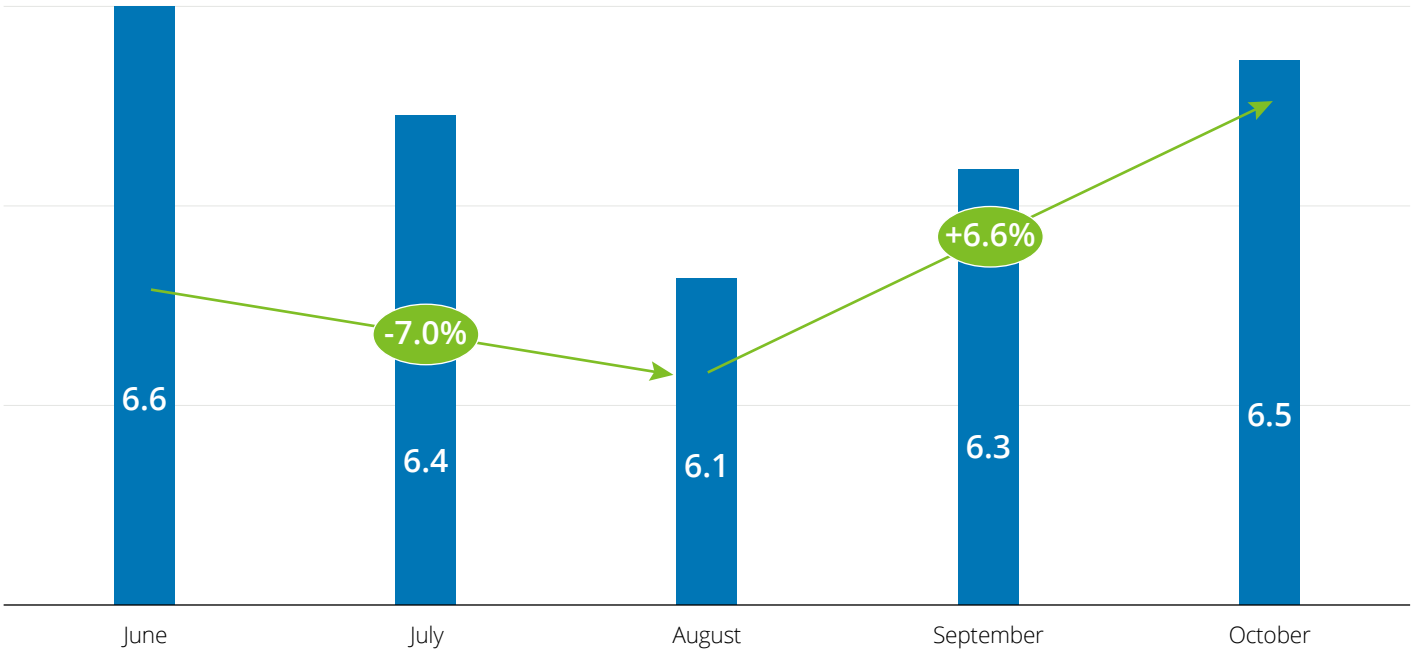
Regions	Decrease rate - August	Decrease rate - September	Decrease rate - October
Central	-73%	-70%	-65%
Northwest	-69%	-59%	-49%
South	-69%	-61%	-59%
East	-66%	-64%	-63%
Southwest	-62%	-66%	-52%
Northeast	-54%	-56%	-50%
North	-54%	-53%	-51%

Source: Deloitte Analysis

A more agile approach to meetings

By focusing on sharing knowledge, a higher proportion of meetings have not had healthcare professionals present. From June to August, there was a decline in the average number of meeting participants, although this recovered steadily from August to October.

Average number of meeting participants



Source: Deloitte Analysis

More robust technology integration

Across company-held meetings and sponsored events, imbedded technology has become the primary mode of medical promotion, surpassing onsite and hybrid activities.

Market trends and key execution points

Adherence to compliance

Giving the ongoing and intensifying national anti-corruption rectification in life sciences and healthcare, it is important to emphasize pharmaceutical companies' role in the initiative. Based on observations so far, this latest anti-corruption initiative is not short-term in duration or impact, but rather an in-depth rectification project that will last for five years followed by rigorous and regular enforcement.

Given these conditions, an increased emphasis on compliance has become inevitable for healthcare companies operating in China. Pharmaceutical companies' compliance management must evaluate all factors to ensure their operations comply with laws and regulations. It is also vital that companies fulfill their corporate social responsibility to improve reputation and competitiveness and support long-term growth. To mitigate the risk of penalties for commercial bribery, healthcare companies should take proactive measures to improve their compliance systems and stay alert to changes in policy, market needs and demands. To ensure ongoing compliance, a successful business and its staff must adapt to change, grow, and innovate.

Decline in "sale expense to revenue"

As regulatory reinforcement intensifies, pharmaceutical companies have made efforts to optimize their cost structures. There have been continuous declines in sales expenses, the proportion of sales expenses to revenue, and the proportion of marketing expenses to sales expenses. Overall, marketing expenses are anticipated to gradually decrease. Industry participants are therefore seeking innovative and diverse distribution channels for targeted, effective promotion to reach customers, while the organizational structure of their sales teams will be modified to eliminate traditional one-on-one sales approaches. Reducing marketing expenditure empowers pharma companies to reallocate revenue to product R&D, leading to the creation of new business opportunities.

A call for "product power"

In the second half of 2023, pharmaceutical companies increased their spending on R&D. The relevance of technology-driven innovation cannot be overstated. In the context of healthcare anti-corruption rectification, product R&D helps pharmaceutical companies improve competitiveness. At the same time, it offers hope that pharmaceutical companies will return to value-based competition and achieve a better balance between sales and R&D spending.

Accelerated digital transformation

Companies in the healthcare industry must prioritize operational compliance and cost reduction while increasing efficiency to achieve sustainable long-term development. Digital transformation can be a practical strategy for companies to meet this objective, particularly with a shift in focus from traditional marketing to academic research and R&D. Through digital transformation, companies can enhance their ability to manage and analyze vast amounts of healthcare data, improve R&D efficiency, cut down on R&D expenses, and optimize their supply chains and sales channels, all while enhancing customer experiences.

Model and strategy innovation

The healthcare industry is experiencing notable changes as policies undergo continuous reform. To seize new opportunities and overcome challenges arising from these changes, companies must adopt a proactive stance towards innovation. Innovation can unfold in numerous forms and three common methods are emerging:

Innovative R&D including collaborative projects, artificial intelligence (AI) and drug re-use

With the maturity of AI technology, there are now more than 700 companies worldwide using AI technologies in product R&D, and dozens of AI-inspired drugs have entered clinical trials. With some AI drug pipelines domestically and internationally entering Clinical Phase II for efficacy validation, the entire AI pharmaceutical industry is also entering a critical phase. Domestic and multinational pharmaceutical companies are embracing AI technology.

Innovative marketing models: digital and social media marketing including live-streamed promotions

Unlike traditional fast moving consumer goods (FMCG) products, the marketing approaches of pharma companies can vary significantly with the impact of policies and changes in consumer patterns and needs.

- **For HCPs:** Interaction with HCPs is gradually shifting to virtual platforms, which not only provide a natural ease of communication but also help companies collect data and statistics to analyze and understand customer's active status, medicine and content preferences, and ultimately achieve targeted, personalized marketing.
- **For patients:** Many pharma companies have partnered with new media platforms in creative ways. The construction of a digital closed loop of "internet + diagnosis + medicine + insurance" and other strategies such as content diversity, scenario authenticity, precise topic selection, and targeted user interest are now raising disease awareness.

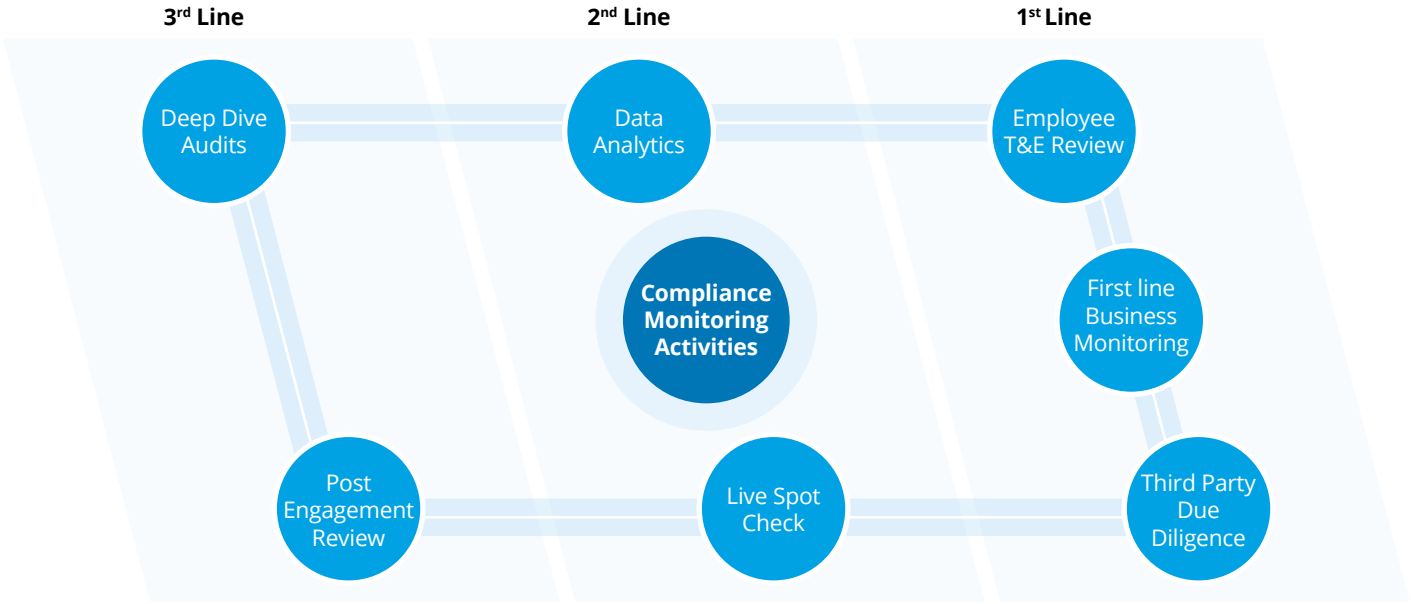
Other innovative models: Integration of diagnosis and treatment, also drugs and medical devices

Promotional activities through benefit transfers are being replaced with a sales strategy centered around improving drug efficacy and the quality of patient lives. Under strict regulatory governance in 2023, there has been a sharp rise in patient care activities. Some pharmaceutical companies are promoting the integration of diagnosis and treatment, either through partnerships or on their own, to analyze comprehensive real-life data and deliver precision treatments directly to patients. Full medical coverage is being realized, from early screening to accurate diagnosis, and from individualized and standardized treatments to follow-up and secondary diagnostic screening.

Upgraded compliance at pharmaceutical and medical device companies

Most China-based life sciences companies have already started using various compliance monitoring controls and activities, extending from the first to the third lines of defense to cover internal and external risks:

The three lines of monitoring controls



Source: Deloitte Analysis

However, the acceleration of centralized anti-corruption rectification has also raised higher requirements for the compliance mechanisms, including:

Comprehensiveness (Breadth)
With increasingly high requirements posed by the market and tightened government regulation, companies' compliance systems need wider coverage and scope.

When working with partners in the pharmaceutical ecosystem and value chain, including channel distributors, agents, contract manufacturing, sales and research organizations (CMOs, CSOs, and CROs), e-commerce platforms, internet hospitals, and HCOs, companies should comprehensively monitor and timely review compliance risks related to flows of cash, information, and intellectual property rights. They should also strengthen monitoring and prevention of key risks in different partnership models. In working with an HCO, for example, companies should gradually establish a risk prevention mechanism for the "4th party", i.e., management risks related to the HCO's level of execution. Companies should comprehensively manage each HCO's project objectives and principles, processes for selecting a 4th party, execution control, regulatory requirements, and payment audits.

On the other hand, companies should strive for more comprehensive internal compliance systems and embed compliance requirements into their business systems through measures such as setting up compliance committees and establishing compliance monitoring responsibilities for business processes.

Professionalism (Depth)
The current round of policies is focused on pharmaceutical consumables relates to various business functions and monitored drugs and addressing issues like high-cost reimbursement, unfair benefit transfers between pharmaceutical companies and distributors and sales representatives, and sub-optimal risk monitoring in marketing and sponsorships.

Companies should formulate special mechanisms for self-checking, self-training, self-monitoring, and rectification based on their business models and strategies. For example, for risky behaviors such as fraudulent buying and selling of drugs covered by medical insurance, the establishment and implementation of self-checking mechanisms allows marketing and compliance departments to conduct collaborative internal self-checking. Furthermore, companies can increase stakeholders' compliance awareness through organized training and testing and comprehensive internal reporting and reward and punishment mechanisms to promote strong participation and supervision across different departments.

Accuracy (Precision)

Apart from establishing closed-loop management before, during and after a potential ABAC event and performing routine monitoring and control, risk prevention and self-correction through accurate risk location can improve the efficiency and efficacy of compliance. On top of comprehensive, dedicated, and effective compliance controls, companies should use digitally enabled big data to establish effective behavior indicators and build prediction models to monitor abnormal behavior accurately and effectively.

In 3rd-party cooperation, for example, to establish management and control systems in advance and make accurate predictions, companies should construct closed-loop supervisory systems based on supplier category, monetary value, cooperation frequency, reviews, and industry benchmarking, creating supplier portraits through predictive models and monitoring suppliers' operation cost controls and risks. Meanwhile, by combining a comprehensive, dedicated compliance system with measures like self-checking, self-correction, and special audits, companies can build more comprehensive compliance systems to serve as a complete defense.

Conclusions

> Compliance and resilience are key to long-term development. With tightened pharmaceutical regulation, pharmaceutical companies must urgently construct comprehensive and effective corporate systems to facilitate compliant business operations.

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