China MedTech intelligence: navigating innovation, regulation, and market dynamics – June 2025

Summary

I. Executive Summary

May 2025 marked a period of significant activity and evolution within China's Medical Technology (MedTech) sector. Regulatory bodies, particularly the National Medical Products Administration (NMPA), continued their drive towards enhancing quality and safety, with a pronounced focus on the burgeoning online sales channels for medical devices and the integrity of clinical trial data. These efforts signal a maturing regulatory environment aiming to balance innovation with robust oversight. Concurrently, the market demonstrated complex dynamics: while facing overarching pressures from policies like Volume-Based Procurement (VBP), which impacted Q1 2025 financial results for some, there were clear signs of resilience, particularly in domestic demand for certain equipment categories and a strong push towards localization.

Corporate activities underscored a strategic focus on both domestic channel integration and international market expansion, alongside sustained investor interest in AI-driven healthcare solutions. Innovation remained a central theme, evidenced by a steady stream of NMPA approvals for a diverse range of medical devices, including high-tech imaging systems and advanced therapeutic devices from both domestic and international manufacturers. Clinical research in areas such as cardiovascular devices and AI-assisted diagnostics continued to advance. Major industry conferences and expos throughout the month, such as the Global AI Device Expo in Shenzhen and PHARMCHINA in Guangzhou, highlighted the pivotal role of artificial intelligence in reshaping healthcare delivery and the national strategic emphasis on digital transformation within the pharmaceutical and MedTech industries. International factors, including increased scrutiny from bodies like the U.S. FDA on data integrity and manufacturing practices, alongside ongoing trade discussions, added another layer of complexity, prompting MedTech companies to enhance due diligence and potentially re-evaluate global supply chain strategies. Overall, May 2025 depicted a Chinese MedTech landscape characterized by rapid advancement, increasing sophistication, and a strategic push for self-reliance and high-quality innovation, all while navigating internal optimization measures and external geopolitical influences.

II. Regulatory and Policy Developments

May 2025 witnessed several pivotal regulatory and policy shifts in China's MedTech sector, reflecting a concerted effort to enhance quality, foster innovation, and manage healthcare costs. These developments have significant implications for manufacturers, distributors, and investors operating in or targeting the Chinese market.

NMPA Strengthens Oversight of Online Medical Device Sales

A significant regulatory update came with the NMPA General Office's notice on May 26, 2025 (Yao Jian Zong Xie Guan Han No. 280), concerning the implementation of the "Quality Management Standards for Online Sales of Medical Devices" (2025 No. 46 Announcement). These standards, set to take effect on October 1, 2025, aim to rigorously govern the rapidly expanding online market for medical devices.[1] The new rules impose comprehensive requirements on online sales operators and e-commerce platforms, covering quality management systems, the accuracy and completeness of product information display, meticulous sales record-keeping, and proactive risk monitoring.

The implementation plan mandates extensive publicity campaigns and personnel training, with the first round of training for key regulatory personnel and enterprise representatives scheduled for completion by August 2025. Enterprises are required to establish or significantly upgrade their quality management systems to meet these new benchmarks, and the national online sales monitoring platform is tasked with enhancing its technological capabilities to improve oversight.[1]

The introduction of these stringent standards is anticipated to elevate the compliance burden for participants in the online medical device space. The comprehensive nature of the regulations, touching upon all aspects of online sales, will likely necessitate significant investments in systems, personnel, and processes. This could, in turn, lead to a consolidation within the online retail market, as smaller entities may find it challenging to meet the heightened requirements by the October 1, 2025 deadline. Consequently, larger, well-established players with robust compliance infrastructures may find themselves in a more advantageous position. Furthermore, the increased regulatory scrutiny on product information and sales practices online might compel MedTech companies to reassess their channel strategies. Some may opt to shift the focus for certain

device categories towards direct-to-institution sales or more tightly controlled proprietary online environments, particularly for higher-value or more complex devices. This could also stimulate innovation in compliant digital health platforms that seamlessly integrate sales with comprehensive patient support and monitoring, aligning with the new quality standards.

Elevating Clinical Trial Integrity: NMPA's Revised Inspection Principles

Effective May 1, 2025, the NMPA's revised "Key Points and Determination Principles for the Inspection of Medical Device Clinical Trials" (Announcement No. 22 of 2025, issued March 12, 2025) came into force.[4] These updated principles are designed to standardize clinical trial inspections nationwide, with a strong emphasis on data integrity—encompassing authenticity, completeness, accuracy, and traceability (ALCOA+ standards)—and the protection of trial participants' rights and safety. This move is critical for ensuring the reliability of clinical data underpinning new medical device registrations.

Core changes include more stringent requirements for ethical review processes, meticulous protocol execution, comprehensive safety information handling, and clearer definitions of what constitutes data authenticity issues versus serious non-conformities.[4] This heightened regulatory focus means that both domestic and international companies conducting clinical trials in China will face more rigorous inspections. The detailed inspection points and stricter judgment criteria imply that any deviation from protocols or inadequate documentation could lead to severe repercussions, including the potential rejection of registration applications. This necessitates a more meticulous approach to the planning, execution, and documentation of clinical trials. To navigate this increasingly complex landscape, MedTech companies, particularly smaller firms or those less familiar with China's evolving regulatory norms, may find themselves increasingly reliant on specialized Clinical Research Organizations (CROs) that possess strong local expertise and robust quality systems. Investment in advanced Electronic Data Capture (EDC) systems compliant with ALCOA+ principles will also become more critical to ensure data integrity and traceability, potentially driving growth in the MedTech CRO and clinical trial technology sectors within China.

Streamlining Innovation: NMPA's Priority and Special Review Pathways

Building on rules published in April 2025, the NMPA continued to emphasize its "Implementation Rules for the Priority Approval Review of Medical Devices" and "Implementation Rules for the Special Review of Innovative Medical Devices" throughout May.[6] These frameworks detail expedited pathways for medical technologies deemed urgently needed or possessing significant novelty. This initiative is a core component of China's broader strategy to stimulate domestic innovation and accelerate the market introduction of high-value medical devices that address unmet clinical needs.

The detailed nature of these rules, covering aspects from application submission and expert selection to final review and objection handling, provides manufacturers with clearer roadmaps for navigating these accelerated pathways. This clarity has the potential to significantly reduce time-to-market for eligible products. However, the pronounced emphasis on "urgent clinical needs" and "novel medical technologies" suggests that incremental product improvements may not be sufficient to qualify for these fast tracks.[6] Companies will likely need to demonstrate substantial clinical value and, ideally, address specific healthcare challenges prevalent within China to fully leverage these opportunities. This aligns with other policy trends, such as the CHS-DRG/DIP 2.0 payment system, which includes exception mechanisms for innovative, high-cost medical devices [7], signaling a governmental preference for breakthrough innovations. This could, in turn, steer R&D investment towards diseases with a high burden in China or technologies that offer transformative improvements over existing solutions.

Navigating VBP and Payment Reforms

Volume-Based Procurement (VBP) continued to be a dominant force shaping the MedTech market. The fifth batch of National VBP significantly impacted prices for cochlear implants and consumables for peripheral interventions, while regional VBP initiatives continued to expand across various device categories.[7] Illustrating this pressure, Danaher Corporation reported a $50 million drag on its China diagnostics business in Q1 2025 due to VBP, though the company expressed optimism for a recovery in the second half of the year.[9]

In parallel, the CHS-DRG/DIP 2.0 policy, introduced in July 2024, offers an important counter-balance by providing exceptions for high-cost, innovative medical devices, exempting them from certain payment constraints.[7] This dual mechanism—cost containment for mature products and incentives for innovation—necessitates a bifurcated market strategy for MedTech companies. Firms must focus on cost optimization and operational efficiency for products susceptible to VBP, while simultaneously investing in robust value demonstration and innovation for products that may qualify for DRG/DIP exceptions or fall outside the scope of VBP. The pressure from VBP on imported mature products, combined with governmental incentives for local innovation, is also likely to accelerate domestic R&D efforts. This may encourage multinational corporations (MNCs) to further localize their R&D and manufacturing operations or to form strategic partnerships with local firms better equipped to navigate the Chinese ecosystem and cost structures, a trend that aligns with the "Made in China 2025" national strategy.[10]

Provincial Governments Champion MedTech Innovation

May 2025 also saw several provincial governments actively promoting their local MedTech industries. Liaoning province announced measures on May 28 to upgrade its biomedical and medical device sectors.[12] On May 26, Shanghai issued its "2025 Shanghai Medical and Health System Reform Work Priorities," which included encouragement for innovative medical device R&D.[13] Zhejiang province launched its "2025 AI Medical Device Innovation Task List Unveiling," aiming to foster development in artificial intelligence applications for medical devices.[14] Similarly, Guangdong's Department of Industry and Information Technology published its recommended list for the 2025 AI Medical Device Innovation Task Unveiling on May 13.[15]

These provincial initiatives underscore a multi-level governmental commitment to cultivating the MedTech sector, with a particular emphasis on AI and cutting-edge innovation. This could lead to the emergence of specialized MedTech clusters across different regions in China, each potentially attracting targeted investment, talent, and resources based on their specific focus areas. The "task list unveiling" approach adopted by Zhejiang and Guangdong, for instance, suggests a competitive mechanism designed to spur innovation in designated fields. While these programs offer significant opportunities, particularly for Small and Medium-sized Enterprises (SMEs) aligning with regional strategic priorities, they also foster a competitive environment. Initiatives like the "together for enterprises" service actions, which include biomedical

roadshows for SMEs [16], indicate support for smaller players. However, the selective nature of task unveilings implies that success will depend on demonstrating strong innovation capabilities and clear alignment with regional development goals.

International Regulatory Scrutiny and Trade Dynamics

The international landscape presented both challenges and areas of engagement. On May 22, the U.S. Food and Drug Administration (FDA) took action against two Chinese third-party testing firms, Mid-Link Technology Testing Co., Ltd., and Sanitation & Environment Technology Institute of Soochow University Ltd. (SDWH), citing data integrity concerns and rejecting their data for premarket submissions.[17] Earlier in the month, on May 6, the FDA also announced an expansion of its unannounced inspections program for foreign manufacturing facilities, explicitly including China.[18] These actions signal heightened international scrutiny of the Chinese MedTech supply chain. In the trade sphere, MedTech firms continued to navigate the impacts of U.S.-China tariffs, although a temporary 90-day pause in the trade standoff was reported around May 22.[19] Furthermore, on May 29, U.S.-based Smart Meter highlighted data security risks associated with Remote Patient Monitoring (RPM) devices potentially sending patient data to China, referencing new U.S. Department of Justice rules on data transfer.[21]

This increased international oversight, particularly from the FDA, is likely to compel MedTech companies relying on Chinese third-party laboratories or contract manufacturers to conduct more rigorous due diligence and potentially diversify their partnerships to mitigate risks. The direct impact of FDA actions, such as rejecting data from non-compliant labs or increasing unannounced inspections, necessitates that facilities maintain a constant state of "inspection readiness." While challenging, this external pressure may also serve as a catalyst for Chinese testing labs and manufacturers to further elevate their quality management systems and align more closely with international standards like Good Laboratory Practice (GLP) and Current Good Manufacturing Practice (cGMP). Such improvements would not only help maintain global market access but also support China's domestic goals of upgrading its MedTech industry. The NMPA's own intensified focus on clinical trial data integrity reflects a parallel domestic push towards higher quality standards. The concerns around data security for RPM devices also point to data governance and cybersecurity for connected medical devices becoming an increasingly critical compliance area, potentially influencing device design, network architecture, and data management strategies for companies operating globally.

Other Regulatory Footnotes

Several other regulatory activities in May are noteworthy. The National Healthcare Security Administration launched a nationwide verification targeting "phantom pharmacists" in designated retail pharmacies on May 28, an initiative affecting nearly 24,000 pharmacies across 24 provinces.[23] This action, while not directly targeting MedTech manufacturing, impacts the retail end of the supply chain and underscores a broadening scope of healthcare system oversight. The Shanghai Municipal Drug Administration (Shanghai YJJ) organized a two-day public training session on 15 medical device standards on May 28-29, aimed at enhancing industry understanding and compliance.[24] Furthermore, the NMPA released an updated "List of Medical Devices Exempt from Clinical Evaluation" on May 13 (reported on May 22), which added 28 new device categories to the list, streamlining market access for eligible products.[25] These activities collectively demonstrate a continuous effort by Chinese regulators to refine market access pathways, ensure industry players are current with evolving technical and safety requirements, and maintain integrity across the healthcare system.

Table 1: Key Regulatory & Policy Updates in China – May 2025

Date (Announcement /Effective)	Issuing Body	Document/Policy Title	Summary of Key Points/Impact on MedTech	Weblink (Language)
2025-05-01 (Effective)	NMPA	Key Points and Determination Principles for the Inspection of Medical Device Clinical Trial (Announcement No. 22 of 2025)	Emphasizes data integrity (ALCOA+), stricter ethical review, protocol execution, and safety handling. Increases scrutiny on clinical trials, impacting both domestic and international sponsors. [4]	NMPA (CN) (CN)

2025-05-06 (Reported)	U.S. FDA	Expansion of Unannounced Inspections at Foreign Manufacturing Facilities	FDA to increase unannounced inspections in countries including China, aiming for parity with domestic oversight. Heightens compliance pressure on Chinese MedTech manufacturers supplying the U.S. [18]	GlobalComplianceNews (EN) (EN)
2025-05-13 (List Released)	NMPA	Updated NMPA Clinical Evaluation Exemption List 2025	Added 28 new medical device categories exempt from clinical evaluation, streamlining market access for eligible products. [26]	Asia Actual (EN) (EN)
2025-05-22 (Announced)	U.S. FDA	Action Against Two Chinese Third-Party Testing Firms (Mid-Link, SDWH)	FDA to reject data from these firms due to data integrity concerns (falsified/invalid data). Impacts sponsors relying on these labs for premarket submissions. [17]	(https://www.fda.gov/news-events/press-announcements/fda-takes-action-address-data-integrity-concerns-two-chinese-third-party-testing-firms) (EN)
2025-05-26 (Issued)	NMPA General Office	Notice on Implementing the "Quality Management Standards for Online Sales of Medical Devices" (Yao Jian Zong Xie Guan Han No. 280)	Standards effective Oct 1, 2025. Mandates stricter quality management, information display, record-keeping for online sellers and e-commerce platforms. Training for key personnel by Aug 2025. [1]	duyaonet.com (CN) (CN)

2025-05-28 (Announced)	Liaoning Provincial Government	Measures to Accelerate High-Quality Development of Biomedical and Medical Device Industries	Provincial initiative to support and upgrade local MedTech sector. [12]	news.pharmnet.com.cn (CN) (CN)
2025-05-28 (Announced)	National Healthcare Security Administration	Nationwide Verification of "Phantom Pharmacists"	Crackdown on non-compliant practices in retail pharmacies, impacting nearly 24,000 pharmacies. Aims to safeguard medication safety and medical insurance funds. [23]	news.cn (CN) (CN)
2025-05-29 (Reported)	Zhejiang Provincial Government	2025 AI Medical Device Innovation Task List Unveiling Work Started	Provincial initiative to promote AI in medical devices through a competitive task-unveiling mechanism. [14]	zj87.jxt.zj.gov.cn (CN) (CN)
2025-05-29 (Reported)	Guangdong Provincial Department of Industry and Information Technology	Public Notice on Recommended List for 2025 AI Medical Device Innovation Task Unveiling (Published May 13)	Provincial initiative to select and support AI medical device innovation projects. [15]	gdii.gd.gov.cn (CN) (CN)
2025-05-26 (Reported)	Shanghai Municipal Health Commission, et al.	"2025 Shanghai Medical and Health System Reform Work Priorities"	Encourages innovative medical device R&D and accelerates drug listing processes. [13]	yicai.com (CN) (CN)

III. Market Landscape & Industry Performance

The Chinese MedTech market in May 2025 presented a nuanced picture of resilience amidst policy-driven transformations and evolving global dynamics. While aggregate financial results from Q1 2025 indicated sector-wide pressures, specific segments and individual companies demonstrated robust performance and adaptability. Key trends included the significant growth in AI-driven healthcare solutions, advancements in high-tech areas like medical imaging and surgical robotics, and a strengthening push towards localization.

Q1 2025 Financial Performance and Market Sentiment

The first quarter of 2025 revealed a mixed financial performance for the A-share listed medical device sector. Overall revenue saw a year-on-year decrease of 6.12%, with net profits declining by 16.48%. Despite these aggregate figures, a substantial majority—106 out of 129 listed companies—remained profitable. The market showed clear segmentation in performance: the consumables segment began to stabilize as destocking completed and VBP impacts were absorbed, whereas the In-Vitro Diagnostics (IVD) and medical equipment segments faced more immediate pressures from ongoing policy adjustments [65 (index 5.2), 40].

Leading domestic players like Mindray Medical reported Q1 2025 revenue of 8.24 billion RMB (a 12.12% YoY decrease) and net profit of 2.63 billion RMB (a 16.81% YoY decrease). Mindray's international business grew by less than 5% YoY, while its domestic business, though down over 20% YoY, showed a significant quarter-on-quarter recovery of over 50%. The company anticipates a return to positive growth in the domestic market by the third quarter of 2025.[20] In contrast, United Imaging (Lianying Medical) posted Q1 2025 revenue of 2.478 billion RMB, a year-on-year increase of 5.42%, and a net profit of 0.370 billion RMB, up 1.87% YoY.[29]

These figures suggest that while policies such as VBP and anti-corruption campaigns have exerted downward pressure on the overall market, underlying demand and the financial health of many companies remain solid. The divergent performance across sub-sectors and companies highlights the complex interplay of market forces. Companies with strong innovation

pipelines, diversified international operations, or those operating in segments less affected by VBP appear to be navigating the challenges more effectively. A particularly positive indicator was the recovery in medical equipment bidding during Q1, which saw an overall market size increase of approximately 67% YoY. The medical imaging equipment segment was especially strong, with an 85% YoY growth in bidding activity. Domestic manufacturers like United Imaging and Neusoft Medical (Dongruan) demonstrated notable gains in market share within these bidding processes [65 (index 5.2), 40]. This surge in equipment bidding suggests significant pent-up demand and points towards potential future growth for equipment manufacturers as healthcare institutions proceed with upgrades and expansions.

The success of domestic firms like United Imaging in Q1 bidding activities, coupled with explicit "Buy China" policy objectives aiming for 70% domestic production of mid-to-high-end medical devices by 2025 [10], indicates that localization initiatives are gaining considerable traction. This trend is creating a more favorable environment for local players and is likely to intensify competition for multinational corporations in certain high-value segments, compelling them to further localize their R&D, manufacturing, and strategic partnerships to maintain competitiveness in the evolving Chinese market.

Artificial Intelligence (AI) and Digital Health: A Burgeoning Frontier

Artificial intelligence continued its ascent as a strategic priority within China's healthcare sector, backed by robust policy support and significant investment. Fangzhou Inc. prominently showcased its AI-driven Hospital-to-Home (H2H) smart healthcare ecosystem at the PHARMCHINA exhibition on May 29. The company emphasized AI's transformative potential in shifting healthcare from a labor-intensive model to an algorithm-driven one, aligning with the national "2025-2030 Pharmaceutical Industry Digital Transformation Implementation Plan".[31] This plan, a collaborative effort by seven regulatory bodies, positions AI and digital transformation as core requirements for the advancement of the pharmaceutical and healthcare industries.

The Global AI Device Expo, held in Shenzhen from May 22-23, further underscored this trend. It featured a wide array of medical AI solutions and saw the announcement of substantial new AI-focused funds, including a 5 billion yuan AI Device Fund and an initial 2 billion yuan AI and Embodied-Intelligence Robotics Industry Fund.[34] Such dedicated funding is expected to significantly accelerate the R&D and commercialization of AI-powered medical devices, particularly in innovation hubs like Shenzhen.

The Remote Patient Monitoring (RPM) market in China is also poised for substantial growth, with a projected Compound Annual Growth Rate (CAGR) of approximately 20.3% from 2025 to 2035. This expansion is fueled by China's aging population, continuous technological advancements in monitoring devices, and strong government support through initiatives like the "Healthy China 2030" plan [65 (index 3.1), 67]. A People's Daily report on May 23 highlighted the use of digital technologies to promote equitable access to public services, citing the "Mobile Hospital" initiative in Fangshan county, Shanxi province. This project equips rural doctors with diagnostic kits enabling remote expert consultations, having already served over 370,000 patients and saving nearly 10 million yuan in medical and travel expenses [65 (index 1.1), 9]. An analysis by CKGSB also noted AI's significant role in medical imaging and its potential to alleviate burdens on the healthcare system, such as the shortage of radiologists [65 (index 1.2), 69].

These developments collectively indicate that AI is increasingly viewed as a critical enabler for addressing systemic healthcare challenges in China, including the demands of an aging population, rising healthcare costs, and the uneven distribution of medical resources. Companies are moving beyond standalone AI tools to develop integrated AI-healthcare ecosystems, like Fangzhou's H2H model. This trend towards comprehensive, AI-driven solutions suggests a future where AI is deeply embedded across the entire healthcare continuum, from prevention and early diagnosis to treatment and long-term chronic disease management. This will, however, necessitate greater interoperability and robust data-sharing frameworks to realize its full potential.

Advancements in Medical Imaging and Surgical Robotics

High-technology segments such as advanced medical imaging and surgical robotics continued to be focal points of innovation and investment. The medical imaging market, which experienced a surge in 2024, is expected to see continued policy-driven growth and intelligent upgrades.[35] Surgical robotics remains a key investment area, with the Chinese market projected to reach 10.88 billion RMB by 2025.[36] The China International Medical Equipment Fair (CMEF) 2025, with outcomes reported in May, showcased significant advancements, including AI-powered orthopedic surgical robots and micro spinal surgical robots.[36]

A key trend in these fields is the deepening integration of AI, not just as an add-on feature but as a core component for enhancing diagnostic accuracy, surgical planning, and operational precision. The CMEF highlights explicitly mentioned AI deep learning in orthopedic robots [36], and other reports confirm AI's role in improving diagnostic accuracy in imaging [65 (index 1.2), 69]. While multinational corporations have historically held a strong position in high-end imaging and robotics, robust government support for domestic innovation and targeted investments are enabling Chinese companies to rapidly enhance their technological capabilities and market share. The "Made in China 2025" strategy and the success of domestic imaging firms in Q1 bidding processes are testaments to this shift [65 (index 5.2), 40]. The Chinese Robotic Assisted Surgery (RAS) market now features 61 unique domestic companies, underscoring the dynamic growth and increasing competitiveness of local players in these advanced MedTech segments.[36] This evolving landscape is likely to spur further localized innovation and strategic partnerships.

Developments in Other Notable Segments

The In-Vitro Diagnostics (IVD) segment, despite facing policy-related headwinds in Q1 2025 [65 (index 5.2), 40], received renewed attention with the NMPA issuing seven new guidelines for IVDs in April, as reported by ChinaMedDevice in May.[38] This regulatory activity may aim to provide greater clarity and support innovation within the IVD sector, potentially fostering more targeted R&D efforts aligned with updated expectations.

The probiotics sector, which often intersects with medical applications, saw significant developments in May. These included the release of the "Top Ten Landmark Achievements of China’s Probiotics Industry from 2005 to 2025," an expert consensus on multi-strain probiotic formulations which anticipates a key role for AI in future development, and notable market growth in children’s probiotics.[39] The emphasis on scientific consensus, precise strain identification, and AI-driven data analysis suggests a maturation of this segment towards more evidence-based and technologically advanced health solutions.

Wearable medical devices continue to be integral to the growth of Remote Patient Monitoring [65 (index 3.1), 67], with increasing consumer and healthcare provider adoption for continuous health tracking and management. Other established MedTech fields such as orthopedics, cardiovascular devices, ophthalmic instruments, and dental devices also saw ongoing innovation, reflected in the continuous stream of product approvals by the NMPA.

Table 2: China MedTech Market & Company News – May 2025

Date	Company/Source	News Category	Headline/Key Finding	Weblink (Language)
2025-05-29	21st Century Business Herald	Market Trend / Financials	Medical device Q1 2025 reports show sector performance divergence; localization trend significant. Overall A-share MedTech revenue -6.12% YoY, net profit -16.48% YoY. Consumables stabilizing. [40]	21jingji.com (CN) (CN)
2025-05-29	Fangzhou Inc. / PR Newswire	AI in Healthcare / Event	Fangzhou showcased its AI-driven H2H smart healthcare ecosystem at PHARMCHINA, aligning with China's digital medicine acceleration and the 2025-2030 Pharmaceutical Industry Digital Transformation Plan. [31]	(https://www.prnewswire.com/news-releases/fangzhou-showcases-ai-driven-healthcare-ecosystem-at-pharmchina-as-chinas-shift-to-digital-medicine-accelerates-302468198.html) (EN)
2025-05-29	Simon-Kucher	Market Outlook / Policy	2025 Outlook for MedTech in China: Report discusses VBP impact, price transparency, early access programs, and DRG/DIP 2.0 policy offering exceptions for innovative devices. [7]	simon-kucher.com (EN) (EN)

2025-05-28	Liaoning Provincial Government / news.pharmnet.com.cn	Policy / Regional Development	Liaoning announced measures to accelerate high-quality development of its biomedical and medical device industries. [12]	news.pharmnet.com.cn (CN) (CN)
2025-05-27	International Probiotics Association / HPA-China	Industry Insights / Product Innovation	HPA-China May news: "Top Ten Landmark Achievements" in probiotics, expert consensus on multi-strain formulations (AI to drive data-driven approach), children's probiotics market growth. [39]	internationalprobiotics.org (EN) (EN)
2025-05-23	Shenzhen Government Online / Global AI Device Expo	AI in Healthcare / Event / Funding	Global AI Device Expo in Shenzhen (May 22-23) showcased medical AI; 5B yuan AI Device Fund & 2B yuan AI and Embodied-Intelligence Robotics Industry Fund announced. [34]	sz.gov.cn (EN) (EN)
2025-05-23	People's Daily Online	Digital Health / Patient Impact	China using digital/intelligent tech for equitable public services; "Mobile Hospital" initiative in Fangshan county uses remote consultations, serving 370k+ patients. [[65] (index 1.1), [9]]	en.people.cn (EN) (EN)

2025-05-22	MedTech Dive	Supply Chain / Trade	MedTech firms managing tariff impacts; US-China agreed to a 90-day pause in trade standoff. [19]	medtechdive.com (EN) (EN)
2025-05-21	Eastmoney / Shenzhen Mindray Bio-Medical Electronics	Financials	Mindray's Q1 2025: Revenue 8.24B RMB (-12.12% YoY), Net Profit 2.63B RMB (-16.81% YoY). Domestic business +>50% QoQ. Expects domestic recovery in Q3. [20]	eastmoney.com (CN) (CN)
2025-05-19	Congenius	Regulatory / Policy	NMPA published "Implementation Rules for the Priority Approval Review of Medical Devices" and "Implementation Rules for the Special Review of Innovative Medical Devices" (April, reported May). [6]	congenius.ch (EN) (EN)
2025-05-16	Citeline Medtech Insight / Danaher	Financials / Market Trend	Danaher's China diagnostics business hit by $50M VBP drag in Q1 2025; expects recovery in H2 2025. [9]	citeline.com (EN) (EN)
2025-05-13	PR Newswire / Fangzhou Inc.	AI in Healthcare / Event	Fangzhou CEO honored at VBEF Conference (May 9-10); company showcased AI medical innovations, including safeguards against AI hallucination. [41]	prnewswire.com (EN) (EN)

2025-05-12	Securities Times / VBEF Conference	Market Trend / AI in Healthcare	VBEF Conference (May 9-10) highlights: AI transforming healthcare, market shifts (in-hospital vs. out-of-hospital), trade impacts creating domestic substitution opportunities. [42]	stcn.com (CN) (CN)
May 2025 (General Report)	Market Research Future	Market Trend / Remote Patient Monitoring	China Remote Patient Monitoring market to grow from $2.1B (2024) to $16.08B (2035), CAGR ~20.3%. Driven by aging population, tech advancements, government support (Healthy China 2030). [65 (index 3.1), 68]	marketresearchfuture.com (EN) (EN)
May 2025 (General Report)	CKGSB Knowledge	AI in Healthcare / Market Trend	AI prominent in China's medical imaging, alleviating radiologist shortage. Healthy China 2030 & Made in China 2025 drive digitalization. 70% hospitals have EHRs. Telemedicine platforms provide data for AI. [65 (index 1.2), 69]	english.ckgsb.edu.cn (EN) (EN)

IV. Corporate Activities: Investments, M&A, and Partnerships

The corporate landscape in China's MedTech sector during May 2025 was characterized by strategic capital allocations, targeted acquisitions aimed at channel integration and market expansion, and a strong emphasis on collaborative initiatives to foster innovation.

Investment and Funding Dynamics

While specific large Series A, B, or C funding rounds for MedTech companies were not prominently detailed in the available information for May 2025, broader investment trends and capital market activities indicate continued interest in the sector. For instance, the financing balance for Meihao Medical reached a one-year high of 54.04 million RMB on May 20, suggesting active capital market engagement for listed entities.[43] Jiuan Medical also reported a substantial financing balance of 1.039 billion RMB on the same day, albeit with a slight decrease.[44]

More strategically, Hong Kong-based venture capital firm Ori Capital was reported on May 18 to be raising a new $350 million fund focused on Chinese healthcare startups, a category that inherently includes MedTech innovators [[14] (index 5.1)]. This new fund signals sustained investor confidence in the long-term potential of China's healthcare innovation ecosystem, driven by factors such as the transformative impact of AI and efficiencies in clinical trials. This development suggests that despite global VC downturns or specific domestic challenges like VBP, the foundational belief in China's capacity for healthcare innovation remains strong. The absence of numerous early-stage MedTech-specific funding announcements in May could imply a market shift, potentially towards fewer but larger and more strategic investments, or a focus on companies closer to commercialization, aligning with the government's push for high-value, impactful innovation. This is consistent with global MedTech venture investment trends noted by J.P. Morgan for Q1 2025, which saw larger deal sizes despite fewer rounds.[45]

Mergers and Acquisitions (M&A)

May saw noteworthy M&A activities pointing towards strategic consolidation and market positioning. On May 13, China Meheco Group Co., Ltd. announced its intention to acquire 100% equity of Beijing Jinsui Technology Development Co., Ltd. for 302.07 million RMB in cash.[46] Jinsui Technology is an e-commerce operator for personal health and broader health-related consumer products, including medical devices, with established partnerships with brands like Philips and Omron. This acquisition, involving state-affiliated entities, is aimed at enhancing China Meheco's marketing and supply chain management capabilities, expanding new channel development for its pharmaceutical, medical device, and health products,

and building out its e-commerce operations platform. This move represents a vertical integration strategy, providing China Meheco with direct access to consumer channels and valuable market data.

Separately, Livzon Pharmaceutical Group Inc., whose business scope includes diagnostic reagents and equipment, announced on May 22 (reported May 27) the acquisition of a majority stake in Vietnamese pharmaceutical company Imexpharm Corporation.[48] While the primary focus of this acquisition is on pharmaceutical market expansion in Southeast Asia, Livzon's existing MedTech interests suggest potential long-term synergies for its diagnostic products in the region. These M&A activities, driven by different rationales—domestic channel integration for China Meheco and overseas market access for Livzon—reflect the dynamic strategies being employed by Chinese healthcare companies. The involvement of state-affiliated enterprises in the China Meheco deal may also signal a broader trend of consolidation led by larger, state-backed conglomerates aiming to build national champions with enhanced domestic and international competitiveness.

Strategic Partnerships and Collaborative Ventures

Collaboration was a prominent theme in May, with multiple initiatives aimed at fostering innovation and market development. Jimin Health Management Co., Ltd. announced on May 30 that its subsidiary, Boao International Hospital, had signed a strategic cooperation framework agreement with Guangzhou Dabo Biotechnology Co., Ltd. on May 28.[49] This partnership aims to accelerate new drug research and clinical translation, particularly in gene therapy, cell therapy, and regenerative medicine, by leveraging the preferential policies of the Hainan Boao Lecheng International Medical Tourism Pilot Zone. This collaboration highlights how companies are strategically utilizing special economic zones to advance cutting-edge biomedical technologies, which often have associated MedTech components such as specialized delivery systems or diagnostic tools.

Government and industry associations also played an active role in facilitating ecosystem development. The "Innovation Driven, Sowing the Future" Innovation Achievement Sowing Action and Science-Industry-Finance Integration Special Roadshow was held in Chengdu from May 29-30. This event, organized by bodies including the Ministry of Industry and Information Technology's SME Development Promotion Center, aimed to connect technological achievements, including those in the biomedical field, with financial institutions to support their commercialization.[16]

International collaboration was also evident. The 2025 China-Korea Health Medical Exchange Meeting took place in Jinan on May 22, focusing on promoting cooperation in various health and medical industry aspects, with specific mentions of In-Vitro Diagnostics (IVD) and digital dental solutions.[50] The 2025 China-Japan Pharmaceutical Industry Exchange Conference, held in Shanghai on May 24, facilitated discussions on pharmaceutical innovation, regulatory policy alignment, clinical research, and market access between the two countries [[71] (document ID Phirda 39006), [71]]. These events underscore a concerted effort by government bodies and industry associations to build a supportive ecosystem for MedTech by addressing key challenges like funding and market access, and by fostering cross-border knowledge sharing and business opportunities. Such structured support can significantly de-risk and accelerate MedTech development and commercialization in China.

Table 3: China MedTech Corporate Development Activities – May 2025

Date (Announced)	Company/Parties Involved	Deal Type	Key Details/Value	Strategic Focus/Implication	Weblink (Language)
2025-05-30 (Agreement signed 2025-05-28)	Jimin Health Management (Boao International Hospital) / Guangzhou Dabo Biotechnology	Strategic Partnership	Framework agreement to accelerate R&D and clinical translation in Hainan Boao Lecheng (gene/cell therapy, exosomes, regenerative medicine).	Leveraging Hainan's pilot zone policies for innovative biomedical and related MedTech advancements. [49]	paper.cnstock.com (CN) (CN)

2025-05-29 (Event May 29-30)	MIIT SME Development Promotion Center, et al.	Industry Event / Roadshow	"Innovation Driven, Sowing the Future" roadshow in Chengdu, including biomedical sector, to connect tech achievements with finance.	Government-facilitated ecosystem building; connecting MedTech innovation with capital. [16]	yjj.sc.gov.cn (CN) (CN)
2025-05-27 (Acquisition announced 2025-05-22)	Livzon Group / Imexpharm Corporation (Vietnam)	M&A	Livzon Group to acquire majority stake in Vietnamese pharmaceutical firm Imexpharm. Livzon's business includes diagnostic reagents and equipment.	Overseas market expansion (primarily pharma), potential long-term MedTech synergies in Southeast Asia. [48]	phirda.com (CN) (CN)
2025-05-22 (Event Date)	China-Korea Health Medical Exchange Meeting (Jinan)	Industry Event / International Cooperation	Promoted cooperation in health/medical industry, including IVD and digital dental solutions.	Bilateral collaboration targeting specific MedTech niches. [50]	news.e23.cn (CN) (CN)
2025-05-21 (Reported)	Meihao Medical (美好医疗)	Financing Balance	Financing balance reached 54.04M RMB on May 20, a near one-year high.	Indicates capital market activity for the listed MedTech company. [43]	eastmoney.com (CN) (CN)
2025-05-21 (Reported)	Jiuan Medical (九安医疗)	Financing Balance	Financing balance of 1.039B RMB on May 20.	Reflects ongoing capital market engagement for the established MedTech player. [44]	eastmoney.com (CN) (CN)

2025-05-18 (Reported)	Ori Capital	New Fund	Hong Kong VC firm Ori Capital raising $350M fund for Chinese healthcare startups (including MedTech/biotech).	Sustained investor interest in China's healthcare innovation. [14 (index 5.1)]	techinasia.com (EN) (EN)
2025-05-13 (Announced)	China Meheco Group (中国医药) / Jinsui Technology (金穗科技)	M&A	China Meheco to acquire 100% of Jinsui Technology (e-commerce operator for health products including medical devices) for 302.07M RMB.	Enhancing e-commerce channels, marketing, and supply chain for MedTech and health products. 46	sse.com.cn (CN) (CN)

V. Innovation: Product Developments & Clinical Research

May 2025 underscored China's continuous drive in MedTech innovation, evidenced by a consistent flow of new product approvals from the NMPA and ongoing clinical research activities. These developments span a wide array of device types and clinical specialties, reflecting both domestic advancements and the integration of international technologies.

Significant NMPA Medical Device Approvals

Throughout May, the NMPA issued numerous medical device approval certificates, covering a broad spectrum of products. The daily approval lists indicate a high volume of regulatory clearances for both domestically manufactured and imported devices.

Among the notable approvals announced on May 29, 2025, were several advanced systems: Sichuan Jinjiang Electronic Medical Devices Technology Co., Ltd. received approval for its Cardiac Pulsed Field Ablation System; Shenzhen Anke High-tech Co., Ltd. for X-ray Computed Tomography (CT) Equipment; GE Medical Systems (Tianjin) Co., Ltd. for a Magnetic

Resonance Imaging (MRI) System; Nanjing Ruide Medical Technology Co., Ltd. for Oral and Maxillofacial Cone Beam Computed Tomography (CBCT) Equipment; and Abbott Medical (via its Shanghai agent) for an Optical Coherence Tomography (OCT) System. Additionally, Shenzhen Wald Surgical Medical Device Technology Co., Ltd. gained approval for its Thoracolumbar Posterior Pedicle Screw Internal Fixation System (Minimally Invasive).[51] Also on May 29, SinoMedical Science Technology Inc. announced that its subsidiary's internally developed Neurohawk™ Intracranial Flow Diverter Stent System received domestic registration approval from the NMPA [[65] (index 5.1), [72]].

The NMPA approval list from May 22, 2025, included 49 devices. Significant approvals featured a Platelet-Rich Plasma Preparation Device by **惠众国**际医疗器械（北京）有限公司, Laparoscopic Articulating Linear Cutter Staplers and Reloads by 强生（苏州）医疗器材有限公司 (Johnson & Johnson), a Radiofrequency Plasma Surgical System by **成都美**创医疗科技股份有限公司, and an Ophthalmic Femtosecond Laser Treatment System by AMO Manufacturing USA, LLC (Agent: **眼力健**（**上海**）**医**疗器械贸易有限公司).[52]

These approvals signify a robust pipeline and continuous market entry for diverse MedTech categories, ranging from common consumables to sophisticated capital equipment and implantable devices. The clearance of advanced domestic technologies, such as pulsed field ablation systems and innovative stents, is particularly noteworthy. This trend indicates the growing capability of Chinese companies to develop and successfully bring to market high-tech medical devices that can compete with, or offer viable alternatives to, established international products, aligning with China's national strategy for self-sufficiency and leadership in high-end MedTech.

Table 4: Significant NMPA Medical Device Approvals – May 2025 (Selected Examples)

Approval Date	Applicant	Product Name (CN / EN)	Device Class/Significance	Registration No.	Weblink (Language)

2025-05-28	三河科达实业有限公司 (Sanhe Keda Industrial Co., Ltd.)	便携式急救设备 (Portable First Aid Equipment)	Emergency Medical Equipment	国械注准 20233080267	NMPA (CN) (CN)
2025-05-23	四川锦江电子医疗器械科技股份有限公司 (Sichuan Jinjiang Electronic Medical Devices Technology Co., Ltd.)	心脏脉冲电场消融仪 (Cardiac Pulsed Field Ablation System)	Class III, Advanced Cardiac Ablation Technology	国械注准 20233012051	NMPA (CN) (CN)
2025-05-27	深圳安科高技术股份有限公司 (Shenzhen Anke High-tech Co., Ltd.)	X 射线计算机体层摄影设备 (X-ray Computed Tomography Equipment)	Advanced Diagnostic Imaging	国械注准 20223061465	NMPA (CN) (CN)
2025-05-28	通用电气医疗系统（天津）有限公司 (GE Medical Systems (Tianjin) Co., Ltd.)	磁共振成像系统 (Magnetic Resonance Imaging System)	Advanced Diagnostic Imaging	国械注进 20203060863	NMPA (CN) (CN)
2025-05-28	南京瑞德医疗科技有限公司 (Nanjing Ruide	口腔颌面锥形束计算机体层摄影设备 (Oral and Maxillofacial Cone Beam	Specialized Dental Imaging	国械注准 20243060068	NMPA (CN) (CN)

	Medical Technology Co., Ltd.)	Computed Tomography Equipment)			
2025-05-23	**深圳市沃**尔德外科医疗器械技术有限公司 (Shenzhen Wald Surgical Medical Device Technology Co., Ltd.)	**胸腰椎后路**钉棒内固定系统（微创） (Thoracolumbar Posterior Pedicle Screw Internal Fixation System (Minimally Invasive))	Class III, Minimally Invasive Spinal Implant	**国械注准** 20203131005	NMPA (CN) (CN)
2025-05-23	Abbott Medical (**雅培医**疗器械) / Agent: **雅培医**疗用品（上海）有限公司	**光学干涉断**层成像系统 (Optical Coherence Tomography System)	Advanced Ophthalmic/Cardiovascular Imaging	**国械注**进 20243060226	NMPA (CN) (CN)
2025-05-29 (Announced)	赛诺医疗科学技术股份有限公司 (SinoMedical Science Technology Inc.) Subsidiary	**血流**导向密网支架产品 (Blood Flow Diverter Stent System - Neurohawk™)	Class III, Advanced Neurovascular Intervention	**国械注准** 20253130971 (Likely, based on applicant and date)	cnstock.com (CN) (CN)
2025-05-20	**惠众国**际医疗器械（北京）有限公司	**富血小板血**浆制备器 (Platelet-Rich Plasma Preparation Device)	Regenerative Medicine Technology	**国械注准** 20223101260	NMPA (CN) (CN)

2025-05-19	AMO Manufacturing USA, LLC / Agent: 眼力健（上海）医疗器械贸易有限公司	眼科飞秒激光治疗机 (Ophthalmic Femtosecond Laser Treatment System)	Advanced Ophthalmic Surgical Equipment	国械注进 20213160021	NMPA (CN) (CN)
2025-05-12	北京术锐机器人股份有限公司 (Beijing Shurui Robot Co., Ltd.)	腹腔内窥镜单孔手术系统 (Laparoscopic single-port surgical system)	Advanced Surgical Robotics	国械注准 20233010833	NMPA (CN) (CN)

(Note: The NMPA publishes extensive lists daily; the table above presents a selection of diverse and significant approvals. Many other devices, including numerous Class II and common consumables, also received approval during May 2025.)

Clinical Trial Updates

Clinical trial activity is a crucial indicator of future product pipelines and areas of research concentration. In May 2025, several trials were noted:

A clinical trial registered on the Chinese Clinical Trial Registry (ChiCTR) with the ID ChiCTR2500102152 was recorded on May 9, 2025. However, specific details such as the study title, sponsor, or intervention were not available in the provided information.53

Hunan Ept Medical Device Co., Ltd. registered a clinical trial around May 29, 2025 (potentially ChiCTR2500100032, associated with project ID proj=274552) concerning a vascular closure device. Full details were also limited in the available snippets.54 The registration of a trial for a vascular closure device suggests ongoing innovation in interventional cardiology or radiology, aiming to improve procedural outcomes and patient comfort.

An ongoing project, NCT06963606, focusing on artificial intelligence-assisted chest X-ray (CXR) screening for tuberculosis (TB) in Chinese primary-care settings, continued its activities. The study protocol indicates various stages planned over three years, with "Implementation of the AI-assisted screening" falling within a timeline that includes May 2025 [[14] (index 8.1), [55]]. This trial is a significant example of leveraging AI to address major public health challenges, aligning with China's national digital health strategies and the push for innovative diagnostic solutions.

The limited accessibility of comprehensive details for some ChiCTR-registered trials, as observed from the provided materials, can present a challenge for international stakeholders attempting to track the full scope of MedTech innovation at the clinical trial stage in China. While registries like ClinicalTrials.gov offer some visibility, a complete picture often requires navigating Chinese-language databases. This information gap could potentially spur efforts towards more harmonized or easily searchable international clinical trial databases in the future, benefiting global competitive intelligence and collaborative research.

Table 5: China MedTech Clinical Trial Updates – May 2025

Date (Registration/Update)	Trial ID / Sponsor	Device / Indication	Phase / Status / Summary of Update	Weblink (Language)
Ongoing (May 2025 activity)	NCT06963606 / Peking Union Medical College Education Foundation (Supported by CMB grant)	AI-assisted Chest X-ray (CXR) system / Tuberculosis (TB) screening	Clustered controlled trial. Stages include AI-assisted CXR system validation, optimization, and implementation of AI-assisted screening. Project timeline spans 3 years. [55]	(https://cdn.clinicaltrials.gov/large-docs/06/NCT06963606/Prot_SAP_000.pdf) (EN)

2025-05-29 (Likely registration/update around this date)	ChiCTR2500100032 (from proj=274552) / 湖南埃普特医疗器械有限公司 (Hunan Ept Medical Device Co., Ltd.)	Vascular closure device	Prospective, multi-center, randomized controlled, non-inferiority clinical trial evaluating a vascular closure device for femoral artery puncture sites post-percutaneous intervention. [54]	(https://www.chictr.org.cn/showproj.html?proj=274552) (CN/EN)

VI. Industry Engagement: Key Conferences & Events

May 2025 was an active month for industry engagement in China, with several key conferences, expos, and training sessions shedding light on prevailing trends, strategic priorities, and collaborative efforts within the MedTech sector. These events served as important platforms for knowledge exchange, policy discussion, and business development.

Focus on AI and Digital Transformation

The **Global AI Device Expo 2025**, held in Shenzhen from May 22-23, positioned itself as China's premier specialized trade show for AI smart devices. The event showcased over 1,000 AI products and technologies and was marked by the announcement of significant new investment vehicles: a 5 billion yuan AI Device Fund and an initial 2 billion yuan AI and Embodied-Intelligence Robotics Industry Fund. The presence of attendees specifically seeking AI solutions for the medical sector underscored the growing integration of AI in healthcare.[34] The establishment of these substantial, dedicated AI funds is poised to accelerate the research, development, and commercialization of AI-powered medical devices, further solidifying innovation hubs like Shenzhen as leaders in this domain.

The **90th PHARMCHINA exhibition in Guangzhou** (around May 29) also highlighted the digital shift. Fangzhou Inc. took center stage at the concurrent 4th Annual "Internet + Pharma" Service Innovation Conference, presenting its AI-powered H2H (Hospital-to-Home) smart healthcare ecosystem. This presentation was particularly timely, aligning with China's

recently introduced "2025-2030 Pharmaceutical Industry Digital Transformation Implementation Plan," a multi-ministerial initiative emphasizing AI adoption across the healthcare and pharmaceutical sectors.[31]

The **VBEF Future Healthcare and Medicine Conference**, hosted by VCBeat in Suzhou from May 9-10 (with outcomes reported throughout May), extensively discussed the transformative role of AI in healthcare. Key takeaways included the consensus that AI is a fundamental driver of change, necessitating adaptation from industry players to evolving market structures (such as the balance between in-hospital and out-of-hospital care) and geopolitical realities, including trade tensions and the push for localization.[41] The conference theme, "THE NOW Critical Point," itself suggested a period of significant industry transition, with strategic agility being paramount.

International Cooperation and Market Development

Bilateral and multilateral engagements also featured prominently. The **2025 China-Korea Health Medical Exchange Meeting** in Jinan on May 22 aimed to foster cooperation within the health and medical industry, with specific focus areas including In-Vitro Diagnostics (IVD) and digital dental solutions.[50] This points towards a trend of increasingly targeted international partnerships, focusing on MedTech niches with mutual interest and complementary strengths.

The **2025 China-Japan Pharmaceutical Industry Exchange Conference**, held in Shanghai on May 24, facilitated discussions on pharmaceutical innovation, regulatory policies, clinical research, and market access [[71] (document ID Phirda 39006), [71]]. While primarily pharmaceutical-focused, such dialogues are crucial for understanding the broader healthcare innovation climate and cross-border regulatory perspectives that invariably influence the MedTech sector.

Regulatory Compliance and Standards

Ensuring industry-wide understanding of and compliance with evolving technical standards was the focus of a public training event organized by the **Shanghai Municipal Drug Administration (Shanghai YJJ) on May 28-29**. This online session covered 15 medical device standards and was conducted by members of national standardization technical committees.[24] Such proactive regulatory guidance and capacity-building initiatives are essential for helping the industry navigate complex

standards, thereby ensuring product quality and facilitating market access. As standards become more numerous and intricate, these training programs play a vital role for both domestic and international manufacturers.

Showcasing Domestic Innovation

The **2025 China Medical Equipment Conference and Medical Equipment Exhibition** in Chongqing, with reports emerging on May 29, featured participation from institutions like the Hangzhou Institute of Extreme Weak Magnetic Field National Major Science and Technology Infrastructure.[59] (It is worth noting that other reports indicated the main conference took place in March [[14] (index 2.1, 2.2), [73]], so the May report might pertain to a follow-up event or a specific showcase). The involvement of such a high-level national research institute highlights the increasing linkage between fundamental scientific research and its translation into practical medical device applications, a cornerstone of a thriving innovation ecosystem.

Table 6: Key MedTech Conferences & Events – May 2025

Date(s)	Event Name	Location	Key MedTech Highlights/Outcomes	Weblink (Language)
2025-05-29 (Event during PHARMCHINA)	4th Annual "Internet + Pharma" Service Innovation Conference (during 90th PHARMCHINA)	Guangzhou	Fangzhou Inc. showcased AI-driven H2H healthcare ecosystem; aligned with China's 2025-2030 Pharmaceutical Industry Digital Transformation Plan. [31]	(https://www.prnewswire.com/news-releases/fangzhou-showcases-ai-driven-healthcare-ecosystem-at-pharmchina-as-chinas-shift-to-digital-medicine-accelerates-302468198.html) (EN)

2025-05-29 (Reported)	2025 China Medical Equipment Conference and Medical Equipment Exhibition	Chongqing	Featured Hangzhou Institute of Extreme Weak Magnetic Field National Major Science and Technology Infrastructure. (Note: Main conference possibly earlier, this may be a specific feature/follow-up). [59]	ysg.ckcest.cn (CN) (CN)
2025-05-28 - 2025-05-29	Shanghai YJJ Medical Device Standards Public Training (Phase 1)	Online (Shanghai)	Training on 15 medical device standards by national standardization technical committees. [24]	sh.gov.cn (CN) (CN)
2025-05-24	2025 China-Japan Pharmaceutical Industry Exchange Conference	Shanghai	Discussed pharmaceutical innovation, regulatory policies, clinical research, market access. Broad relevance to MedTech innovation environment. [[71] (document ID Phirda 39006), [71]]	phirda.com (CN) (CN)
2025-05-22 - 2025-05-23	Global AI Device Expo 2025	Shenzhen	China's first specialized AI smart device expo. Showcased medical AI solutions. Announced 5B yuan AI Device Fund & 2B yuan AI and Embodied-Intelligence Robotics Industry Fund. [34]	sz.gov.cn (EN) (EN)
2025-05-22	2025 China-Korea Health Medical Exchange Meeting	Jinan	Promoted cooperation in health/medical industry, including IVD and digital dental solutions. [50]	news.e23.cn (CN) (CN)

2025-05-09 - 2025-05-10 (Outcomes reported in May)	VBEF Future Healthcare and Medicine Conference	Suzhou	Fangzhou CEO honored; AI medical innovations showcased. Discussions on AI in healthcare, market shifts, trade impacts, investment sentiment. [41]	stcn.com (CN) (CN) /(https://www.prnewswire.com/news-releases/fangzhou-ceo-honored-at-2025-vbef-conference-as-company-showcases-ai-medical-innovations-302453511.html) (EN)

VII. Manufacturing, Supply Chain, and Recalls

May 2025 brought developments related to MedTech manufacturing capabilities in China, ongoing international scrutiny of supply chain integrity, and routine post-market surveillance activities including product recalls.

Manufacturing Initiatives and Recognition

The scale and sophistication of MedTech manufacturing within China were highlighted by GE Healthcare. Its Wuxi manufacturing base, noted as its largest global ultrasound production facility, announced that global shipments of its Versana series ("Hua" series) ultrasound equipment had surpassed 60,000 units, as reported around May 18.[60] This milestone underscores China's critical role not just as a consumer market but as a key manufacturing hub for multinational MedTech corporations catering to global demand. The "Hua" series, designed for worldwide applications and produced in Wuxi, signals a high level of quality and efficiency at these localized manufacturing sites.

The emphasis on advanced manufacturing was also reflected in the recognition of domestic companies. ChengTian Technology was reportedly re-selected for the "Future Healthcare 100 Strong 2025 China Innovative Devices and Intelligent Manufacturing" list.[61] While the exact date of this news was not specified in the provided information, its relevance in May

discussions points to "intelligent manufacturing" as a key competency. This aligns with national strategies like "Made in China 2025," which aim to upgrade the nation's manufacturing processes through automation, AI, and data analytics, thereby enhancing quality, efficiency, and the capability to produce more complex medical devices.[10]

Supply Chain Integrity and International Scrutiny

The Chinese MedTech supply chain faced significant external pressures in May. On May 22, the U.S. FDA announced actions against two Chinese third-party testing firms—Mid-Link Technology Testing Co., Ltd. (Tianjin) and Sanitation & Environment Technology Institute of Soochow University Ltd. (SDWH, Suzhou)—due to data integrity concerns. The FDA stated it would reject data from these facilities for premarket submissions, citing falsified or invalid data discovered during inspections.[17] This followed earlier FDA warnings in September 2024 to the same firms regarding laboratory oversight failures and animal care violations.

Furthermore, on May 6, the FDA announced an expansion of its unannounced inspection program for foreign manufacturing facilities, a program that explicitly includes China.[18] This initiative aims to ensure that foreign facilities receive the same level of regulatory oversight as domestic U.S. facilities. These FDA actions collectively signal increased compliance and operational risks for MedTech companies globally that rely on Chinese testing laboratories or contract manufacturers. The direct consequences of such scrutiny, including the rejection of critical testing data or findings from unannounced inspections, necessitate more rigorous due diligence, robust quality oversight mechanisms, and potentially the diversification of supply chain partners by international MedTech firms.

Adding to supply chain complexities, U.S.-China trade tensions and tariffs remained a concern for the MedTech industry, although a 90-day pause in the escalation was noted around May 22.[19] On May 29, U.S.-based RPM solutions provider Smart Meter issued an alert regarding potential security risks associated with some connected medical devices routing sensitive patient data through Chinese servers. This warning highlighted new U.S. Department of Justice rules, effective from April 8 with a 90-day enforcement discretion period until July 8, 2025, which set restrictions on transferring data to U.S. adversaries, including China.[21] This development underscores that data governance and cybersecurity for connected medical devices are rapidly emerging as critical compliance and geopolitical considerations. As RPM and telehealth services expand, the

cross-border flow of sensitive patient data increases, prompting stricter regulations that MedTech companies in this space must navigate carefully.

Medical Device Recalls

Post-market surveillance activities included a couple of notable recalls in May. On May 22, Covidien Medical Devices International Trading (Shanghai) Co., Ltd. initiated a voluntary recall for its micro-sidestream end-tidal carbon dioxide monitoring sampling tubes. The recall was due to reports of difficulty in disconnecting the sampling tube connector from a patient's tracheal intubation, although no patient injuries or adverse events were reported in China.[62]

On May 29, Carl Zeiss Meditec AG announced a voluntary recall of its phacoemulsification system (Lens Fragmentation Device). This Class III recall was due to product labels not complying with the regulatory requirements of Japan, the importing country. Importantly, the announcement specified that this particular recall did not affect products imported into China.[63] These instances, while differing in scope and impact on the Chinese market, highlight the ongoing importance of robust post-market surveillance systems and the complexities of ensuring product compliance across multiple international regulatory jurisdictions.

Table 7: China MedTech Manufacturing, Supply Chain & Recall News – May 2025

Date	Company/Source	News Type	Summary of Event/Issue	Implication for China Market/Industry	Weblink (Language)
2025-05-29	Smart Meter	Supply Chain Alert / Data Security	Alerted on security risks of RPM devices sending U.S. patient data to China; cited	Increased scrutiny on data security and cross-border data	(https://www.businesswire.com/news/home/20250529680608/en/Smart-Meter-

			new DOJ rules on data transfer to adversaries (effective April 8, enforcement discretion until July 8, 2025).	flows for connected medical devices operating in or transmitting data from the U.S. to China. [21]	Highlights-Security-Risks-of-Remote-Patient-Monitoring-Devices-Sending-Patient-Data-to-China) (EN)
2025-05-29	Carl Zeiss Meditec AG / NMPA	Recall (Voluntary)	Phacoemulsification system (Lens Fragmentation Device) recalled due to labeling non-compliance in Japan. **No impact on products imported to China.**	Highlights international regulatory compliance complexities for MNCs. [63]	NMPA (CN) (CN)
2025-05-28 (Reported)	U.S. FDA / GlobalComplianceNews	Supply Chain / Regulatory	FDA expanding unannounced inspections at foreign manufacturing facilities, including China (announced May 6). FY2025 (as of May 8) saw 81 FDA drug/device inspections in China.	Increased compliance pressure and need for constant inspection readiness for Chinese MedTech manufacturers supplying the U.S. market. [18]	GlobalComplianceNews (EN) (EN)
2025-05-23	NMPA Food and Drug Inspection Center	Regulatory / Compliance	Published "Medical Device Flight Inspection Situation Notice (2025 No. 1)"; Jiangsu Baiyide Medical Technology	Ongoing domestic regulatory oversight and enforcement of production quality standards. [64]	duyaonet.com (CN) (CN)

			Co., Ltd. cited for non-compliance with GMP.		
2025-05-22	U.S. FDA	FDA Action / Data Integrity	FDA issued General Correspondence Letters to Chinese testing firms Mid-Link Technology and SDWH, rejecting their biocompatibility and animal study data due to falsification/invalidity.	Significant impact on MedTech sponsors relying on these labs for U.S. premarket submissions; heightens due diligence needs for third-party lab data. [17]	(https://www.fda.gov/news-events/press-announcements/fda-takes-action-address-data-integrity-concerns-two-chinese-third-party-testing-firms) (EN)
2025-05-22	Covidien Medical Devices (Shanghai) / NMPA	Recall (Voluntary)	Patient monitor sampling tubes recalled due to difficulty in disconnecting connector from patient's tracheal intubation. No injuries reported in China.	Post-market surveillance leading to corrective action for device performance issue. [62]	cqn.com.cn (CN) (CN)
2025-05-18 (Reported)	GE Healthcare	Manufacturing Update	Wuxi manufacturing base (global ultrasound hub) announced Versana series ultrasound shipments exceeded 60,000 units.	Demonstrates scale and global role of MedTech manufacturing in China for MNCs. [60]	js.chinanews.com.cn (CN) (CN)

May 2025 (General Report)	Rhodium Group / US Chamber of Commerce	Manufacturing / Policy Analysis	Report on "Made in China 2025" notes success in localizing some medical device production, though dependencies remain in high-tech components. AI poised to transform manufacturing. [10]	Hg	rhg.com (EN) (EN)

VIII. Conclusion & Strategic Outlook

May 2025 was a dynamic and multifaceted month for the Chinese MedTech sector, characterized by a strong regulatory push towards higher quality standards, continued emphasis on innovation, and complex market adjustments. The NMPA's actions, particularly the new "Quality Management Standards for Online Sales of Medical Devices" and the implementation of revised "Key Points and Determination Principles for the Inspection of Medical Device Clinical Trials," signal a maturing regulatory framework focused on safety, efficacy, and data integrity across the entire product lifecycle. This will undoubtedly increase compliance burdens but also foster a more reliable and trustworthy MedTech ecosystem.

The market landscape continues to be shaped by the interplay of cost-containment policies like VBP and incentives for innovation such as the DRG/DIP 2.0 exceptions and dedicated fast-track approval pathways for novel devices. While VBP exerts ongoing price pressure, particularly evident in Q1 2025 financial reports for some segments, the clear avenues for high-value innovations are driving R&D and investment in advanced technologies. Artificial intelligence and digital health solutions remain at the forefront of this innovation wave, with significant government backing at both national and provincial levels, as seen in initiatives from Zhejiang, Guangdong, and the national digital transformation plan for the pharmaceutical industry. Events like the Global AI Device Expo and PHARMCHINA underscored the strategic importance and rapid integration of AI into healthcare.

Corporate activities reflected these trends, with M&A aimed at channel integration (China Meheco/Jinsui Technology) and strategic partnerships focused on leveraging policy advantages in innovation hubs like Hainan Boao Lecheng (Jimin Health/Dabo Biotechnology). The consistent stream of NMPA approvals for a diverse range of medical devices, including sophisticated domestic products, points to a robust R&D pipeline and the growing capabilities of local manufacturers.

However, the sector is not without its challenges. International regulatory scrutiny, exemplified by FDA actions concerning data integrity at Chinese testing labs and increased unannounced inspections, alongside ongoing trade and tariff discussions, necessitates heightened vigilance and adaptability from companies with global operations or supply chains involving China. Data security for connected devices is also emerging as a critical area of concern and regulatory focus.

Strategic Outlook:

Looking ahead, several key trajectories are likely to define the Chinese MedTech sector:

1. **Intensified Drive for Quality and Compliance:** Expect continued regulatory efforts to elevate standards across manufacturing, clinical research, online sales, and post-market surveillance. This will favor companies with strong quality management systems and a proactive approach to compliance.
2. **Innovation as the Core Growth Engine:** The emphasis on "true innovation," particularly in AI-powered diagnostics and therapeutics, advanced surgical robotics, and high-value implantables, will persist. Funding and policy support will likely continue to flow towards these areas.
3. **Strategic Navigation of Market Pressures:** Companies will need to employ sophisticated strategies to navigate the dual pressures of VBP-induced cost containment for mature products and the demand for high-cost, high-value innovations. This may involve portfolio diversification, localized R&D, and innovative commercial models.
4. **Acceleration of Localization and Domestic Capabilities:** The "Made in China 2025" objectives, coupled with market dynamics, will further accelerate the growth of domestic MedTech champions and encourage MNCs to deepen their localization efforts, including R&D and strategic partnerships.

5. **Evolving International Landscape:** The MedTech sector will remain sensitive to geopolitical and trade dynamics. Companies will need to monitor international regulatory trends, particularly concerning data security and supply chain integrity, and build resilient global strategies.
6. **Data Governance as a Key Focus:** As digital health and connected devices proliferate, regulations around data privacy, security, and cross-border data flows will become increasingly stringent and impactful.

In conclusion, the Chinese MedTech market in May 2025 showcased a sector in dynamic transition, balancing the pursuit of cutting-edge innovation with the imperatives of regulatory tightening and market efficiencies. Success for industry players will increasingly depend on their ability to innovate meaningfully, comply rigorously, and adapt strategically to both domestic policies and the global operating environment. The ongoing development of regional MedTech clusters and the interplay between central government directives and provincial execution will be crucial factors in shaping the future of this strategically vital industry.

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