RCCB MedTech & Life Sciences Newsletter

Q4 2025 – Early Q1 2026

RCCB Royer Cooper Cohen Braunfeld

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MEDTECH & LIFE SCIENCES

RCCB and its team of lawyers help clients stay on top of impactful MedTech and Life Sciences developments and forge strategies for commercial success with regulated products. We highlight recent regulatory and compliance issues, M&A activity in these sectors, and intellectual property issues that affect regulated products.

CORE SERVICE AREAS

RCCB provides integrated legal counsel across a broad range of core practices, including Banking & Financial Services; Business Restructuring & Bankruptcy; Cannabis; Corporate & Business; Employment; Family Law; Healthcare; Intellectual Property; International; Litigation; Nonprofit & Tax-Exempt; Private Client Services; Real Estate; Solar & Alternative Energy; and Tax.

This multidisciplinary platform allows us to support clients through complex, evolving legal and business challenges with coordinated, practical solutions tailored to their objectives.

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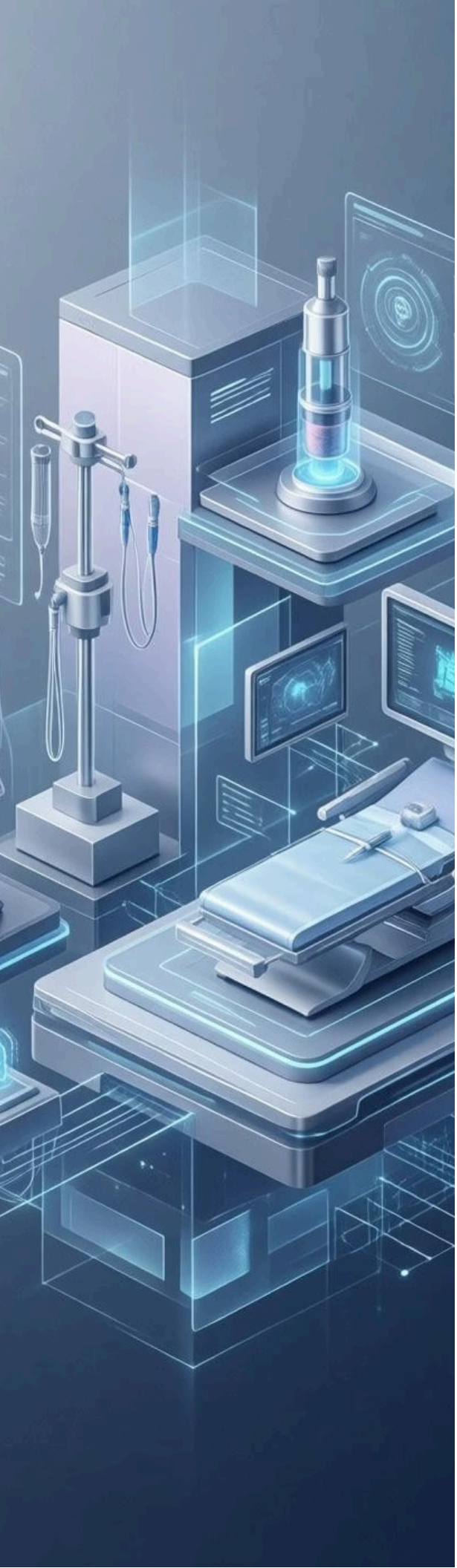


Key Regulatory Updates: FDA & EU MDR (Q4 2025–January 2026)

Clarity, But Narrower Margins for Error

Over the past several months, regulatory authorities on both sides of the Atlantic have sent consistent signals: while there is continued willingness to modernize approval pathways and reduce unnecessary burden, regulators are tightening expectations around evidence, compliance, and post-market obligations.

Recent FDA activity reflects a continued effort to streamline review pathways—particularly for digital health, AI-enabled devices, and novel trial designs—while maintaining heightened scrutiny around evidence quality and post-market performance. FDA is signaling greater openness to modern statistical methods, real-world evidence, and the use of enforcement discretion for lower-risk digital tools. However, when AI software falls into medical device categorization, there are heightened requirements on manufacturers and developers. Oversight continues to focus on post-market surveillance, quality systems, and lifecycle management regulations.

This dual focus—greater procedural clarity paired with more rigorous execution requirements—has real implications for (a) companies budgeting for and relying on regulatory timelines, and (b) buyers' approaches to deal diligence, valuation, and transaction structuring.

U.S. FDA: Modernization Matched With Elevated Expectations

Evidence Standards and Trial Design – FDA Removes Approval Barriers

In December 2025, the FDA issued a new guidance permitting submission of real-world evidence (RWE) in medical device submissions, without requiring identifiable individual patient data to be included. Previously, the FDA required that RWE submissions include private, confidential information at the individual patient level, thus functionally eliminating the use of large databases of aggregate or de-identified data in product applications.

> *"We're removing unnecessary barriers that have prevented us from using powerful real-world evidence to get life-changing treatments to patients faster," noted FDA Commissioner Marty Makary. "This common-sense reform will unlock access to vast databases like cancer and cystic fibrosis registries that contain critical insights about how treatments work in the real world."*

This change enables the use of large, de-identified databases containing millions of patient records, including national cancer registries, hospital system databases, insurance claims databases, and electronic health record networks. It will make the approval process easier to use scientifically-sound information to demonstrate safety and efficacy.

Digital Health & AI Governance – Software as a Medical Device ("SaMD") and General Wellness

FDA's risk-based stance on digital health and software products continues to evolve. Recent drafts emphasize that software functions with diagnostic or treatment claims will be regulated, and that adaptive AI changes may require post-market controls and validation frameworks that mirror traditional devices. By contrast, FDA now emphasizes enforcement discretion for purely informational tools, but the boundaries are tightening as regulators demand clarity on algorithm updates and change control.

On January 6, 2026, FDA issued revised guidance documents on both general wellness digital products and AI clinical diagnostic software (CDS). In general, these two new guidance documents effectively broaden the scope of digital health products that FDA will not regulate, either via definitional scopes or non-enforcement discretion.

General Wellness vs. SaMD

When a product is classified and regulated as SaMD, and not a General Wellness product, those device developers have to maintain all of the records, quality protocols, and cybersecurity measures required for medical devices, requiring a substantial investment in quality systems and personnel. Thus, FDA's categorization of the software can be hugely impactful on the commercial success or failure of the product.

"General Wellness" products are those that satisfy two factors: (1) "present a low risk to the safety of users and other persons;" (2) are intended only for uses that (a) "relates to maintaining or encouraging a general state of health or a healthy activity," or (b) "relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition." For software to be a General Wellness product, it must be for "maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition." FDA's Revised General Wellness Guidance makes clear that low-risk general wellness products can be marketed without FDA oversight and expands the scope of "General Wellness" products. FDA provided two new examples of low-risk general wellness now included in the expanded scope of the definition: (1) wrist-worn wearable products, like the Apple Watch, that records biodata, but the claims about the product only fall within General Wellness definitions above; (2) wearable products advertised toward elite athletes, intended for biomonitoring using sweat instead of blood, and disclaimed use in diagnosing any condition or disorder (like the Flowbio Sensor and Nix Hydration Biosensor).

FDA's January 2026 guidance on Clinical Decision Software sets forth the four factors under FD&C Act section 520(o)(1)(E) for software products to slide out of the CDS/SaMD category and into the General Wellness rules:

- Is not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;
- Is intended to display, analyze, or print medical information about a patient or other medical information, like clinical practice guidelines;
- Is intended to support or provide recommendations to a healthcare profession ("HCP") about prevention, diagnosis, or treatment of a disease or condition; and
- Is intended to enable HCPs to independently review the basis for the software's recommendations so HCPs do not primarily rely on the recommendations when making a clinical diagnosis or treatment decision.

FDA makes clear that, if the software is used to provide diagnostic, preventive, or treatment options that replaces or directs the healthcare provider's medical judgment, then that product will be CDS and SaMD. On the flip side, software is not regulated as SaMD if it supports medical decisions, but does not drive the analysis and diagnosis.

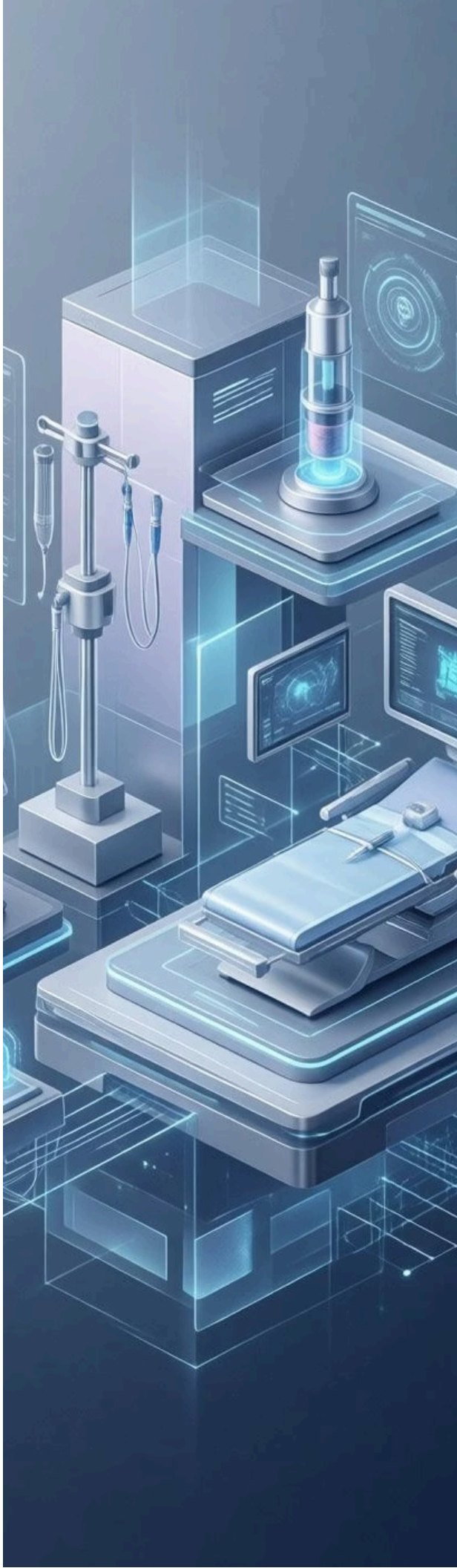
Developers choosing to bring such products to market as low-risk General Wellness products should pay close attention to the criteria FDA has set out, particularly with regard to product advertising, promotion and use instructions that may undercut contrary disclaimers of SaMD status. New product launches have to align the design and intended use with FDA's definition of low-risk General Wellness products.

Overall, the Revised CDS Guidance and Revised General Wellness Guidance represent a significant expansion of digital health technologies that FDA will consider as falling outside of active regulation as either CDS or a general wellness product. *Deal implications:* More products will commercialize faster, with less oversight to catch flaws or red flags. Is that recipe for a bubble for investors?

Post-Market and Quality Systems

Enforcement actions in 2025 reveal a sustained focus on post-market surveillance, quality systems, and complaint handling. Even products cleared efficiently are subject to scrutiny after launch for compliance.

Deal implication: Strong quality systems and clean inspection histories support valuation, deal certainty, and reduced post-close risk.



EU Regulatory Signals: Simplification of MDR, With Conditions

Under the EU's the Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), frustrations were growing throughout the 2020s with regulators' lack of responsiveness in moving products through the CE review and approval process, causing delays in commercialization and revenue generation for hundreds of companies.

Across the EU, regulators have taken notable steps toward simplifying device regulation and easing transition hurdles — but with accompanying duties that condition such flexibility on compliance performance. On December 18, 2025, long-awaited changes to ease the substantial burdens were proposed for adoption by the European Commission. The legislative proposal seeks to simplify the regulations and to reduce complexity and administrative burden while maintaining patient safety.

While the proposed changes are myriad, here is a brief list of the most impactful proposed changes to the MDR and IVDR:

- **Streamlined procedures for low-risk technologies**. By introducing a definition of "well-established technology device," the EU will be lessening the requirements for sale for products with an established track record of safety and clinical efficacy. Additional proposals address fee reductions for small manufacturers, structured dispute resolution mechanisms, and greater flexibility for post-certification manufacturing changes.

- **Audits and Certification:** The proposed rule changes will (1) eliminate the 5-year term of an ISO certificate, opting for renewal inspections that are based on risk instead of a calendar schedule; (2) reduce time-consuming and expensive on-site surveillance audits, opting for more remote "desktop" audits; and (3) the annoying "surprise audit" now will be done only when there is "cause" to do so.

Notified Bodies: Efficiency and Accountability.

a. Manufacturers have been frustrated for years by Notified Bodies that will not engage in dialogue about issues as they arise (because that is too close to "consulting" and not "auditing"). The new rules now allow for this kind of "structured dialogue" to make the process more iterative and efficient. [Note: *The regulatory decision-makers in the EU, known as "Notified Bodies," are private companies that carry out the regulatory oversight of medical device manufacturing site compliance and the approval of the device for sale in the EU.*]

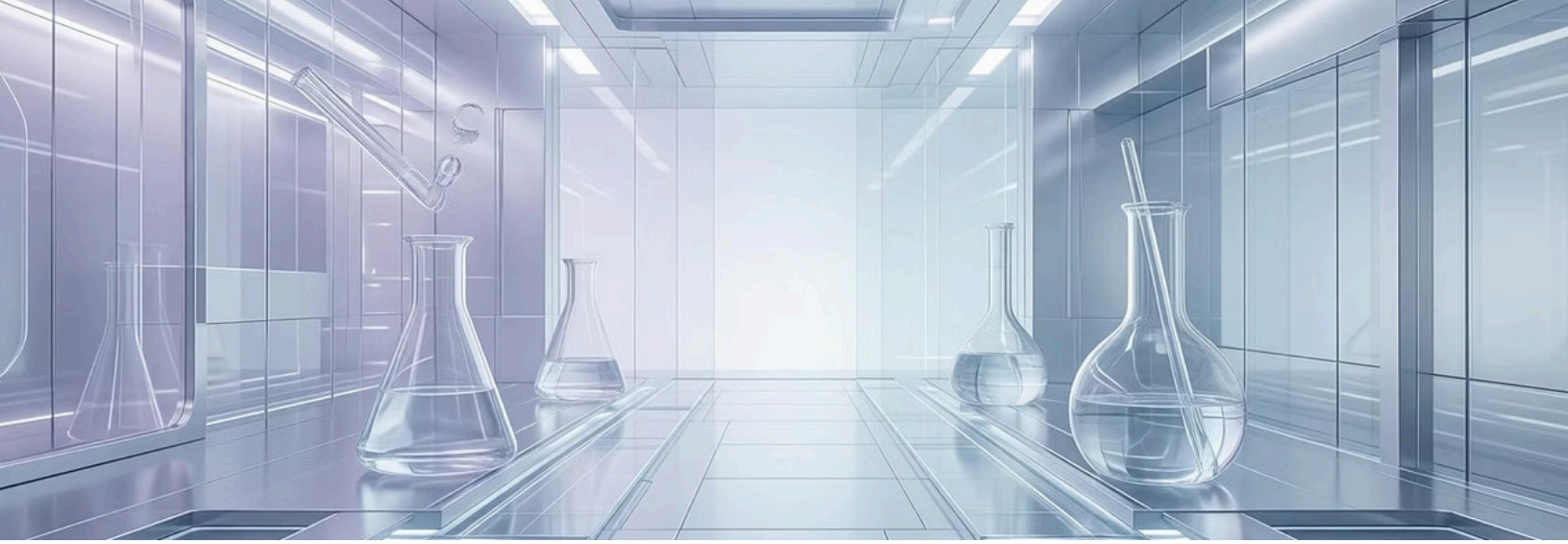
b. The heavy costs of compliance will be addressed by fee reductions for small manufacturers.

c. The frustrations of a substantive or procedural dispute with a Notified Body will now be addressed via an "ombudsperson" in place to help resolve disputes between manufacturers and Notified Bodies.

Change Process after Certification Issued.

In so many instances, manufacturers need to make adjustments or changes to the manufacturing process or facility, or to the product itself. However, under the MDR, implementing needed changes requires pre-approval from the Notified Body, making a change extremely time-consuming and burdensome. Now, there will certain changes allowed by the manufacturer without prior notice to, or approval of, the Notified Body, and other changes that must be approved by the Notified Body before implementation.

For companies with global MedTech strategies, RCCB's lawyers and its partner firms in the International Lawyers Network stand ready to advise clients on developments in international regulatory and quality issues. The ILN is an association of 91 high-quality, full-service law firms with over 5,000 lawyers worldwide, including in 67 countries across six continents. RCCB's lawyers have experience in global regulatory issues, as well as experience representing U.S. and foreign companies in cross-border M&A transactions, joint ventures, licensing and distribution agreements.



FDA 510(k) Product Approval Trends and Data

510(k) Statistics

Year	510(k) Submissions
2023	3,000
2024	3,107
2025	3,000 (1,856 through July; 753 in Q3)

- FDA has a target review period of 90 days for 510(k) filing for medical devices. In 2025, FDA 510(k) review times averaged between 140-175 days. Between 70-80% of 510(k) submissions exceeded the 90-day target.
- In 2025, FDA reviews of 510(k) applications for artificial intelligence or machine learning software (“AI/ML”) took approximately 142 days on average, but nearly a quarter of the devices were cleared in under 90 days. Thus, submissions that are comprehensive and complete can get through the approval process in a timely manner. However, more complex cases are taking longer to review and process, well beyond 200 days in total. Adjust company planning and revenue timelines accordingly.

2025 AI/ML Medical Device 510(k) Clearances: Coming In Heavy Numbers

According to a comprehensive Innolitics industry analysis, in 2025, FDA granted clearance to 295 AI/ML software medical devices, well above historical averages. This rapid increase demonstrates generative AI's sweeping scope and momentum in these regulated spaces. The 295 clearances went to 221 different manufacturers, 183 of which had only one clearance. This reflects a marketplace of both long-standing players and many startup ventures leveraging the AI technology to quickly innovate and iterate.

Particularly given FDA's January 2026 guidance on both general wellness digital products and AI CDS, discussed above, it is noteworthy that 62% of the clearances were designated as SaMD, most predominantly in diagnostic products like radiological AI software. Of course, when a product is classified and regulated as SaMD, and not a General Wellness product, those device developers have to maintain all of the records, quality protocols, and cybersecurity measures required for medical devices, requiring a substantial investment in quality systems and personnel.

FDA averaged about 20-30 AI/ML 510(k) clearance per month in 2025.

Metric	Value
Total Clearances	295
Unique Manufacturers	221
Average Days to Clearance	150
Median Days to Clearance	142
SaMD Devices	183 (62%)
Diagnostic Devices	187 (63%)

Regulatory & Competitive Implications

The breadth and speed of AI/ML clearances in 2025 have had several effects on regulatory strategy, commercialization, and M&A:

Regulatory predictability affects valuation

Devices with recently granted AI/ML 510(k) clearances often enjoy more sophisticated buyer interest and tighter diligence timelines, whereas products in earlier stages or without clear machine-learning predicates tend to see more contingent pricing.

SaMD regulatory pathways are a moat

Companies with robust real-world performance data are building regulatory-driven competitive advantages that extend beyond IP or clinical outcomes alone. Leveraging the data being collected during use improves the product's performance and safety, the speed of the machine learning, and post-market surveillance compliance.

Integration risk influences deal structure

As buyers have to rely on the stability of software and its algorithms, they are increasingly scrutinizing post-market surveillance plans, QMS maturity, and cybersecurity readiness in diligence — factors that can affect escrow, pricing, earnouts, indemnity scopes, and integration commitments.

M&A in MedTech and BioPharma

Q4 2025 – Early Q1 2026

Recent MedTech and Life Sciences M&A activity reflects a selective but durable transaction environment.

Regulators continue to modernize approval pathways while demanding clearer evidence and post-market oversight. Buyers remain active but selective; and intellectual property quality (particularly when it is tied to revenues) is increasingly determinative of valuation and deal structure. These trends reinforce a simple proposition: regulatory readiness, defensible IP, and transaction preparedness are inseparable.

From an M&A perspective, FDA pathway has become a core valuation driver for buyers, not a diligence afterthought. Because financial horizons are tied to compliant product commercialization, buyers are increasingly underwriting:

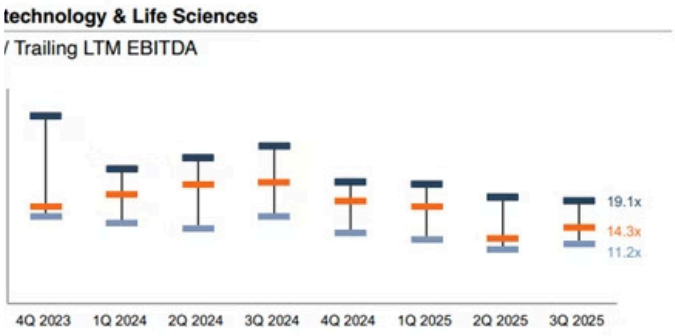
- probability-weighted regulatory outcomes
- timing risk associated with clearance or approval
- exposure to post-market corrective actions

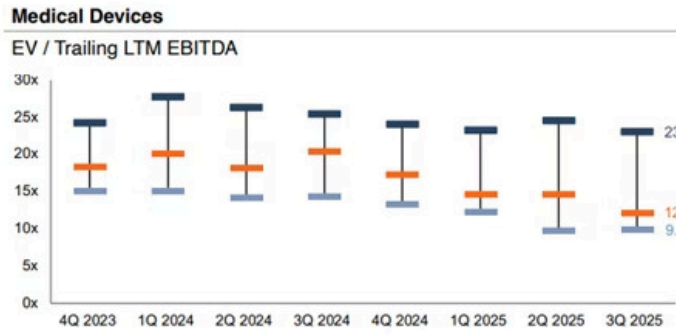
These considerations can directly influence purchase price, escrow sizing, and contingent consideration structures.

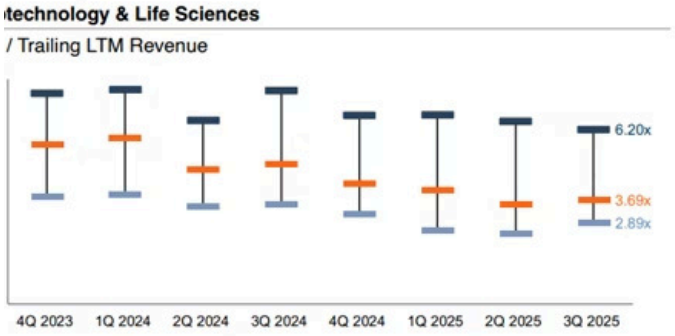
Valuation Environment

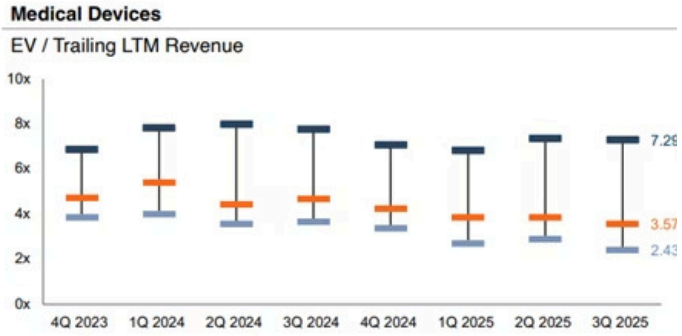
EBITDA and Revenue Multiples (Source: Mercer Capital Q4 2025 Industry Report)

- **Revenue multiples** for medical device targets generally cluster around **3.5 - 7.25 (75th%)**, with meaningful premiums reserved for software-enabled platforms due to high margins, scalability, and IP.
- **EBITDA multiples** for scaled, profitable assets remain in the **12 - 23 (75th%)** range, with upper-quartile valuations supported by recurring revenue, defensibility, and margin durability.









(Source: Mercer Capital Q4 2025 Industry Report)

Premium valuations remain concentrated in software-enabled platforms with scalable models and defensible IP.

Deal Structure & Terms

With the constant investment and regulatory uncertainties in MedTech and Life Sciences discussed throughout, buyers have been relying more on structured consideration where the deal compensation is tied to post-close performance and milestones.

- Earn-outs and milestone payments remain common, particularly for development-stage or early-commercial assets.
- Performance triggers are increasingly tied to regulatory approval, reimbursement milestones, or revenue thresholds, rather than purely technical development events.
- Buyers are applying more rigorous fair value discipline to contingent consideration, influencing both upfront pricing and post-close accounting treatment.

Key Patents & IP News

Patent Landscape Trends

- AI/ML devices are a major driver of new intellectual property, with hundreds of FDA clearances tied to such tools in 2025. As result, there should be many developers and investors seeking both offensive and defensive patent strategies.
- Patent litigation is on the rise. Life sciences companies are watching patent litigation accelerate again. In 2024, more than 500 life sciences patent infringement lawsuits were filed in the U.S. and another 250 new patent suits were filed in 2025.

Have you heard of the ingenious solution to the explosion of patent lawsuits presented by the LOT Network of 5,800 global companies?

Because so much of the patent litigation and expense is being driven by patent trolls ("Patent Acquisition Entities"), this network of innovators (including in MedTech) who are frequently targeted by trolls have circled the wagons.

According to their **website**, the average PAE suit costs "over $4 million to defend – and costs companies an aggregate $29 billion annually – money that could otherwise be put toward R&D, marketing or better serving customers."

Here is how the LOT Network protects its members – it is worth checking out:

- You join LOT Network.
- Another member of LOT Network of 5,800 companies sells or transfers one of its patents to a PAE.
- Due to the conditional license in the LOT membership agreement, every member of LOT Network is granted immunity for the life of that patent.
- The PAE cannot sue anyone in LOT Network for infringing that patent.

Introducing MedTech & Life Sciences

Regulatory Services

RCCB provides FDA and international regulatory advice and guidance to early stage through more mature companies in the medical device, pharmaceutical, cosmetic, food product, additive manufacturing, and life sciences industries through every stage of the business and product lifecycle. We advise on regulatory strategy, product development requirements and documentation, quality and compliance systems (including FDA, ISO, and cGMP frameworks), site registrations, audits, and commercialization readiness.

Integrated Approach

Our approach is integrated with corporate and transactional counsel, helping clients align regulatory compliance with product development, strategic partnerships, financing, M&A activity, and market expansion. Utilizing business and legal experience in managing FDA-regulated businesses, the practice delivers practical, business-focused guidance that helps clients bring products to market efficiently while managing regulatory risk and supporting long-term growth.

Healthcare Group

RCCB's Healthcare Group advises healthcare providers, medical practices, and healthcare-related businesses on the legal, regulatory, and business issues that arise in a highly regulated and rapidly evolving industry. We combine transactional, regulatory, and litigation capabilities to deliver practical, business-focused guidance tailored to the operational realities of healthcare organizations.

We support clients across the full lifecycle of their businesses, from formation and growth through strategic transactions, regulatory scrutiny, and dispute resolution. Clients include physicians, group practices, hospitals, ambulatory surgery centers, healthcare facilities, management service organizations, and other healthcare-adjacent businesses navigating complex legal and compliance environments. Our Healthcare Group is chaired by RCCB Partner, Sheila Mints.

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View Biography

Ira Rosenau is a partner in the firm's Corporate & Business, Litigation, and Healthcare practices, where he advises companies operating in highly regulated industries, including medical devices, pharmaceuticals, food products, additive manufacturing, and life sciences. With 30 years of experience as a commercial attorney and business leader—and a background as a trial lawyer, business executive, and in-house counsel—Ira is an exceptional problem-solver who helps clients navigate complex legal and regulatory environments. He offers a practical, commercially grounded perspective, particularly in matters where regulatory, business, and litigation considerations intersect, to advance his clients' commercial goals.

MedTech & Life Sciences

Bringing regulated products to market requires detailed planning and execution. Ira guides FDA-regulated clients through regulatory and quality compliance for product commercialization, including regulatory roadmaps, product development requirements, FDA and international clearances, quality management systems (ISO, FDA, and cGMP), QMS implementation, and site registrations and audits.

Litigation

In his litigation practice, Ira represents businesses in commercial disputes involving contracts, business torts, partnership and shareholder matters, real estate and construction issues, tax disputes, and regulated products. He brings extensive trial experience and a business-focused approach to litigation strategy, supported by an advanced law degree (LLM) in trial advocacy.

Sources Relied Upon:

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- LOT Network – Member Organizations