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Navigating Medical Technology Trends by Adopting the Digital Thread

JANUARY 2025

Executive Summary

The pace of change across the medical technology, or MedTech, industry has dramatically accelerated in recent years, creating new needs and concerns for medical technology firms across four domains.

- **Technology**
- **Business**
- **Patient Care**
- **Compliance**

In our blog series, originally published in 2024, we focused heavily on technology trends in the MedTech industry. This compendium, enhanced with new insights and updated data, provides a view on some of the leading technology trends.

In 2025, we will continue the series with additional trends, so keep an eye out for our latest articles on Viewpoints.

For now, let's dig into what technology trends are really shaping the MedTech industry.

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Key Trends Impacting the MedTech Industry

The pace of change in the medical technology industry is both exciting and extraordinary.

Major market forces are causing core paradigm shifts in business strategies and processes alike. These include:

- Intensifying regulatory scrutiny
- Emerging digital technologies, especially artificial intelligence (AI) and Internet of Medical Things (IoMT)
- A shift to services-focused product lifecycles
- Supply chain resilience
- New cybersecurity regulations
- A shift in quality system regulations

The medical technology market is expected to surpass $600 Billion by 2025. This growth is supported heavily by demographics and new technology breakthroughs.

It's also increased by the advancement of AI, IoMT, extended reality, scalable cloud computing and technologies that are accelerating the development of digital twins.

Companies need to brace for a rapidly evolving future and invest now. There are now well over 100 medical technology companies (including divisions embedded within Pharma) with revenues in the billions, but not all companies are truly making the investments necessary to compete in the near future.

At the same time, we see most of the mega-sized tech companies making inroads in the MedTech, diagnostics and healthcare space. These companies are uniquely positioned with their super-sized AI models, massive capital, unprecedented talent (some from medical acquisitions) and incredible compute power to make significant dents in the industry.

Discovering the Digital Thread

MedTech companies must see digital thread investment augmented with AI models as their number one strategic imperative or risk falling behind. The digital thread refers to the seamless flow of data and information across different stages of a product's life cycle. This includes ideation, design, manufacturing, use and service, creating an integrated and connected data ecosystem.

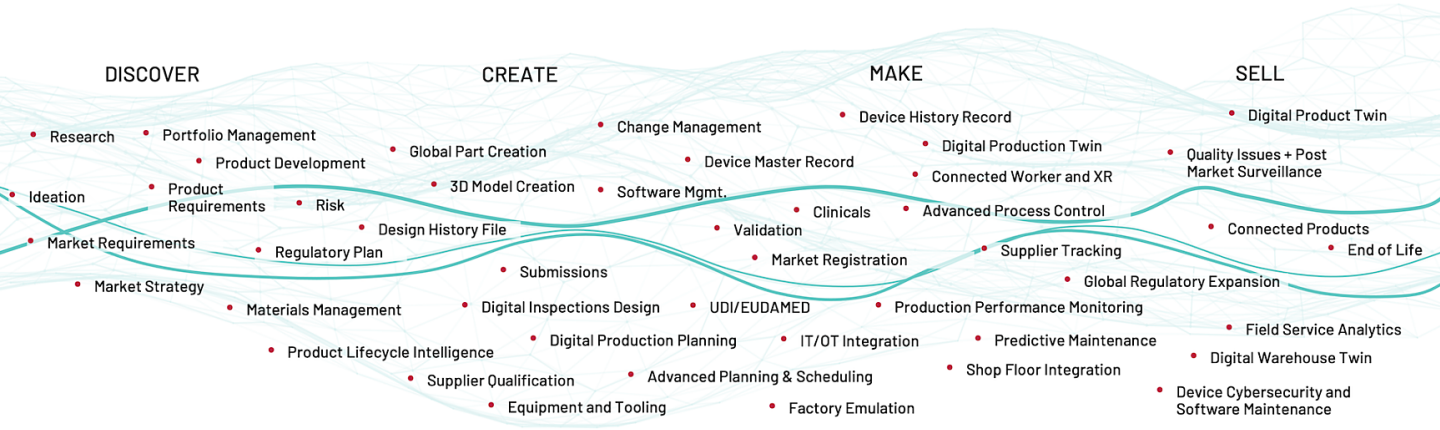
Adoption of the digital thread will create opportunities for medical technology companies to better serve more people around the world with increasingly innovative and affordable diagnostics, treatments and combination devices.

Benefits of the digital thread include:

- Faster development cycle time
- New product-driven growth
- Enablement of business scaling
- Streamlined regulatory compliance
- Reduced business and clinical risk
- Simplified product registrations
- Improved asset utilization and reduced downtime
- Reduced scrap and waste in prototyping and manufacturing
- Better energy management / reduced environmental footprint
- Reduced manufacturing and field service costs
- Closed-loop quality management
- Improved insights from connected products

The MedTech industry has unique processes and requirements that span the value chain. These include research, design, quality and product engineering, clinical trials, validation, pre-market approval, production, post-market support and product obsolescence. Increased regulatory pressures and value-based healthcare are shifting strategic priorities. However, the digital thread is transforming product development, manufacturing, clinical processes and real-world care (as well as evidence capture). Adopting the digital thread throughout the value chain is essential for scaling organizations in response to industry growth. It enables companies to proactively address or leverage disruptive forces more effectively.

Figure 1 below illustrates the digital thread concept for medical technology companies. This is just representative and not all inclusive of the dozens of processes and capabilities that span the entire product lifecycle. It is worth noting how the digital thread spans the Total Product Lifecycle (TPLC), which is a key FDA concept and expectation for many aspects of managing data within the quality system.



The digital thread is a seamless flow of data that connects business processes across the value chain

Figure 1

TPLC and the Digital Thread

The FDA mandates a TPLC approach. TPLC expects manufacturers to integrate pre- and post-market activities into a holistic view to help ensure device safety and effectiveness from design through commercialization. The digital thread mirrors and expands upon this concept by integrating engineering, regulatory, manufacturing quality and service processes into a more seamless flow of information, which is then enhanced by data extrapolation and analytics.

The Explosion of Devices with AI/ML

One of the initial uses of AI in clinical settings was for early detection of atrial fibrillation. In 2014, the Food and Drug Administration (FDA) approved AliveCor's mobile application, Kardia, for this purpose.

Since then, the FDA has seen an increasing number of marketing submissions and pre-submissions for devices utilizing AI/ML and expects this trend to continue. To help navigate the complex landscape of digital health, the FDA has established a Digital Health Center of Excellence. This move shows the FDA's recognition of the immense potential of AI as well as their support of it in the industry. It is also worth noting that the FDA has published 10 Good Machine Learning Practices for medical technologies with embedded AI/ML.

Here are a few examples of AI/ML embedded in devices:

Image Analysis: Medical imaging devices generate large amounts of data that can be hard for a human to interpret. Newer AI/ML models are getting even better at identifying patterns that may indicate disease, such as detection of tumors.

Monitoring and Diagnosis from IoMT Products: AI/ML is now being used to analyze data from wearables, like monitors for heart conditions and sleep apnea or smart orthopedic implants, to identify patterns that may indicate the presence of disease. This is useful in the detection and diagnosis of diseases and conditions, and the understanding of the efficacy of a surgery - as in the case of an orthopedic implant.

Personalized Medicine: AI/ML is being used to analyze data from medical technologies to create personalized treatment plans for individual patients. This can help to ensure that patients receive the most appropriate treatment for their condition.

Natural Language Processing (NLP): Medical technologies can have significant potential to leverage NLP to understand natural language inputs and provide relevant outputs. This can facilitate communication between patients and medical technologies, making the interaction more intuitive and user friendly. Undoubtedly large language models (LLMs) will soon be integrated into medical assistant devices. It's not hard to imagine examples where NLP medical data (scrubbed for privacy) will be incorporated along with data from medical technologies to enhance real-world data capture.

Research Assistance: LLMs are already being used in clinical research, for example to better match patients to clinical trials.

Spotlight on Technology

We are already witnessing breakthroughs in many uses of artificial intelligence (AI) and machine learning (ML) in devices, including medical robots, patient apps, diagnostics and smart connected devices or IoMT. AI is perhaps the most profound mega-trend that will influence the industry.

Broadly, AI refers to the use of artificial intelligence. Machine learning (ML) is a branch of AI focused on enabling computer systems to autonomously learn and adapt through the analysis of large datasets.

In this blog, we will refer to both with the combined term, AI/ML.

The advancement of AI/ML in everyday life is impacting us at an accelerating pace, with applications such as smart homes, self-driving cars and LLMs like OpenAI's GPT, Anthropic's Claude and Google's Gemini. These technologies are increasingly present in our lives, sometimes in subtle and other times in highly noticeable ways.

There are many ways AI/ML is affecting the MedTech industry. This includes:

1. Integration of AI/ML within the medical technology itself
2. Utilization of AI/ML for the development and design of new or enhanced iterations of medical technology products
3. Application of AI/ML in the processes of manufacturing or servicing the device

The FDA publishes a list of medical technologies with AI/ML embedded. It's currently dominated by diagnostics, but the range of applications is growing.

As of 2024, this number is clearly rising rapidly per *Figure 2*, while *Figure 3* illustrates categories of devices where AL/ML is utilized. *Figure 4* highlights the major players in the market today. It will be fascinating to see how this data changes as GenAI, Agentic AI and other forms of AI get incorporated in the coming years.

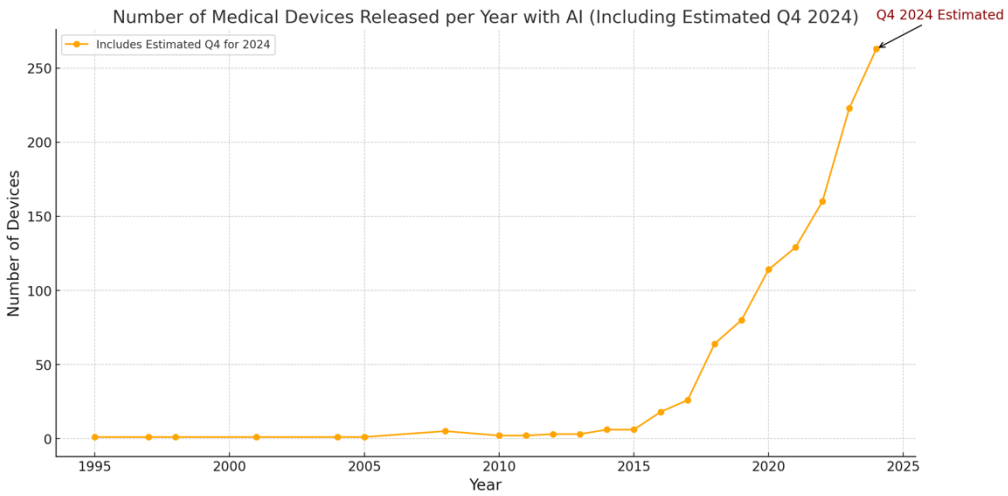


Figure 2: The rapid rise of AI/ML within medical technologies
(Q4 2024 estimated at ~90 devices, as the data was not published at the time of writing)

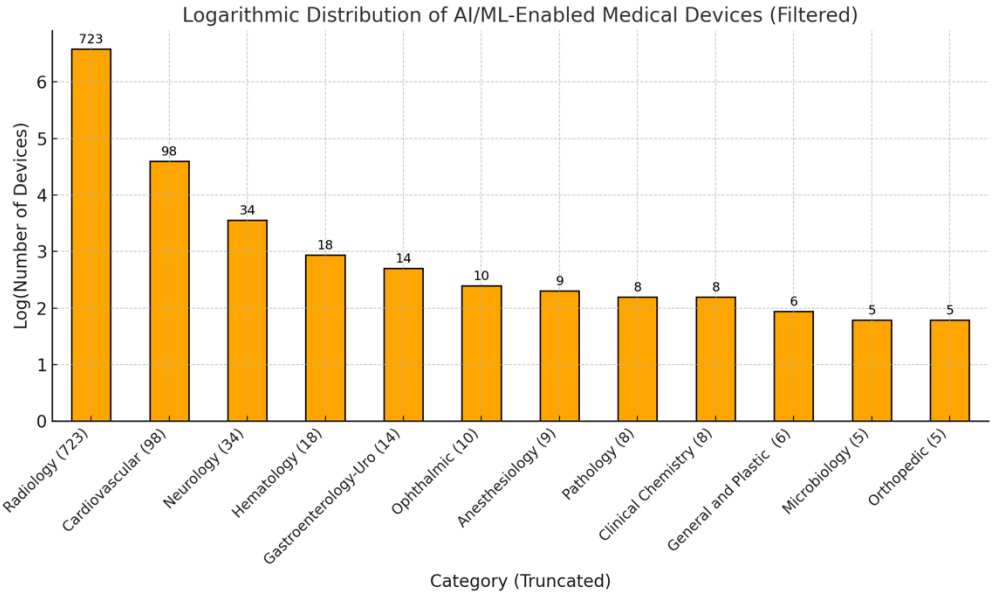


Figure 3: The categories of devices with AI within medical technologies
(logarithmic scale shown) filtered to categories >= 5 devices on market

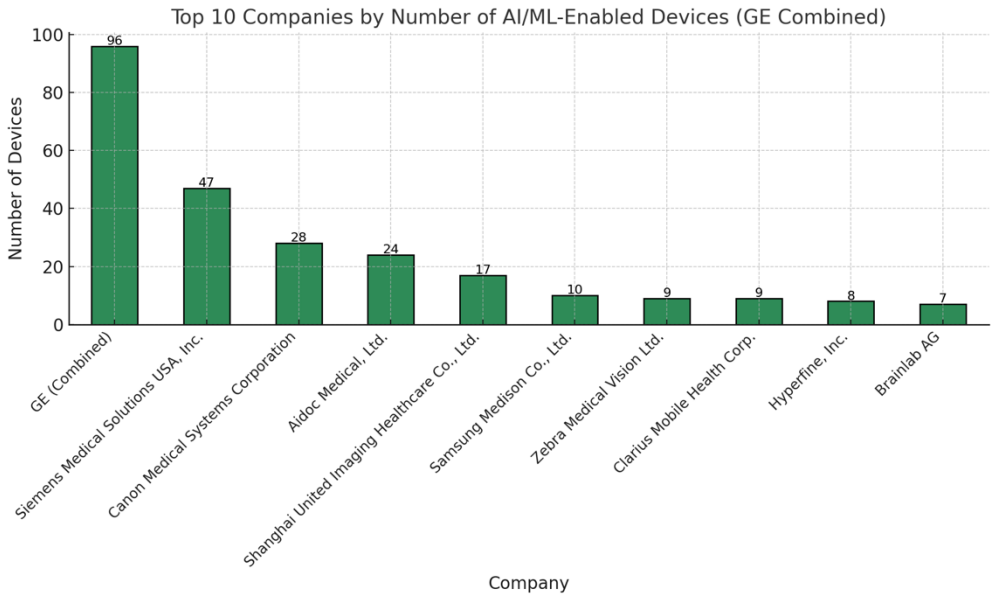


Figure 4: Highlights the major companies in the market

Regulatory Framework for Machine Learning in Medical Technologies

FDA Risk-Based Framework

The FDA has established a risk-based framework outlined in both pre-market and post-market guidance documents regarding the use of ML in medical products. This framework is available publicly and lists all medical technologies that incorporate some form of ML.

In 2023, the FDA introduced specific guidance on integrating a Predetermined Change Control Plan (PCCP) for ML within medical technologies. This guidance addresses both automatically and manually implemented changes to models, facilitating a process where modifications can be made without additional approval.

The PCCP is structured into three key components:

1. Description of modifications
2. Modification protocol
3. Impact assessment

These elements are designed to streamline the management of ML modifications, ensuring safety and compliance while enabling innovation.

FDA Progressive Commitment

The FDA is clearly committed to enabling the use of AI/ML in medical products, including those that continuously learn within a safe set of parameters, and bringing more structured regulation.

Relevance to Digital Thread

Organizations can use AI/ML to optimize the performance and capability, safety and efficacy of medical technologies.

The FDA has left room to allow AI to learn and adapt within a safe set of parameters as devices are used without resubmitting through a regulatory process with PCCP.

Businesses will need to advance their digital thread backbone to incorporate AI/ML in the way the FDA envisions – the TPLC approach.

The following will need to be well-controlled and digitized:

- Management of the product (including software and model) design and development
- The PCCP
- Manufacturing, setup and monitoring of data
- Service of the device

It is simply too complex to handle these kinds of requirements without a well-controlled set of interconnected capabilities supported by modern platforms which ideally would include the following minimum list:

ML-Ops: Manages the development, compression and maintenance of the AI/ML models

Systems Engineering and Application Lifecycle Management (ALM): Manages requirements, risk, test and software through its lifecycle

Product Lifecycle Management (PLM): Controls as many as 60 aspects of the digital thread, but most notably the Design History File, Device Master Record and Change Control Process

Regulatory Information Management (RIM): Controls registrations and submissions

Quality Management System (QMS): Controls the management of quality incidents

Manufacturing Execution Systems (MES): Controls the production of devices and the Device History Record

Smart Connected Product (SCP)/IoMT: Platform which connects the device and gathers real-world data

Data Lake: Allows for robust data analytics of data generated by these systems and on-market devices including descriptive, diagnostic, predictive and prescriptive models

Electronic Health Record (EHR) Integration System: Allows for robust collection of real-world data

The interconnectivity of processes and data are significant. Changing one aspect of the design will pull on many other elements even more so than ever before.

Capabilities within a mature digital thread will allow companies to manage this information in a way that is efficient and compliant.

Further, the capture of real-world evidence (RWE), which will require companies to gather data from devices in secure and robust methods, adds to the increased importance of getting the model well-managed and under control.

The Digital Thread – Application of PCCP

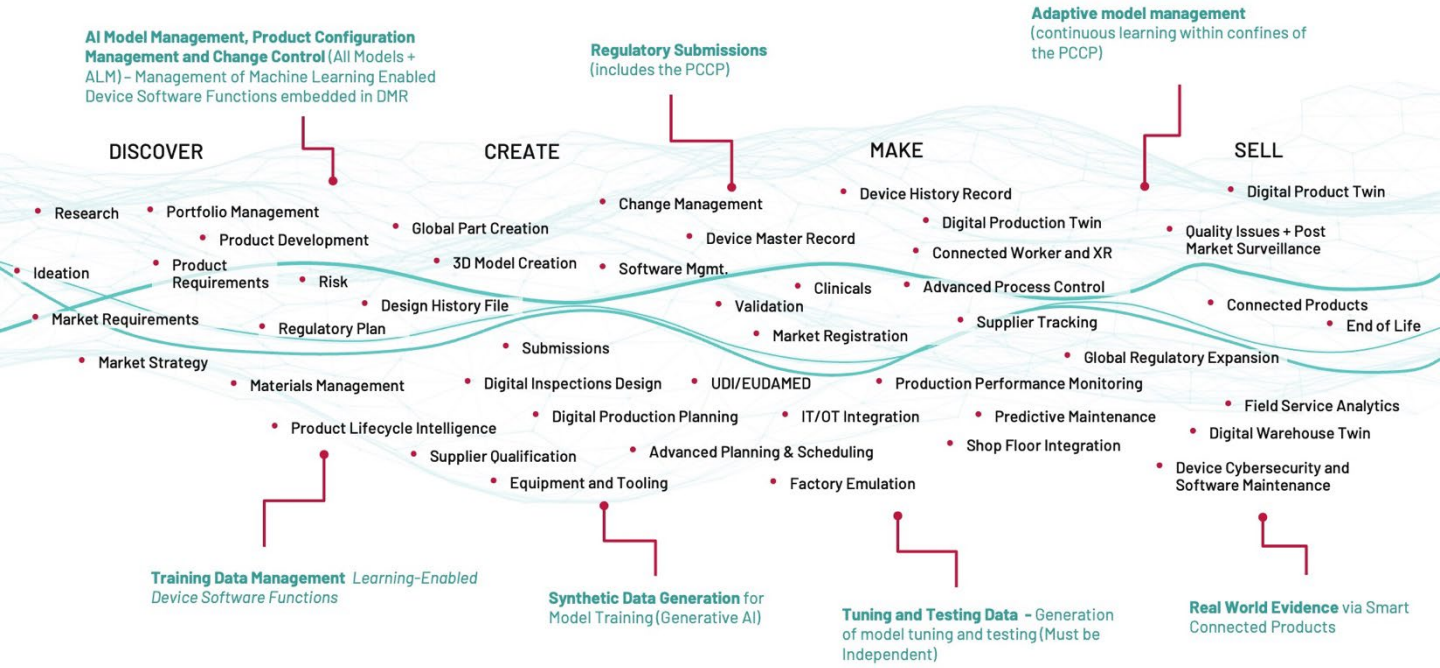


Figure 5

Figure 5 is a summarized depiction of the digital thread across the total product lifecycle and the broader value chain and illustrates just some of the key aspects of the AI model, its PCCP and collection of RWE that can be automated and managed across each part of the digital thread.

Emerging Frontiers

Model Compression and Edge Computing Opens New Frontiers

Breakthroughs in model compression make for easier portability and consumption at the edge. This is especially important because not all hospitals and clinics are willing or able to permit the IoMT or "connected" concept and there will be many instances where an internet connection is either not fast enough (too much latency) or just unavailable. It also reduces burden on validation, privacy concerns and cybersecurity.

It is worth noting that a mature ML-Ops facilitates the automation of various stages in the ML pipeline, including the integration of model compression techniques.

This automation can include the optimization of models for deployment, where model compression plays a crucial role.

Multi-Model Use Cases

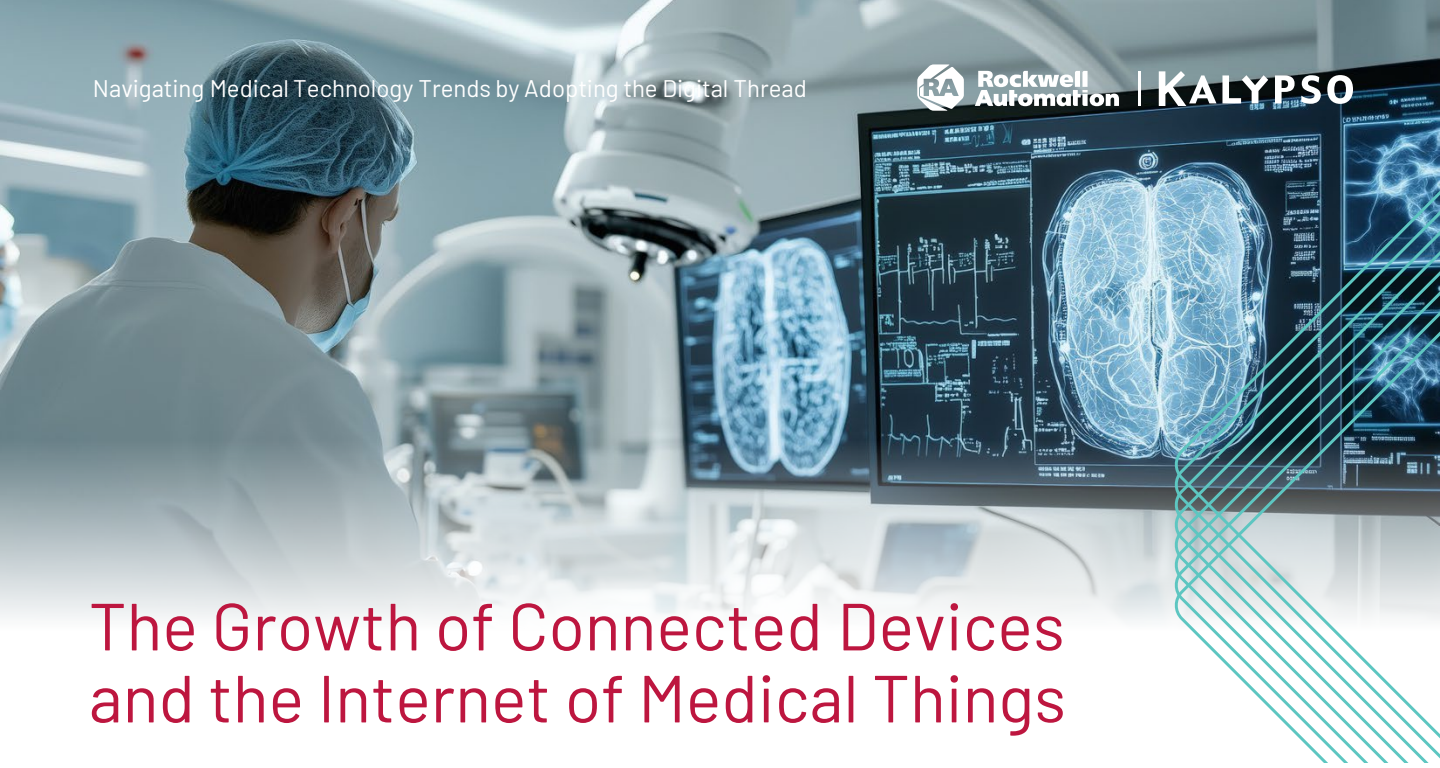
Multiple AI models are being combined to further drive patient outcomes, and many small advancements in these large AI models are being developed at a breakneck pace but aggregate into major advancements in the field. AI is further being incorporated into the broader clinical workflow and there are many variants.

Agentic AI Models

Agentic AI refers to artificial intelligence systems that exhibit agency, meaning they can:

1. **Act autonomously:** Take actions and make decisions independently, without constant human intervention
2. **Pursue goals:** Designed to achieve specific objectives and can adapt their behavior to reach those goals
3. **Learn and adapt:** Learn from their experiences and adjust their actions based on changing conditions

The potential application to healthcare and MedTech will likely be profound. Please keep a look out for future blog series entries with a focus on agentic AI in early 2025.



The Growth of Connected Devices and the Internet of Medical Things

We've been exploring technology as a trend in MedTech, so let's dive deeper.

The growth of smart connected products continues and the list of applications of IoMT continues to grow including:

- Ventilators
- Anesthetic machines
- "Smart" orthopedics
- "Smart" wound patches
- Infusion pumps
- Pacing devices
- Organ support
- A large array of monitoring devices

Competitive Pressure and Seemingly Unlimited Opportunity

MedTech manufacturers are feeling the pressure to keep up and incorporate IoMT capabilities into their products or improve existing offerings.

With the incorporation of AI in the medical technology, considering innovations in model compression and increased access to 5G and connectivity overall, the list and complexity of applications is only likely to increase in terms of clinical application, real-life integration and, of course, business opportunity.

Market forces are also playing into this trend including shortage of clinical staff, globalization of healthcare and remote care integration into the clinical process.

Many device manufacturers have shifted or are shifting to a condition, disease or patient lifecycle service model away from a strictly product-oriented sale. This can be done in multiple ways including acquisitions and integration of telehealth services, development of apps and treatment plans or partnerships with service providers. This has further increased the appeal of IoMT-enabled devices, monetizing the relationship between the manufacturer and the patient.

Here are some examples of how these devices can be used:

1. Track patient data and safety information
2. Deliver remote care
3. Provide software patches
4. Offer patient/provider insights

Real-World Evidence

As previously discussed, the FDA seeks manufacturers to generate RWE of medical technologies.

Below are some examples of how connected devices can provide a method to do so:

Usage Scenarios:

1. Observe the frequency of clinicians or patients overriding a safety setting
2. Check the level of optimization applied during use (e.g. how often a device optimization command was executed based on real-time-monitoring)
3. Track the impact of optimization settings on clinical outcomes, such as how frequently optimized settings result in better patient results
4. Collect data from patient and/or provider surveys integrated into device apps to measure satisfaction, usability, or perceived effectiveness
5. Analyze whether certain user groups (e.g., experienced vs. novice clinicians) engage with optimization features differently
6. Use wearable or home-based devices to track real-world patient adherence and outcomes

Patient Results and General Safety and Efficacy Monitoring:

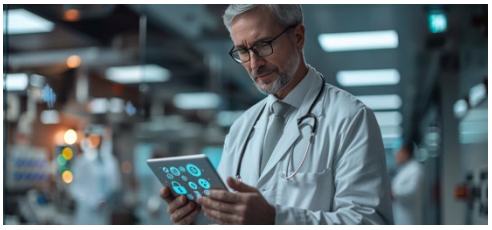
1. Track outcomes from surgeries involving comorbid patients to refine safety margins for high-risk groups
2. Gather patient health metrics during a surgery, comparing this data to previously assumed risk/safety and efficacy assumptions
3. Use continuous monitoring data to assess the long-term impact of surgical devices on recovery metrics
4. Use connected devices to monitor and report adverse events automatically, offering more complete and timely data
5. Monitor chronic condition devices (e.g., insulin pumps) over years to understand trends in adherence, efficacy, and safety
6. Track metrics like time-to-decision or user interaction errors during emergencies to assess usability under stress

Machine Performance and Reliability:

1. Review device performance characteristics, such as Mean Time Between Failure (MTBF)
2. Analyze failure rates in specific environmental conditions (e.g., temperature, humidity) to assess robustness across diverse clinical settings
3. Track real-time maintenance data to refine predictive maintenance algorithms
4. Analyze how devices perform across various clinical environments (e.g., rural vs. urban hospitals)
5. In devices using AI/ML, track how frequently algorithms are updated and the corresponding impact on safety and performance

Healthcare Facility Adoption Challenges

With this capability, manufacturers ideally work in concert with healthcare facilities and/or distributors to ensure supply of equipment is both uninterrupted and optimized and can monetize beyond the device. However, a chief challenge in the integration of IoMT within healthcare facilities is their reluctance to adopt new technologies, often due to concerns over security, liability, privacy and costs as well as resource constraints with internal service and IT personnel.



Cybersecurity: A Real Threat to Patients

Cybersecurity is a chief concern. Ransomware attacks are increasingly common and can severely impact patient safety, liability, costs and operating margins. Per the NIH, "This exponential increase in the IoMT and the increasing wireless connectivity of anesthesia and ICU devices as well as implantable devices presents a real and present danger to patient safety."

Not only is it essential to address cybersecurity concerns at a technological level, but it's crucial to address as a full TPLC app in concert with new guidance on cybersecurity that mandates that medical technology manufacturers embed cybersecurity throughout a device's lifecycle.

As discussed previously, TPLC integrates pre- and post-market activities into a holistic view that helps ensure device safety and effectiveness from design through commercialization. It's important to note that while the FDA strongly regulates medical technologies, it does not dictate hospital policies directly, ensuring that the adoption of such technologies within hospitals remains governed by the facilities themselves and not by the FDA.

Relevance to Digital Thread

Adopting IoMT requires a considerable technology backbone and improved digital thread.

Beyond the sensors, embedded software/models and compute modalities, companies must also consider connectivity, cybersecurity, cloud computing, edge computing, analytics/insight, data storage and management.

A key component of the digital thread starts with quality engineering, system engineering and robust software as a medical technology (SaMD) development. Having a capable ALM platform is *essential* and must be integrated into upstream and downstream applications such as DevOps and MLOps as well as systems engineering, PLM, labelling and MES.

The insights derived from IoMT data within the organization's PLM platform/s can be used to inform product design improvements, manufacturing optimizations and post-market surveillance activities. This creates a feedback loop that helps organizations continually improve their medical technologies based on real-world performance data. Therefore, it's critical that the IoMT platform integrates tightly with systems engineering, PLM platforms and Quality Management Systems (if separated from PLM).

Real-world data can inform both product and process design and development, including cybersecurity controls.

Analyzing the combined product and IoMT data can reveal trends and patterns in device performance, user behaviors and environmental factors that may impact the device's operation. These insights can help product development teams make data-driven decisions to optimize the device's operating parameters.

Further, predictive analytics can help identify potential device failures or malfunctions before they occur by analyzing patterns in the IoMT data. This allows manufacturers to build preventive measures into the device to alert of potential failure and can be a selling point to hospitals and healthcare facilities to reduce asset utilization issues.

Let's look at some examples of what we're talking about:

Device Performance & Technical Data:

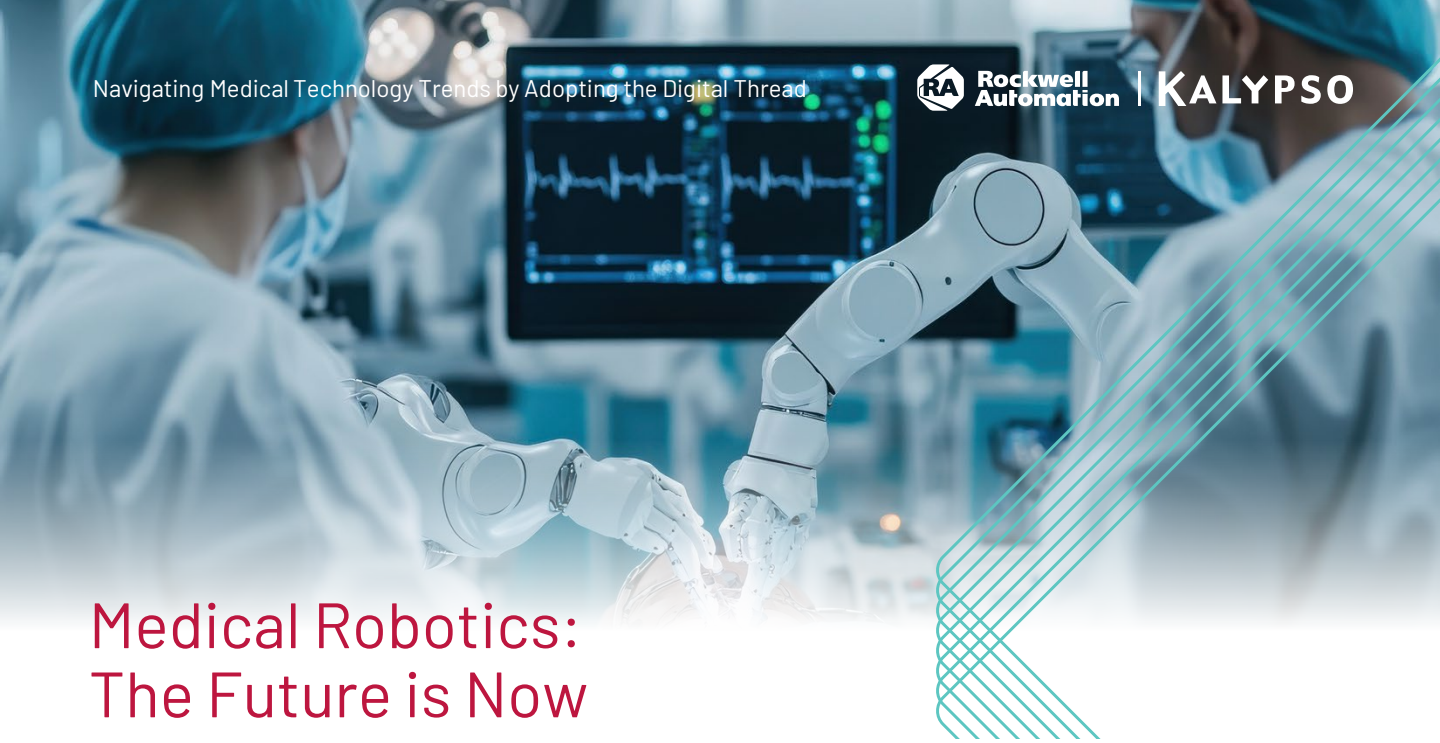
- **Sensor Readings:** Raw or processed data from sensors (e.g., heart rate, blood glucose, activity levels, temperature)
- **Calibration Data:** Information on sensor calibration Battery Life/Power Consumption
- **Connectivity Data:** Information on connection issues
- **Error Logs:** Detailed logs of device errors, including timestamps, error codes and diagnostic information.
- **Device Settings:** Configuration settings chosen by the user or healthcare provider
- **Processing Time:** How long it takes for the device to process a certain command

Environmental Data (if applicable):

- **Ambient Temperature:** Temperature of the environment where the device is used
- **Humidity:** Humidity levels in the environment
- **Altitude/Pressure:** Atmospheric pressure data
- **Light Levels:** Ambient light levels
- **Location Data (with appropriate privacy considerations):** GPS or other location data, if relevant and collected with user consent

User Interaction & Behavior Data:

- **Frequency of Use:** How often the device is used
- **Duration of Use:** How long each session of use lasts
- **Feature Usage:** Which features are used most/least
- **UI Navigation Patterns:** How users navigate menus
- **User Errors**: Frequency and type of errors encountered



Medical Robotics: The Future is Now

Although the concept of medical robots may still seem futuristic, their increasing viability is driven by numerous advancements in robotic engineering and related technologies. They are now popular in fields like orthopedics, gynecology and neurosurgery.

Medical robots can improve the precision, accuracy and efficacy of surgeries and reduce the invasiveness of and recovery time from these procedures. Better safety and efficacy measures are also resulting in accelerated procedure times and growing regulatory support, fostering increased trust in and reliance on these systems.

Growth of the Medical Robotics Market

The global medical robotics market will reach $30.41 Billion in 2027 from $9.69 Billion in 2021, growing at a CAGR of 21%.

This growth can be attributed to things such as:

1. Enhanced artificial intelligence
2. Component miniaturization
3. Improved compute power
4. 5G and other wireless communication capabilities
5. Cloud computing
6. Improved battery life

New innovations for these robots are being continuously developed, including

- Advanced data analytics from devices
- Increased integrated components
- Improved user interfaces, such as better displays and forced-feedback mechanisms that allow the surgeon to "feel" the robot's movements

Medical Robotics and Clinical Applications

Robots are also showing promise in improving clinical workflow efficiency and overall accuracy. Given the shortage of clinical workers, robots may increasingly fill a critical gap! We anticipate that the diversity and adoption of medical robotics, as well as the integration of medical and surgical robotics into existing product platforms, will continue to expand at an accelerating pace.

Types of Clinical Robots

- Surgical robots
- Orthopedic robots
- "Soft robots" that can adapt to a patient's uniquely shaped organs
- Exoskeletons to help with rehabilitation
- Telerobots to deliver medical care remotely (see more below)
- Clinical support droids to, for example, deliver linens and medicines around a hospital
- Sanitation robots to help clean hospitals
- AI-driven diagnostic robots
- Surgical preparation robots

Telerobots

Telerobots, such as InTouch Health or Intuitive's da Vinci system, are particularly interesting. Although the idea isn't exactly new, the first transatlantic operation was conducted in 2001 by surgeons in New York on a patient in France, these robots could increasingly allow surgeons to conduct or proctor other surgeons during robotic-assisted procedures. This could democratize access to care.

Relevance to Digital Thread

MedTech companies are learning how to incorporate surgical and medical robotics into their product portfolio, increasing the need for digital capabilities to manage more complex designs versus traditional products.

Companies may face a far more complex system to develop robotics vs. traditional products, which comes with orders-of-magnitude increase in requirements, risks, components and BOM complexity often involving many disciplines. Integration of these product types into traditional portfolios (like the implant itself) creates harmonization challenges around business processes and data. This is forcing clients to adopt more sophisticated digital thread tools.

Medical robot complexity increases the need for digital thread capabilities to manage:

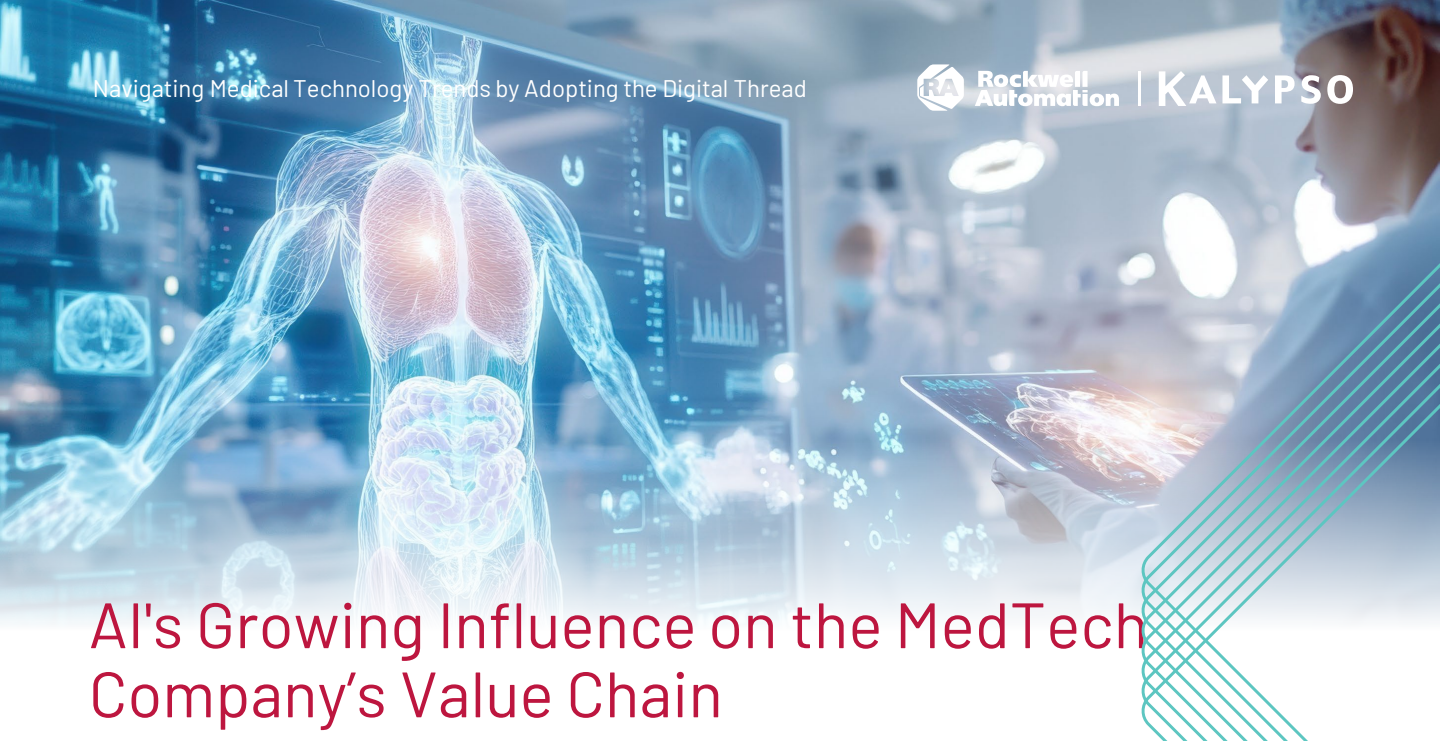
- Requirements
- Risk
- Components and Bill of Material configurations
- Device development
- Process harmonization with traditional product lines
- Regulatory approval
- Quality and quality issue tracking
- Manufacturing data
- Real-world data capture

Medical Robot Digital Twins

Digital twins of robotic operations within the clinical setting further allow companies to offer services to remote monitor, issue robotic missions and understand the operations of large fleets of robots at scale.

As robots are integrated into traditional product portfolios, they must effectively coexist with conventional device systems, such as orthopedic implants, alongside orthopedic robotic platforms. This necessitates the development of compatible configuration management, PLM and ALM tools, which can support various product release methodologies, with hardware, software engineering and AI model development.

By ensuring seamless configuration management and change management interoperability between cutting-edge robotic systems and traditional medical products, healthcare providers can effectively leverage the benefits of both technologies to improve patient outcomes as well as drive agility and integration within engineering, quality, regulatory and manufacturing teams.



AI's Growing Influence on the MedTech Company's Value Chain

Earlier we discussed the increased adoption of AI and ML within medical technologies. Now, we'll discuss the use of AI in the **execution of the product lifecycle through the value chain** and across various functions. There are many useful, pragmatic and interesting use cases that medical technology companies have implemented and continue to experiment with, ideally as part of a more holistic and strategic plan.

With the rise of interest around AI since the release of LLMs, there is pressure on MedTech executives to get ahead of industry peers regarding AI, not only within devices but in the conception, design, manufacturing, approval, distribution and post-market management of devices.

Those who can get ahead of the curve and carefully leverage AI/ML in this context will be most competitive in the coming years. It's essential to have an effective digital thread strategy that considers practical and realistic uses of AI to supercharge processes throughout the value chain.

Let's look at examples of how your organization can use AI across the product lifecycle including:

- Research and development
- Quality
- Regulatory
- Manufacturing engineering
- Manufacturing
- Supply chain
- Post market & field

R&D Oriented

Generative Design and Incomplete-Design-Finishing: Generate new designs for new products such as medical technologies, allowing for faster and more efficient design exploration.

Simulation: CAD simulation tools are used for simulating part design performance such as finite element analysis, computational fluid dynamics and electromagnetic simulation.

Labeling/Instructions for Use (IFU): Develop various IFU content for readability and accuracy with LLMs. An LLM can also produce clear, comprehensive instructions that are easy to understand for end-users. Streamline the process of document creation and ensure consistency across documents.

Translation Services: Translate content from one language to another. While we would not yet advocate for full human replacement, there is potential to reduce costs in this space.

Medical Technology Software Development: Use AI in the development of SAMD with AI. Many large tech companies such as Microsoft, IBM and Google are now providing integrated AI-based frameworks and toolkits for custom purposes for developers of healthcare applications.

Product Lifecycle Intelligence (Data Analytics of Product Data): Leverage analytics to describe and diagnose the state of the process as well as *predict* the future and *prescribe* actions. An example may be predicting the speed of engineering changes and the likelihood of rejection at any given stage.

Quality Oriented

Synthetic Test Data: Manufacture synthetic data for simulating the performance of medical technologies or components of devices, for testing and validation.

Personalization: Manufacture customized medical technologies for individual patients based on their medical imaging and other data with Generative AI. This has been used by companies like UNYQ.

Analytics: Describe the state of a process, diagnosing issues as well as predicting and prescribing outcomes.

Computer Vision (Inspections): Use cameras and algorithms to capture, process and analyze images of objects to gather information, make decisions, or perform inspections. While setting up and optimizing this process is not without challenges, it can greatly speed up the inspection process vs. using more traditional, slower and expensive tools.

Regulatory Oriented

Submission Package Review: Review and draft individual artifacts or subsections of submission packages and seek potential gaps and make recommendations to increase the likelihood of success for a particular regulation.

Product Registration Data Harvesting: Understand what can or cannot be shipped to a certain country and within what date-span to remain compliant. This includes translating data from certificates into structured data that can be managed by RIMS. This information may otherwise not be well tracked as the data cleansing, enrichment and migration obstacle is too high to get reliable information into RIMS.

Analytics: Apply analytics to the regulatory process, including predicting the likelihood a submission would be accepted and how long it may take.

Manufacturing Engineering Oriented

Co-Piloting of PLCs: Streamline PLC development. This can result in better code, which can improve production efficiency. Additionally, given the current skilled labor shortage, making PLC developers more efficient through these types of AI-empowered tools may be increasingly crucial.

Digital Twin:

- Simulation: Create virtual modeling of shop floor processes with Simulation tools, enabling the identification and rectification of bottlenecks. Test different scenarios without disrupting actual operations.
- Emulation: Involves creating a digital twin of the production environment, allowing for real-time analysis and optimization of workflows. We are seeing increasing demand for digital twinning of plants, especially as manufacturers with high-demand products seek to scale up operations.

Cost and Risk Analysis: Assess the cost and risks associated with different process designs by analyzing and predicting raw material and component costs, labor and potential reliability. Simulating these variables in a production design could improve overall production throughput.

Manufacturing Oriented

Material Flow Optimization: Optimize flow on the shop floor using a variety of tools including simulation and emulation which was discussed previously. Autonomous Mobile Robots (AMRs) can significantly boost flow and improve yield. AMRs are versatile, intelligent machines capable of navigating and performing tasks autonomously within the shop floor environment. They can transport materials and products efficiently, reducing the need for manual labor and minimizing human errors.

Shop Floor Analytics: Combine these various automated systems, AMRs and IoT devices to provide your organization with real-time data and analytics, further enhancing decision-making processes.

Model Predictive Control: Leverage trained AI models to predict the future behavior of manufacturing equipment and optimize control actions. It repeatedly solves an optimization problem at each control step to find the optimal control inputs and make time-based predictions. The model will try to close the gap continuously between desired and predicted outputs.

Worker Support: Support many personas throughout the supply chain and in the plant. There is a premium on understanding and training. For newer workers, LLMs are proving useful in simplifying complex work instructions and providing an interactive knowledge engine. For more advanced use cases or experienced workers, information can be provided in real time and contextualized, enabling skilled workers to make faster decisions.

Supply Chain Oriented

Supply Chain Stability: Have access to good quality internal data, integrated with external data sources. This is key to having a resilient supply chain. Internal data sources can include items such as inventory on-hand and demand forecasts. External data feeds may include predictions for supplier and shipment disruption, regulatory changes and supplier performance monitoring.

Post Market and Field Oriented

Predictive Maintenance: Predict failures for manufacturers and set up new service business models that can result in improved asset utilization by hospitals.

Real-World Data Contextualization: Contextualize RWD along with other inputs from R&D, such as the Design and Manufacturing Failure Effects Analysis (DMFEA), to understand failures and provide early warning signals if issues arise. The FDA requires medical technology companies to gather RWD and RWE, which is a beneficial practice overall.

Sentiment Analysis: Understand market sentiment to products by taking data feeds from external sources such as social media. This is especially useful for consumer medical technologies. There is a general expectation from regulatory authorities that if the information is publicly available, MedTech companies need to pay attention and consider the impact of evolved understanding.

Traditionally this has been quite challenging with conventional tools, certainly without considerable human intervention.

Real Results are Possible Now!

When applied to the real world we have seen many remarkable examples of excellent business results such as 18% improvement in production yield, 35% reduction in inventory and between 10-20% reductions in machine down time.

Validation and Humans in the Loop

Not all forms of AI can be hands-off, especially in a validated environment. When implementing AI throughout the value chain, a risk-based approach is warranted to determine the level of validation needed and consider how much a human must be in the decision-making process. In general, the FDA's stance remains progressive on the use of AI in the value chain, especially in more recent years where quality is prioritized over "compliance for compliance sake".

As previously mentioned, FDA's Good Machine Learning Principles are a good example of how the FDA is supportive. However, heavy use of validation across a variety of scenarios remains critical, whether a human is involved or not. Organizations need to ensure that decisions are made about the use of any technology by the right persons, with the right skill level and this is all verifiable.

Relevance to the Digital Thread

The digital thread seeks to automate and integrate the flow of data across the value chain and AI integrated automation can super-charge this flow.

All use cases cited above are dotted throughout the digital thread. These also leverage core enterprise systems such as:

- Systems engineering/application lifecycle management
- Product lifecycle management
- Enterprise resource planning
- Manufacturing execution systems
- Supply chain management systems
- Customer resource management systems
- Data warehouse and analytics

These can often feed upon each other. The more mature these base systems are, especially if the data models are harmonized or at least well translated, the more likely AI will be useful to the manufacturer. It's essential to have strong programs focused on core enterprise systems to be in the best position to take advantage of these exciting capabilities.

Supply Chain Resilience

Over the past several years, between the COVID-19 pandemic and other global supply chain disruptions, we have seen how badly the global supply chain was impacted, with issues lasting for multiple years past the initial disruption. This was a wake-up call for the industry.

While many supply chain issues cause inconvenience to our daily lives, medical equipment delays can completely disrupt surgeries and procedures, causing severe downstream ramifications that can endanger patients.

And while COVID disruptions may be over for some, how long will it be until another pandemic hits?

MedTech companies that invest in supply chain programs have reported revenue growth by an average of 23%.

Specific strategies that medical technology manufacturers can employ include:

- Acceleration of the stage at which parts are sourced during the new product introduction or product revisioning processes. This is especially helpful for parts with longer lead times or vulnerable to disruption
- Initiatives that support design-anywhere/manufacture-anywhere approaches. This includes shifting manufacturing back domestically
- Securely integrating suppliers into the design and development process
- Multi-vendor sourcing
- Building partnerships with single-source manufacturers
- In-depth supply chain analysis
- Blockchain adoption

The supply chain issues we saw during the COVID era reflected a true threat to public health and caused the FDA to weigh in on the global supply chain resiliency problem. Starting in 2022, the FDA introduced the Resilient Supply Chain Program, aiming to fortify public health supply chains and ensure medical technologies remain accessible in emergency situations. Its primary objective is proactively monitoring, assessing and communicating supply chain risks and vulnerabilities with a goal to alleviate disruptions and shortages in the medical technology supply chain while also improving supply chain visibility.

The FDA now maintains a Critical Medical Technology List (CMDL). This list is updated every three years and includes medical technology types where disruptions can lead to serious injury or death to patients or healthcare providers. Additionally, as future supply chain disruptions arise, the program intends to work closely with government partners and MedTech stakeholders to evaluate and resolve any issues as they appear.

The FDA continuously monitors the supply of critical medical technologies through data from manufacturers, healthcare facilities and external data sources. medical technology manufacturers are required to report anticipated shortages or supply disruptions, particularly for devices on the CMDL.

Relevance to Digital Thread

A robust digital thread based on high-quality and consolidated enterprise systems helps organizations manage the supply chain more effectively, improve revenues, reduce the risk of supply shortages and stay compliant with FDA requirements pertaining to CMDL.

This process starts in the design phase where considerable decisions are made about the types of parts to be sourced and continues through procurement and manufacturing, and into the field.

Enterprise PLM will manage an approved suppliers list which can be linked to parts and equipment in the process design. Planning teams receive that data in Enterprise Resource Planning (ERP) and can begin the procurement process. This is often ahead of the time of final product or product iteration and process definition approval allowing them to get ahead of long lead times. Supply chain management (SCM) could be considered a sub-function of ERP that focuses specifically on the supply chain.

It's critical these systems be connected and clear data ownership is established. In general, PLM deals with product and process definition under change control, while ERP and SCM deal with the specific transactions needed to procure and receive parts and equipment.

External data brokers can be integrated into enterprise systems and further enhanced by artificial intelligence. Similarly, manufacturers may provide portals to suppliers to feed real-time supply information that can be used in planning.

These tools can improve an organization's ability to make informed decisions about internal questions like production, inventory, pricing, marketing strategies, bottlenecks and areas for improvement *AND* external events like weather, regulatory changes or geo-political disruption.

We encourage clients to implement a supply chain-specific strategy that includes a reference architecture encompassing the above systems as a key deliverable. This architecture typically consolidates multiple legacy tools into enterprise platforms and optimizes the integration of systems, external data sources and analytics to enhance overall supply chain performance. We also recommend establishing data governance with clear goals around data ownership, mastership and interoperability.

Digital twins can be enabled as a result of an improved digital thread providing enhanced data quality of physical assets through simulation and emulation tools, like Emulate3D. When these twins are integrated with the Internet of Things (IoT) for facility equipment and smart connected workers, they can provide a dynamic, real-time model of manufacturing and distribution operations.

These digital replicas simulate a wide range of scenarios, which can help optimize operational processes and improve the overall supply chain function. By mirroring the physical environment, digital twins capture and analyze continuous data streams from machinery, environmental factors and worker interactions. This integration empowers facilities to detect inefficiencies, identify bottlenecks and improve resource allocation.

In summary, the digital thread enables proactive risk mitigation by providing real-time visibility across the supply chain, such as the ability to detect early disruptions, evaluate alternate suppliers and make agile adjustments to sourcing and production. Digital twins enable optimized manufacturing through planning and execution improvements.

Our series will continue as we discuss additional trends, so head over to Viewpoints to read on.

Transform the way you discover, create, make and sell medical devices with the digital thread

We help companies embrace the digital thread and leverage technologies to fundamentally improve the way they discover, create, make and sell medical technologies.

The medical device industry is experiencing extraordinary opportunities and challenges causing significant shifts in business strategies and operations alike. As the medical technology market continues to expand rapidly, companies must innovate and commercialize products efficiently while also navigating significant regulatory, economic and pricing pressures.

Businesses have been forced to reconsider their processes and broaden their digital capabilities to improve value chain flexibility and resilience.

Establishing a digital thread across the product value chain creates opportunities to accelerate product development timelines, reduce manufacturing latencies and improve integration with quality and regulatory information management systems. Ultimately, creating opportunities for companies to better serve more people around the world with increasingly effective and affordable medical technologies, diagnostic equipment, supplies and combination products.

About Kalypso

Kalypso, a Rockwell Automation business, helps companies bring digital solutions to product problems. Whether it's weaving a digital thread from product ideation all the way through manufacturing and service, or advancing operations from automation to autonomy, Kalypso specializes in improving what's being made and how it's made. Kalypso serves the largest names in the discrete, hybrid and process industries, around the world. Visit our website to learn more about Kalypso and our services.

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