Rethink Post-market Surveillance (PMS) for Medical Devices

How Smart, Connected Medical Devices Can Deliver Critical Insights

Six years after receiving FDA clearance, a medical device company's investment in a new therapeutic area is finally paying dividends. But a new patient injury report could send the company reeling if it can't identify the root cause of the device failure quickly.

The financial impact for product recalls and related corrections can be significant. The medical device industry spends $2.5-$5 billion annually to address non-routine quality events in the US – such as major observations, recalls, warning letters, consent decrees, warranties, and lawsuits – according to McKinsey & Company[1].

The consulting firm also reports the cost of a major medical device recall or other single non-routine quality event can reach $600 million.

The incident review and remediation process itself can take months or years to complete due to manual processes such as gathering old device data.

So, even if a device did not cause an adverse event, the company's sales and its reputation could still be negatively affected during this protracted process.

Eliminate Performance Blind Spots

The lack of visibility into device field performance has a significant impact beyond patient safety and risk management. Failure to truly understand how customers are using a device represents a missed opportunity to make user-driven enhancements and to identify untapped market needs.

To address this challenge, medical device companies are incorporating secure Industrial

Internet of Things (IIoT) capabilities to gain live product performance monitoring and to apply analytics to improve business operations.

Expand PMS to Gain Real-Time Insights

PMS is mandated for medical devices cleared/approved in the US and in the EU. The US Food and Drug Administration (FDA) defines PMS as the "process of active, systematic, scientifically valid collection, analysis, and interpretation of data" for a medical device.

Annex III of the Medical Device Report (MDR) takes guidance one step further by requiring a "proactive" and "vigilant" posture.

Despite the FDA's "active" mandate, PMS programs traditionally only capture snapshots of past product performance. This includes customer surveys, focus groups, anecdotes from sales teams, and field action documentation.

Drive Business Value through Monitoring

To gain timely insights into field use, medical device firms are incorporating sensors into their product designs to monitor safety, performance, and usage trends. Key performance indicators (KPIs) can include motor RPMs, device vibration, temperature, and battery power levels.

Using an IIoT platform such as PTC ThingWorx, KPI data is transmitted securely from field devices to either a cloud or an on-premise database in real time. Then device performance is analyzed, centralized, and aggregated. Executives can use ThingWorx to:

- Monitor an aggregated dashboard of all devices
- Display alerts for performance that is out of range
- Analyze and display device trends, averages, etc. (e.g., if procedure times are 30% longer than projected, it could cause a device to run at the high-end of its accepted temperature range)
- Detect malfunctions before they escalate into safety issues or reportable events
- Drill down to individual device performance (e.g., review the RPM motor history of a single device in a Los Angeles hospital)
- Gather data required for MDRs and related adverse event reporting quickly

Strengthen Risk Management

To comply with quality processes, new PMS findings should be integrated into a company's overall risk management system, including design failure mode and effect analysis (DFMEA) processes.

Field complaints and other information uncovered via PMS are important inputs for management review. Capturing all root-cause failure investigation findings, for example, will provide clear steps for corrective actions.

Device KPI Dashboard

Out of Range	RPM	Temp	Pressure
	2-5k	65°-75°	20 - 30psi
Site			
London	2,500	68	22
Tokyo	2,750	62	28
Australia	3,000	73	15
Rio	3,100	80	25
Los Angeles	5,200	67	23

Frame New Product Development Accurately

Despite the rigor applied to DFMEAs and risk management during new product development, this process is far from complete and does not address unintended team biases or other limitations including:

- **Assumptions:** Are you testing the right parameters or use cases?

The LexaGene LX6 Fully Automated Pathogen Detection Platform with IIoT KPIs Shown

- **Cybersecurity:** Safeguarding a connected device requires data protection to be central throughout the product development process – from early concepts; software and hardware selection; prototyping; validation of business processes for the data; through ongoing device management for performance and security.
- **Usability testing:** Is there too much weight placed on select medical advisors or key opinion leaders instead of broad user representation?
- **Sample size:** Is there access to field data across multiple geographies/environmental conditions? And is the sample size large enough to conduct meaningful analysis?

For new product line/platform development, IIoT performance monitoring can be piloted with prototypes for deeper insights.

No amount of lab testing can replicate real-world environments for globally distributed products. Device temperature may trend high in parts of Asia due to electrical current fluctuations, while regions in North America may face network connectivity interruptions.

Prototype performance monitoring will also provide the team with an opportunity to investigate significant usage variations among geographies. As an example, does one group require more training, do they use a different surgical process, or is there a usability challenge due to device size and weight?

Launch Enhancements Rapidly with User Feedback

Once commercialized, IIoT data can play a pivotal role in shaping the product development roadmap (multi-generational platform development).

Tracking usage and performance via IIoT provides companies with unfettered information. Product device teams can focus on concrete actions instead of debating opinions.

Regular feedback from the field will enable the product management team to re-prioritize enhancements and to accelerate subsequent releases.

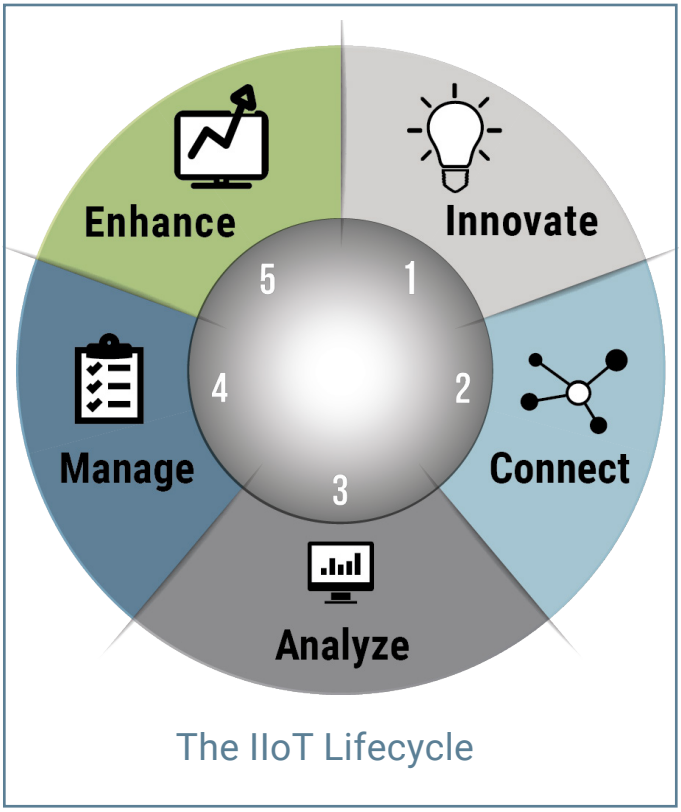
This information can provide product development teams with important information to guide new product development. Examples:

- How do customers typically use the device (e.g., settings most and least used, etc.)?
- Are component designs meeting requirements?
- Are components over designed?
- Have usage patterns changed since the product introduction?

Next Steps

The adoption of smart, connected medical devices offer new opportunities to improve patient care, to gain a deeper understanding of the user, to reduce service costs, and to deliver product enhancements based on real-world use.

Additionally, European directives (known as MDD) will require PMS to include ongoing device analysis by 2024. Multinational efforts to harmonize medical device regulatory efforts make it likely that additional countries will also adopt this mandate.



The IIoT Lifecycle

Key steps in the path to IIoT include:

1. **Define the business case:**
   - **What's the value to individual departments** (e.g., quality, compliance, and sales)?
   - **What's the overall business value?** This can range from X% reduction in service calls to the opportunity cost of not acting on initiatives
2. **Establish the business process:** Map how each department would use IIoT insights (e.g., identify who has access to data, how the information will be used – including feedback loops)
3. **Take a holistic approach to development:** Cybersecurity and business processes are just two key considerations for connected devices:
   - **Product engineering:** Align all development areas (mechanical, electrical, software, connectivity) to mitigate risks
   - **Data processes:** Ensure your integrated team includes business process and technical systems expertise from product lifecycle management (PLM) to IIoT connectivity, storage, and management
4. **Start small:** Launch IIoT in one operation such as service. Then, follow the roadmap to expand
5. **Evaluate and calibrate:** Follow ISO 13485:2016 best practices for continual improvement

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Endnote:
1) "The Business Case for Medical Device Quality," McKinsey & Company; Ted Fuhr, Katy George, and Janice Pai; 2013

About Boston Engineering

Boston Engineering provides product design and engineering consulting from concept through commercialization and connectivity. Boston Engineering is also the Northeast's largest PTC software reseller and is a ThingWorx IoT partner.

Certified for ISO 9001 and ISO 13485, the company's industry expertise includes commercial, defense, and medical. Founded in 1995, Boston Engineering is headquartered in Waltham, Mass.

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