APACMed
The voice of MedTech

# Post-Market Surveillance & Vigilance for Medical Devices

APACMed Position Paper



APACMed **Position Paper**

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# Executive Summary

In the rapidly evolving landscape of medical technology, effective post-market surveillance (PMS) and vigilance are essential for ensuring the ongoing safety and efficacy of medical devices. APACMed's position paper offers a thorough analysis of current PMS practices across key APAC markets and their alignment with global frameworks, along with actionable recommendations for National Regulatory Authorities (NRAs) to enhance their regulatory frameworks.

The MedTech industry is experiencing unprecedented growth and innovation, driven by advancements in technology and an increasing demand for improved patient outcomes. However, this dynamic environment also brings new challenges in monitoring and ensuring the safety of medical devices once they are on the market. Effective PMS is vital for identifying and addressing potential risks, ensuring that devices continue to meet safety and performance standards throughout their lifecycle.

Our analysis highlights several key best practices in PMS, emphasizing the importance of a risk-based approach. By adopting this strategy, regulatory authorities can focus their resources and efforts on areas with the highest potential for issues, rather than conducting systematic testing that may not be necessary. Trend reporting is a critical component of this approach, as it enables regulators to identify emerging issues and respond proactively. This ensures that testing - such as sterility testing  is carried out only when specific trends or issues are observed, optimizing resource allocation and enhancing the effectiveness of surveillance activities.

Harmonization and convergence among regulatory agencies play a pivotal role in shaping a cohesive and efficient regulatory landscape. Aligning PMS practices with global frameworks, such as the International Medical Device Regulators Forum (IMDRF) and the World Health Organization (WHO) guidelines, ensures consistency across jurisdictions. This alignment facilitates smoother market access for innovative MedTech solutions and promotes global collaboration in addressing safety concerns.

To build a robust PMS framework, it is essential for NRAs to collaborate closely with the industry in determining appropriate initial adverse event (AE) reporting timeframes and requirements. As NRAs become more established, these timeframes and requirements can be adjusted to better reflect the evolving regulatory landscape and resource capabilities.



Our recommendations are designed to help NRAs enhance their post-market surveillance systems and foster a safer and more effcient healthcare environment. Key recommendations to NRAs include:

- **Establishing Robust Post-Market Surveillance Systems**
- **Promoting Alignment with International Guidance**
- **Adopting a Risk-Based Approach for PMS and PMV**
- **Enhancing Data Sharing and Communication**
- **Strengthening Monitoring and Control Processes**
- **Developing Awareness Programs for Reporting Adverse Events**

The regulations for medical devices have frequently been borrowed from the pharmaceutical industry without considering the specific needs and characteristics of medical devices. By implementing these recommendations, NRAs can create a more efficient, transparent, and risk-focused post-market surveillance framework for medical devices. This approach not only ensures timely detection and response to potential issues but also supports a conducive environment for innovation and patient-centric care. APACMed's position paper aims to provide insights and practical guidance to help regulators and industry stakeholders navigate the complexities of post-market surveillance and drive improvements in healthcare safety and effectiveness.

# Introduction

The landscape of medical technology is rapidly evolving, driven by innovations that promise to transform healthcare delivery and address complex medical challenges while improving patient outcomes.

However, this journey is not without its challenges. As regulatory frameworks evolve and global markets interconnect, the MedTech industry faces a complex array of hurdles that demand collective attention and proactive solutions.

One key challenge is the non-harmonized post-market surveillance and vigilance practices for MedTech products[1]. Medical device vigilance is crucial for monitoring and responding to safety concerns throughout a device's lifecycle. Timely identification and reporting of adverse events, incidents, and potential hazards are pivotal in enabling regulatory authorities, manufacturers, healthcare professionals, and patients to take appropriate actions to mitigate risks and prevent harm.

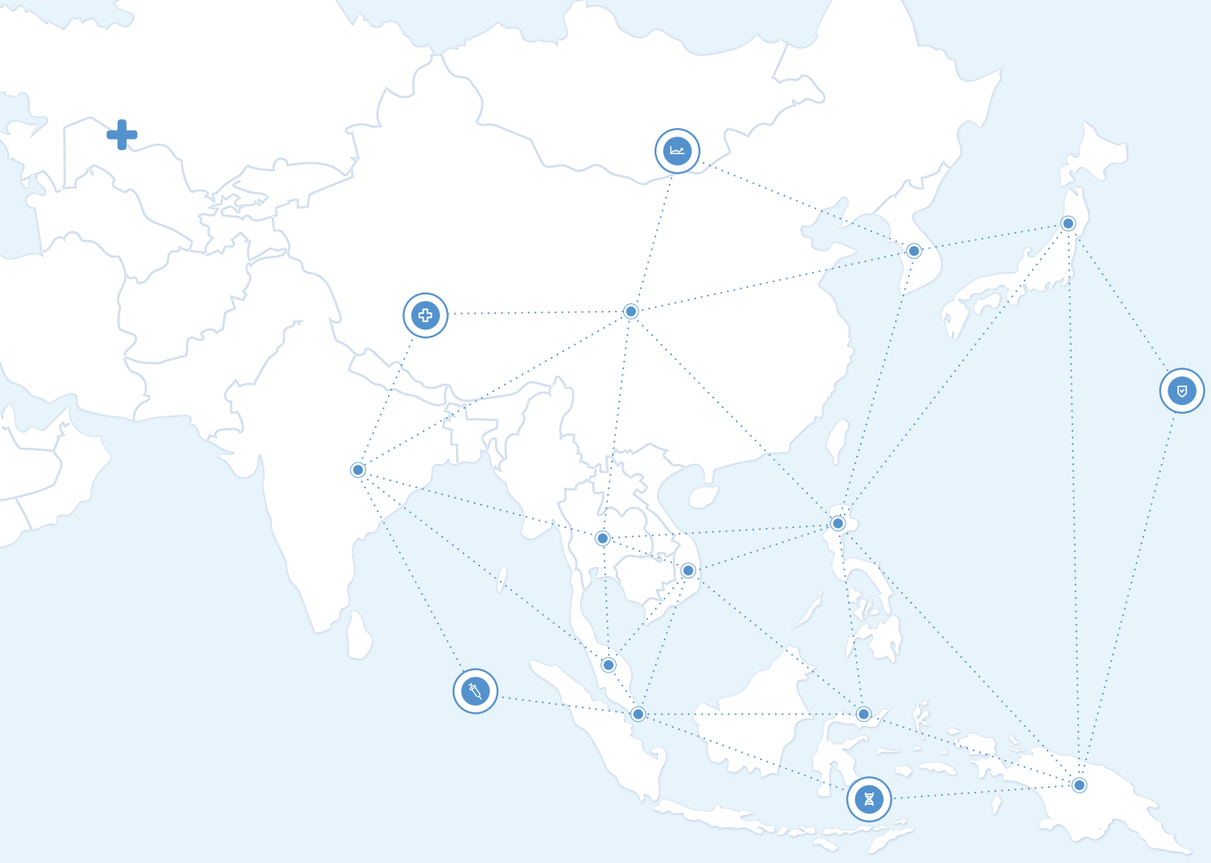


A comprehensive approach to medical device vigilance encompasses multiple facets, including vigilance reporting systems, post-market surveillance, risk assessment, signal detection, and effective communication among all stakeholders. It goes beyond mere compliance with regulatory requirements, striving for excellence in patient safety and continual improvement throughout the device's lifespan. This approach underscores a shared responsibility between the public and private sectors, emphasizing the need for transparency, accountability, and patient-centricity in the MedTech ecosystem.

However, it is important to acknowledge that the regulations governing medical devices have often been adapted from the pharmaceutical industry without considering the unique characteristics and requirements of medical devices. Practices such as post-marketing testing and sampling, which may be effective in the pharmaceutical industry, often fall short in the context of medical devices. Unlike pharmaceuticals, where batch testing can confirm the safety of a product line, post-market testing of medical devices generally only indicates that a single device is safe, without guaranteeing the safety of others in the market. Therefore, promoting robust Quality Management Systems (QMS) for medical devices is a more effective approach. These systems ensure consistent quality across all products and enhance the overall safety and performance of medical devices throughout their lifecycle.

Additionally, the limited capacity within the industry and regulatory bodies to conduct comprehensive post-market testing-especially without standardized testing protocols per device category and considering the 18-24 months average product lifecycle for devices-poses a significant challenge. The financial implications of post-market testing cannot be overlooked. The substantial costs associated with sample size requirements, control groups, shipping logistics, and laboratory testing contribute to the financial strain on industry stakeholders without evidence of improvement in patient or user safety.

This industry position paper aims to outline existing regulatory frameworks for post-marketing surveillance and vigilance, identify key policy considerations, and share our recommendations for effective post-market surveillance and vigilance for medical devices. By addressing these challenges head-on, we can not only improve the safety and effectiveness of medical devices but also strengthen public trust in these life-saving technologies.



# Regulatory Frameworks for Post-Marketing Surveillance and Vigilance in Key APAC Markets

The landscape of post-market surveillance (PMS) and vigilance for medical devices across the APAC region is marked by significant diversity and fragmentation. Through extensive desk research and collaboration with our member companies, APACMed has gathered and analyzed data from 11 key APAC markets: Australia, China, India, Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Thailand, and Vietnam.

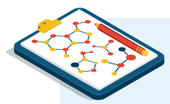
This chapter provides a detailed overview of the current regulatory frameworks, highlighting key differences and offering insights into areas for improvement. In the context of PMS, vigilance systems and Field Safety Corrective Actions (FSCA) are crucial for ensuring the ongoing safety and performance of medical devices. Vigilance systems capture, analyze, and respond to adverse events and incidents that may occur after a device has been placed on the market, while FSCA and recall processes are essential for promptly addressing identified risks through device modifications, communication to users, or product recalls. By examining these two critical components across the APAC region, we aim to assess the robustness of existing regulatory frameworks and identify opportunities for enhancing patient safety and device efficacy.

It is important to note that the data and information presented in this position paper reflect the regulatory frameworks and requirements as of the publication date. Regulatory environments are dynamic and subject to change; therefore, stakeholders are encouraged to consult local regulatory authorities for the most current information.



# Vigilance Systems

The following table presents a comparative analysis of key components of post-market surveillance and vigilance practices across different National Regulatory Authorities (NRAs) in the Asia-Pacific region. It highlights the regulatory requirements for adverse event reporting, the role of different stakeholders in vigilance activities, and the adoption of international guidelines and standards.



| | REPORTING OF SERIOUS AE BY MAH TO NRA | REPORTING OF EVENTS BY HCP | SUBMISSION OF INVESTIGATION REPORTS TO NRA | ADOPTION OF IMDRF EVENT CODES BY THE MARKET'S NRA | ADOPTION OF IMDRF/GHTF GUIDELINES |
|---|---|---|---|---|---|
| AUSTRALIA | ● | ● | ● | ● | ● |
| CHINA | ● | ● | ● | ○ | ○ |
| INDIA | ● | ● | ● | ○ | ○ |
| INDONESIA | ● | ● | ● | ○ | ○ |
| JAPAN | ● | ● | ● | ● | ○ |
| MALAYSIA | ● | ● | ● | ● | ○ |
| PHILIPPINES | ● | ● | ○ | ○ | ○ |
| SINGAPORE | ○ | ● | ● | ○ | ○ |
| SOUTH KOREA | ● | ● | ● | ● | ○ |
| THAILAND | ● | ○ | ○ | ● | OWN PMV SYSTEM |
| VIETNAM | ○ | ○ | ○ | ○ | ○ |

**MAH:** MARKET AUTHORIZATION HOLDER | **HCP:** HEALTHCARE PROFESSIONAL
**IMDRF:** INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM | **GHTF:** GLOBAL HARMONIZATION TASK FORCE

The table offers insights into the level of regulatory harmonization and the effectiveness of PMS systems in ensuring the safety and performance of medical devices. This analysis aims to identify areas where improvements can be made to enhance patient safety and support a more consistent approach to vigilance practices across the region.

# Field Safety Corrective Action ( FSCA ) and Recalls

The following table provides an overview of regulatory practices related to Field Safety Corrective Actions (FSCA) and recalls in the Asia-Pacific region. It focuses on three key aspects: defined requirements for FSCA and recalls by the NRAs, the existence of market-level centralized systems for reporting FSCA and recalls, and the public availability of information related to these actions.

| COUNTRY | DEFINED REQUIREMENTS FOR FSCA AND RECALLS | MARKET-LEVEL CENTRAL SYSTEM FOR FSCA/RECALL REPORTING | PUBLIC AVAILABILITY OF FSCA/ RECALL INFORMATION |
|---|---|---|---|
| AUSTRALIA | ● | ● | ● |
| CHINA | ● | ● | ● |
| INDIA | ● | ● | LIMITED INFO ONLY |
| INDONESIA | ● | ● | ● |
| JAPAN | ● | ● | ● |
| MALAYSIA | ● | ● | ● |
| PHILIPPINES | ○ | ○ | ○ |
| SINGAPORE | ● | ● | ● |
| SOUTH KOREA | ● | ● | ● |
| THAILAND | ● | ● | LIMITED INFO ONLY |
| VIETNAM | ● | ○ | ○ |

The table offers insights into the robustness and transparency of recall processes across different regulatory environments. This analysis aims to identify opportunities for improving the management of FSCA and recalls, ensuring that risks associated with medical devices are addressed promptly and communicated e ectively to protect patient safety.



# Industry Challenges

The analysis of PMS requirements and practices across APAC markets highlights both best practices and significant challenges. A robust mechanism for collecting feedback on device performance is fundamental to an effective PMS system. However, several challenges impede the efficiency and efficacy of these systems.

Inconsistent Regulatory Requirements and Burdensome Local Post-Market Testing: one of the most pressing challenges for manufacturers in the APAC region is the lack of harmonization in PMS, FSCA, and recall requirements across markets. Companies operating in multiple countries must navigate a fragmented regulatory landscape, which increases complexity and cost. This inconsistency complicates the scaling of standardized safety practices and delays timely, coordinated responses to potential risks. Furthermore, the diverse nature of medical devices and their heterogeneous production processes make standardized, localized post-market testing unsuitable for effective surveillance. While manufacturers often conduct trend analyses, manpower shortages within regulatory bodies hinder cross-industry analysis for similar product categories. This limits the ability of National Regulatory Authorities to initiate for-cause testing, a critical component of patient safety, especially when unexpected adverse reactions arise.

Limited Regulatory Oversight: some NRAs have limited control over hospitals and healthcare professionals, resulting in inconsistent mandatory reporting of adverse events. Without proper oversight, many incidents go unreported or are reported late, compromising the ability of manufacturers to investigate and address potential risks. Additionally, manufacturers frequently face challenges in obtaining defective products for causality assessments, making it di cult to determine if incidents stem from product defects or user error.

Fragmented Reporting Infrastructure: the absence of centralized, user-friendly incident reporting systems is a major impediment. Existing reporting portals are often complex and time-consuming, discouraging healthcare professionals from submitting timely reports. In turn, manufacturers are left without the detailed information needed to investigate events, assess causality, and implement corrective actions where necessary.

To address these challenges, it is essential to enhance regulatory frameworks by implementing effcient, user-friendly reporting systems and ensuring adequate regulatory oversight and resources for comprehensive trend analysis and causality assessments. By fostering collaboration among stakeholders, including regulators, manufacturers, and healthcare providers, APAC markets can move towards a more convergent and effective post-market surveillance system that not only protects patient safety but also encourages innovation and public trust in medical technologies.

# Regulatory Frameworks for Post-Marketing Surveillance and Vigilance in Other Markets

This section provides an overview of PMS and vigilance frameworks from key global markets that represent a mix of regulatory maturity and varying approaches to PMS requirements, o ering insights for comparison with APAC practices.

To facilitate understanding, the table below summarizes top-level PMS elements such as import and distribution records, complaint handling, adverse event reporting, FSCA reporting, and recall/disposal processes. This table serves as a foundation for the detailed analysis that follows, highlighting key similarities and di erences in PMS frameworks across these global markets.

| | IMPORT/ DISTRIBUTION RECORDS | COMPLAINT HANDLING | ADVERSE EVENT REPORTING | FSCA REPORTING | RECALL & DISPOSAL |
|---|---|---|---|---|---|
| AMDD | ● | ● | REPORTING CRITERIA, TIMELINE & TEMPLATE | ● | ● |
| WHO | NOT MENTIONED | ● | REPORTING CRITERIA, TIMELINE & TEMPLATE | REPORTING CRITERIA, TIMELINE & TEMPLATE | ● |
| JAPAN | ● | ● | REPORTING CRITERIA, TIMELINE & TEMPLATE | DOMESTIC & OVERSEA | RECALL IS CLASSIFIED IN LEVEL 1,2,3. BASED ON THE RISK OF HARM TO HEALTH |
| SINGAPORE | ● | ● | REPORTING CRITERIA, TIMELINE & TEMPLATE | DOMESTIC | UNCLASSIFIED RECALL |
| AUSTRALIA | ● | ● | REPORTING CRITERIA, TIMELINE & TEMPLATE | DOMESTIC | RECALL IS CLASSIFIED IN LEVEL 1,2,3. BASED ON THE RISK OF HARM TO HEALTH |



# US' Food & Drug Administration ( FDA )

The US FDA's PMS for medical devices[2] is a cornerstone of ensuring the ongoing safety and effectiveness of medical devices once they are on the market. The Safe Medical Devices Act (SMDA) of 1990 and the Medical Device Amendments of 1992 mandated a unified reporting standard for user facilities, manufacturers, and importers, significantly impacting adverse event reporting. 21 CFR, Chapter I, Sub Chapter H, part 803[3] specifies manufacturers, importers, and device user facilities are required to report certain adverse events and device malfunctions to the FDA. The Medical Device Reporting (MDR) system encourages healthcare professionals and consumers to report adverse events and device-related problems, facilitating a comprehensive monitoring process.

Post-approval studies (PAS) are integral to gathering additional information about a device's safety and effectiveness. These studies are often a condition of approval for certain devices, ensuring that data is collected and submitted to the FDA in a timely manner. Similarly, under Section 522 of the Federal Food, Drug, and Cosmetic Act, the FDA can order PMS studies for specific high-risk (class II or class III)* devices to address safety or effectiveness concerns. Compliance with these orders is crucial for manufacturers.

Real-World Evidence (RWE) is increasingly utilized, leveraging data from electronic health records (EHRs), insurance claims databases, and patient registries to monitor device performance in real-world settings.

In instances where devices are found defective or pose health risks, timely recalls are essential. Proper classification and communication of recalls to healthcare providers and the public ensure swift and effective risk mitigation. Compliance with the Quality System Regulation (QSR) under 21 CFR Part 806[1] is mandatory for manufacturers, requiring regular audits and inspections to maintain device quality and address issues promptly.

Collaborative efforts and stakeholder engagement, including partnerships with healthcare providers, manufacturers, and patient groups, are vital for enhancing PMS. Education and training for stakeholders on reporting and addressing device issues further support this goal. The Manufacturer and User Facility Device Experience (MAUDE) database, a searchable online repository of reported events, promotes transparency by providing additional information such as device and patient problems and demographic data.

International collaboration and adherence to global standards, such as those proposed by the IMDRF's National Competent Authority Report (NCAR) Working Group in their document "Medical Devices: Post Market Surveillance National Competent Authority Report Exchange Criteria and Report Form[4]," ensure harmonized PMS practices and the sharing of safety information worldwide. By following these best practices, the FDA aims to uphold the safety and effectiveness of medical devices, promptly addressing emerging risks.

* Section 522 of the FD&C Act gives the FDA the authority to require a manufacturer to conduct post market surveillance of a class II or class III device that meets any of these criteria:

Its failure would be reasonably likely to have serious adverse health consequences.

It is expected to have significant use in paediatric populations.

It is intended to be implanted in the body for more than one year.

It is intended to be a life-sustaining or life-supporting device used outside a device user facility.

# Health Canada

Health Canada

Health Canada plays a pivotal role in collecting and evaluating reports of suspected medical device adverse reactions post-approval. This post-market information is gathered from various sources, and risk assessments are conducted to recommend appropriate measures, including informing the public and healthcare professionals, suggesting labeling changes, or removing products from the market.

Risk management and intervention are central to Health Canada's PMS activities. Risk Management Plans (RMPs) are used to identify, prevent, or minimize known or potential risks to patients, with effective communication of risk information being a key component.

Two recent additions to the Regulations ensure ongoing monitoring of risks after a product is authorized for sale in Canada:

- Preparation of summary reports (MDR sections 61.4 to 61.6)
- Completion of issue-related analyses of safety and effectiveness when requested by the Minister (MDR sections 25(1) and 39)

For summary reports, medical device license holders must conduct a concise, critical analysis every year or every two years about the use of their licensed device(s). This information comes from reports of:

- Adverse effects problems reported to the manufacturer, importer or distributor of the device relating to performance characteristics or safety, including any customer complaints
- Incidents that have come to the attention of the manufacturer or the importer of the device
- Serious risks of injury to human health that were identified outside of Canada

Medical device license holders must then prepare a report that summarizes the relevant information received during the reporting period.

Health Canada has established guidelines for determining reportability, setting criteria for reportable events and timeframes for reporting, including user errors. Hospitals in Canada are mandated to report medical device incidents (MDIs) within 30 days of documentation. These reports are critical for promoting the safe use of health products and may signal previously unrecognized serious MDIs.

Health Canada’s PMS system is designed to collect feedback on device performance, collaborate with manufacturers to identify root causes of incidents, and ‘if required,’ take necessary field safety actions. This system ensures a comprehensive approach to post-market surveillance and vigilance, safeguarding public health and patient safety.



# The Health Sciences Authority of Singapore ( HSA )

HSA Health Sciences Authority

The HSA of Singapore employs several post-market surveillance and risk assessment measures to ensure medical device safety. Medical device companies, including manufacturers, importers, suppliers, and registrants, are required to report adverse events (AEs) related to their products for events occurring in Singapore[5]. These reports include serious threats to public health, death, serious deterioration in health, and AEs that could lead to death or serious injury if they recur. Specific timelines for reporting vary from 48 hours for serious threats to public health 30 days for potential AEs.

Field Safety Corrective Actions (FSCAs) such as recalls or product modifications must be reported to the HSA at least 24 hours before initiating the action, with preliminary and follow-up/final reports submitted within 24 hours and 21 days, respectively if applicable. The HSA’s centralized Online Safety, Compliance Application and Registration (OSCAR) system facilitates the reporting and monitoring of FSCAs, ensuring detailed information is provided.

Healthcare professionals, patients, and consumers are also encouraged to report AEs to the HSA as soon as they become aware of them. Feedback from all users contributes to a comprehensive PMS system. International collaboration with other ASEAN member states enhances post-market surveillance and vigilance.

The HSA provides various guidance documents to help companies comply with regulatory requirements for PMS and vigilance. These include guidelines on adverse event reporting, complaint handling, and FSCA reporting, which are accessible to the public through the HSA’s website.


# The European Union

The EU Medical Device Regulation (EU MDR) and In Vitro Diagnostic Medical Devices Regulation (EU IVDR), effective from May 2021, enforce stringent PMS requirements tailored to the risk profile of medical devices[6]. Higher-risk devices must undergo post-market clinical follow-up (PMCF) studies to collect additional data on their long-term safety and performance. Manufacturers and other economic operators, such as authorized representatives, importers, and distributors, are responsible for maintaining records of complaints and adverse events, reporting incidents to authorities, and supporting PMS activities to ensure traceability across the supply chain[7].

The EU framework emphasizes the use of Real-World Evidence (RWE) from electronic health records and patient registries to monitor device performance. Effective recall procedures and safety communications are critical for managing identified risks.

A key challenge with the EU MDR and IVDR is the departure from IMDRF guidelines in reporting timelines, which can lead to a high volume of reports, including some that may be unnecessary. This divergence results in a significant resource burden for both manufacturers and NRAs. The European Databank on Medical Devices (EUDAMED), still under development, aims to improve transparency by providing access to reported events and data.

Collaboration with healthcare providers, manufacturers, and patient groups, along with robust education and training on reporting, is essential to the EU's PMS strategy. Adhering to international standards and engaging with global regulatory bodies are critical for harmonizing PMS practices and sharing safety information. The EU MDR and IVDR framework seeks to balance rigorous monitoring with the need to manage the resources required for effective post-market oversight.



# International Medical Device Regulators Forum ( IMDRF )

The IMDRF framework for adverse event reporting, as outlined in the GHTF/SG2/N54R8:2006 document[8], emphasizes a risk-based approach. Events involving medical devices that lead to death, serious injury, or have the potential to cause serious injury if they recur must be reported within 10 to 30 days, depending on the severity. This framework establishes standardized terminology for adverse event reporting, improving consistency and communication among national regulatory authorities and manufacturers.

Manufacturers are required to have documented procedures for handling complaints and adverse events. The framework also specifies scenarios where events do not need to be reported, such as those caused by patient conditions, events occurring after the device's service life, and events with negligible likelihood of causing serious injury. A focus on high-risk events allows for prioritizing resources and regulatory attention on significant safety concerns.

The IMDRF framework supports summary reporting of near misses and certain reportable malfunctions, enabling better focus on high-risk cases and identifying trends that may not be evident from individual reports. This approach helps improve the efficiency and effectiveness of post-market surveillance activities.

# World Health Organization (WHO)

The WHO advocates that if National Regulatory Authorities (NRAs) receive feedback from users they should forward it to manufacturers.[9] NRAs may conduct risk assessments to ensure that feedback concerns registered or authorized medical devices. A market surveillance plan, prioritizing devices using a risk-based approach, should be developed with appropriate human and financial resources.

NRAs should review investigation reports from manufacturers, which include descriptions of actions taken in response to reported incidents, root cause analyses, and impact assessments on similar products[9]. The NRA may decide to take regulatory action until they have objective evidence that products placed on their market do not present any safety issues. Overseeing FSCAs undertaken by manufacturers is part of this responsibility, ensuring public safety.

Implementation of market surveillance measures depends on the maturity and capacity of NRAs. Testing activities, guided by a risk-based approach, may be phased in as procedures for reviewing investigation reports are established. The ultimate goal is to protect citizens by ensuring that medical devices on the market are safe and effective.

NRAs should maintain a continuous dialogue with manufacturers to ensure timely responses to feedback and compliance with regulatory requirements. They may need to undertake their own regulatory actions if manufacturers fail to act adequately or promptly. Sharing information with other NRAs enhances global PMS efforts and contributes to a comprehensive approach to medical device safety[9].



# Industry Recommendations

Regulatory convergence and collaboration among regulatory agencies are essential in shaping a regulatory landscape that fosters innovation while ensuring patient safety. Prioritizing proactive surveillance, data-driven decisionmaking, and harmonized standards aligned with global frameworks such as the International Medical Device Regulators Forum (IMDRF) will create an environment conducive to sustainable growth and market access for MedTech innovations. Effective collaboration and dialogue among stakeholders, including industry players, healthcare providers, National Regulatory Authorities (NRAs), and patient advocacy groups, are crucial for addressing challenges collectively.

Through shared insights, best practices, and collaborative initiatives, the MedTech industry can navigate the complexities of post-market surveillance and vigilance, driving towards a safer and more effcient healthcare future.

## Establish Robust Post-Market Surveillance Systems

Ensure that post-market surveillance and vigilance systems are robust and in line with quality management system standards both regionally and globally. These systems should be integrated into the regulatory framework to ensure the ongoing safety, quality, and effectiveness of medical devices.

## Promote Alignment with International Guidance

Promote alignment with guidance from the World Health Organization (WHO) and the International Medical Device Regulators Forum (IMDRF), with a particular focus on adverse event reporting. This includes aligning the content and timelines of adverse event reports with IMDRF's Global Guidance for Adverse Event Reporting for Medical Devices and adopting IMDRF's adverse event codes across the region. Such alignment will enhance the effectiveness of global post-market surveillance systems, especially in facilitating the exchange of information on specific incidents, devices, or trends among regulatory authorities.

## Adopt a Risk-Based Approach for PMS and PMV

Adopting a risk-based approach instead of post-market testing, guided by IMDRF and the WHO GMR's recommendations. Trend analysis of reported adverse events by NRA should drive decisions, leading to sterility testing or other specific tests when relevant. This approach ensures that testing is targeted and not conducted on a systematic basis, thus focusing resources where they are most needed.

## Enhance Data Sharing and Communication

Facilitate cross-NRAs data sharing, such as the IMDRF's National Competent Authority Report (NCAR) or GHWP's Safety Alert Dissemination System (SADS),or the Medical Device Post Market Information Exchange for ASEAN Member States, to streamline notification processes and improvecommunication between manufacturers and NRAs. This collaborative approach will enhance transparency and efficiency in post-market surveillance activities, enabling quicker responses to potential issues.

## Strengthen Monitoring and Control Processes

NRAs should maximize the monitoring and control of existing policies without necessarily adding new regulations. This includes closely following up on high-concern cases reported by the industry, including the investigation report, and strengthening monitoring and control processes. Effective follow-up on reported cases is essential to ensure that regulatory responses are timely and appropriate.

## Develop Awareness Programs for Reporting Adverse Events

Create awareness programs for healthcare professionals (HCPs) and end users to encourage the reporting of adverse events. Such programs will help increase the reporting rate and improve the overall effectiveness of the post-market surveillance system by ensuring that all relevant data is captured and acted upon.



# In Conclusion

As regulatory agencies continue to develop and refine their PMS systems, it is crucial to consider available resource capabilities and capacities. For NRAs still in the process of establishing their medical device regulatory frameworks, aligning priorities, objectives, and timelines with available resources will ensure more effective and sustainable PMS systems. Collaboration with industry stakeholders can provide valuable insights and support, facilitating a phased development approach that integrates international best practices. By leveraging industry resources and expertise, NRAs can enhance their PMS capabilities over time, fostering a regulatory environment that balances innovation with patient safety. This collaborative and resource-conscious approach will contribute to a more robust and efficient global healthcare system.

# Glossary

**Adverse Events (AE):** malfunction or deterioration in the safety, quality or performance of a device made available on the market, any inadequacy in the information supplied by the manufacturer and undesirable side-effects. Note: Depending on jurisdictions, the term adverse event (in its post-market meaning) and incident can typically be used interchangeably.[10]

**Field Safety Corrective Action (FSCA):** a FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device. Such actions should be notified via a field safety notice. In assessing the need of the FSCA the manufacturer may use the methodology described in the international standard ISO 14971.
FSCAs may include:

- Return of a medical device to the manufacturer or its representative
- Device modification
- Device exchange
- Device destruction
- Advice given by manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use e.g. implants).[11]

**Market surveillance:** the activities carried out and measures taken by competent authorities (regulatory authorities) to check and ensure that devices comply with the requirements set out in the relevant legislation and do not endanger health, safety or any other aspect of public interest protection.[12]

**Periodic Safety Update Reports (PSURs):** PSURs are pharmacovigilance documents intended to provide an evaluation of the risk-benefit balance of a medicinal product at defined time points after its authorization. The objective of the PSUR is to present a comprehensive and critical analysis of the risk-benefit balance of the product, taking into account new or emerging safety information in the context of cumulative information on risk and benefits.[13]

**Post-Market Clinical Follow-up (PMCF) study:** study carried out following marketing approval intended to answer specific questions relating to clinical safety or performance (i.e. residual risks) of a medical device when used in accordance with its approved labelling.[14]

**Post-market surveillance:** systematic process to collect and analyze experience gained from medical devices that have been placed on the market.[9]

**Post-market Vigilance:** reporting of serious incidents and field safety corrective actions.[15]

**Real-world data (RWD):** real-world data are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status.[16]

**Real-World Evidence (RWE):** real-world evidence is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.[16]

**Serious Adverse Events (SAE):** a SAE is any undesirable experience associated with the use of a medical product in a patient. An event is considered serious and should be reported to the NRA when the patient outcome involves death, is life-threatening, or results in hospitalization (either initial or prolonged). It should be reported if admission to the hospital or the extension of hospitalization was due to the adverse event. Other reportable outcomes include disability or permanent damage, congenital anomaly/birth defect, or when intervention was required to prevent permanent impairment or damage. For devices, report if you believe that medical or surgical intervention was necessary to prevent permanent impairment of a body function or avoid permanent damage to a body structure. Additionally, other serious (important medical) events, suspected to be due to the use of a medical product, should also be reported.[17]

**Trend Analysis:** the investigation involved trend analysis of adverse event of the actual device involved in the adverse event and/or of products from the same and/or different batches/lots. It should be noted that trend analysis typically is not considered sufficient as a stand- alone method but should be used in conjunction with other investigation methods for providing for instance complementary information.[18]

**Trend Reporting:** any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.[19]

**Unique Device Identifier (UDI):** a series of numeric or alphanumeric characters created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI (device identifier) and UDI-PI (production identifier).[20]



# Resources


1 *https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices#:~:text=Under%2021%20CFR%20806%2C%20Medical%20Devices%3B%20Reports%20of%20Corrections%20and,a%20violation%20of%20the%20act*
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## Additional Resources


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The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. For more information, visit **www.apacmed.org**