

Post-Market Surveillance and Vigilance

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Post-Market Surveillance (PMS) and Vigilance are critical components of the medical device lifecycle management process. They involve monitoring and evaluating the performance of medical devices once they have been placed on the market to ensure their safety and effectiveness.

Post-Market Surveillance (PMS)

Post-Market Surveillance (PMS) refers to the systematic process of monitoring and evaluating the performance and safety of medical devices once they are on the market. The primary goal of PMS is to identify and address any issues that may arise with the devices in real-world use. This includes collecting and analyzing data on device performance, adverse events, complaints, and other relevant information to ensure ongoing safety and effectiveness.

Related Terms: Adverse Event, Complaint Handling, Risk Management, Signal Detection

Example: A medical device manufacturer implements a robust post-market surveillance program to monitor the performance of their devices in clinical settings. Through regular data collection and analysis, they identify a potential safety issue with one of their products and take immediate action to address it, including issuing a recall if necessary.

Challenges: One of the main challenges of post-market surveillance is the need to collect and analyze large amounts of data from diverse sources, including healthcare providers, patients, and regulatory authorities. Ensuring the timeliness and accuracy of this data can be a complex and resource-intensive process.

Vigilance

Vigilance is a regulatory requirement that mandates medical device manufacturers to promptly report any serious incidents or potential safety issues associated with their devices to the relevant regulatory authorities. This includes the reporting of adverse events, field safety corrective actions, and recalls to ensure the timely and appropriate management of risks to patient safety.

Related Terms: Adverse Event Reporting, Field Safety Corrective Action, Recall, Risk Assessment

Example: A medical device manufacturer receives reports of unexpected device failures that have resulted in serious injuries to patients. In accordance with regulatory requirements, the manufacturer initiates a vigilance process to investigate the incidents, assess the risks, and take appropriate corrective actions, including issuing a recall if necessary.

Challenges: One of the key challenges of vigilance is the need for clear and effective communication between the manufacturer, regulatory authorities, healthcare providers, and patients. Timely reporting and

response to safety issues is essential to prevent harm to patients and maintain public trust in the safety of medical devices.

Regulatory Requirements

Regulatory requirements for post-market surveillance and vigilance vary by country and region but are generally aimed at ensuring the safety and effectiveness of medical devices throughout their lifecycle. Manufacturers are typically required to establish and maintain processes for monitoring and reporting adverse events, conducting risk assessments, implementing corrective actions, and communicating with regulatory authorities and other stakeholders.

Related Terms: Regulatory Authority, Compliance, Quality Management System, Medical Device Regulation

Example: A medical device manufacturer must comply with the regulatory requirements for post-market surveillance and vigilance set forth by the Food and Drug Administration (FDA) in the United States. This includes reporting adverse events, conducting risk assessments, and implementing corrective actions as needed to ensure the safety and effectiveness of their devices.

Challenges: Keeping up with evolving regulatory requirements for post-market surveillance and vigilance can be challenging for manufacturers, especially in the rapidly changing healthcare landscape. Adapting to new regulations, guidelines, and standards requires ongoing monitoring and continuous improvement of processes and systems.

Adverse Event

An adverse event is any undesirable or unintended occurrence associated with the use of a medical device that results in harm to a patient or user. Adverse events can range from minor incidents, such as skin irritation, to serious events, such as device malfunctions or patient injuries. Reporting and investigating adverse events are essential components of post-market surveillance and vigilance to ensure the safety of medical devices.

Related Terms: Serious Incident, Harm, Reporting, Signal Detection

Example: A patient using a medical device experiences an allergic reaction to the device components, resulting in skin irritation and discomfort. This adverse event is reported to the manufacturer, who initiates an investigation to determine the cause of the reaction and implement corrective actions to prevent similar incidents in the future.

Challenges: Identifying and reporting adverse events can be challenging due to underreporting, lack of awareness, or difficulty in determining causality. Healthcare providers, patients, and manufacturers must work together to improve the reporting and investigation of adverse events to enhance patient safety.

Complaint Handling

Complaint handling is the process of receiving, documenting, investigating, and resolving complaints related to medical devices. Complaints can include reports of device malfunctions, quality issues, usability

problems, or other concerns raised by healthcare providers, patients, or users. Effective complaint handling is essential for identifying potential safety issues and implementing corrective actions to prevent harm to patients.

Related Terms: Customer Feedback, Non-Conformity, Corrective Action, Root Cause Analysis

Example: A healthcare provider submits a complaint to a medical device manufacturer about a device malfunction that led to a patient injury. The manufacturer initiates a complaint handling process to investigate the issue, determine the root cause of the malfunction, and implement corrective actions to prevent similar incidents in the future.

Challenges: Managing and resolving complaints in a timely and effective manner can be challenging for manufacturers, especially when dealing with a large volume of feedback and diverse stakeholders. Establishing clear processes, procedures, and communication channels is essential for ensuring that complaints are addressed promptly and appropriately.

Risk Management

Risk management is the systematic process of identifying, assessing, and controlling risks associated with the use of medical devices to ensure patient safety and regulatory compliance. This includes conducting risk assessments, implementing risk controls, monitoring residual risks, and documenting risk management activities throughout the device lifecycle. Effective risk management is essential for minimizing the likelihood and impact of adverse events and ensuring the overall safety and performance of medical devices.

Related Terms: Hazard, Risk Assessment, Risk Control, Risk Mitigation

Example: A medical device manufacturer conducts a risk assessment to identify potential hazards associated with a new device design. The manufacturer implements risk controls, such as design modifications and warning labels, to reduce the likelihood and severity of risks and ensure the safety of the device in clinical use.

Challenges: Balancing the need to innovate and bring new devices to market with the requirement to manage risks effectively can be challenging for manufacturers. Developing a robust risk management process that considers all potential hazards, assesses risks comprehensively, and implements effective controls is crucial for ensuring patient safety and regulatory compliance.

Signal Detection

Signal detection is the process of identifying potential safety issues or emerging trends related to the use of medical devices through the analysis of data from various sources. Signals can indicate new risks, patterns of adverse events, or other concerns that warrant further investigation and action. Timely and effective signal detection is essential for proactive risk management and post-market surveillance to ensure the ongoing safety and effectiveness of medical devices.

Related Terms: Data Analysis, Trend Analysis, Risk Assessment, Signal Evaluation

Example: A medical device manufacturer uses data analytics tools to analyze adverse event reports and complaints related to a specific device model. The manufacturer identifies a signal indicating an increased risk of device malfunction in certain patient populations and initiates further investigation to determine the cause and implement corrective actions.

Challenges: Detecting signals of potential safety issues can be challenging due to the complexity and variability of data sources, the need for accurate and timely analysis, and the interpretation of signals in the context of real-world use. Developing robust signal detection processes and tools is essential for proactive risk management and vigilance.

Regulatory Authority

A regulatory authority is a government agency or organization responsible for overseeing and enforcing regulations related to the safety, quality, and performance of medical devices. Regulatory authorities establish guidelines, standards, and requirements for the design, manufacturing, distribution, and use of medical devices to protect public health and ensure compliance with legal and ethical standards.

Related Terms: FDA, CE Mark, Health Canada, TGA

Example: The Food and Drug Administration (FDA) in the United States is a regulatory authority that regulates medical devices to ensure their safety and effectiveness. The FDA reviews and approves new devices, monitors device performance in the market, and takes enforcement actions against manufacturers that fail to comply with regulatory requirements.

Challenges: Medical device manufacturers must navigate complex regulatory frameworks and requirements established by multiple regulatory authorities in different countries and regions. Understanding and complying with regulatory requirements, submitting timely and accurate regulatory submissions, and maintaining ongoing communication with regulatory authorities are key challenges in the medical device industry.

Compliance

Compliance refers to the act of adhering to laws, regulations, standards, and guidelines set forth by regulatory authorities and other governing bodies. Ensuring compliance with applicable requirements is essential for medical device manufacturers to maintain the safety, quality, and effectiveness of their products, as well as to meet legal and ethical obligations. Non-compliance can result in regulatory sanctions, product recalls, financial penalties, and damage to reputation.

Related Terms: Regulatory Requirements, Quality Management System, Audit, Certification

Example: A medical device manufacturer undergoes a regulatory audit by a notified body to assess the company's compliance with the requirements of the Medical Device Regulation (MDR). The audit includes a review of the manufacturer's quality management system, documentation, processes, and procedures to ensure compliance with regulatory standards.

Challenges: Achieving and maintaining compliance with evolving regulatory requirements, standards, and

guidelines can be challenging for manufacturers due to the complexity and variability of the regulatory landscape. Establishing robust compliance processes, training personnel, and conducting regular audits are essential for ensuring ongoing compliance and mitigating risks.

Quality Management System

A quality management system (QMS) is a set of policies, procedures, processes, and resources established by a medical device manufacturer to ensure the quality, safety, and effectiveness of its products. A QMS encompasses all aspects of the device lifecycle, including design and development, manufacturing, distribution, post-market surveillance, and vigilance. Implementing a robust QMS is essential for achieving regulatory compliance, continuous improvement, and customer satisfaction.

Related Terms: ISO 13485, Good Manufacturing Practice (GMP), Documentation, Audit

Example: A medical device manufacturer implements an ISO 13485-certified quality management system to ensure the consistent quality and safety of its products. The QMS includes procedures for design control, risk management, supplier management, post-market surveillance, and corrective and preventive actions to meet regulatory requirements and customer expectations.

Challenges: Establishing and maintaining a quality management system that complies with regulatory requirements, industry standards, and best practices can be challenging for manufacturers. Ensuring the effectiveness of the QMS, training personnel, conducting internal audits, and adapting to changes in the regulatory environment are key challenges in quality management.

Medical Device Regulation

Medical Device Regulation (MDR) is a set of laws, regulations, and guidelines that govern the design, manufacturing, distribution, and use of medical devices to ensure their safety, quality, and effectiveness. MDRs are established by regulatory authorities in different countries and regions to protect public health, promote innovation, and ensure compliance with legal and ethical standards. Medical device manufacturers must comply with MDRs to bring their products to market and maintain regulatory approval.

Related Terms: EU MDR, FDA Regulations, Regulatory Requirements, Compliance

Example: The European Union Medical Device Regulation (EU MDR) sets forth requirements for the classification, conformity assessment, labeling, and post-market surveillance of medical devices sold in the EU. Manufacturers must comply with the EU MDR to obtain CE marking and market their devices in EU member states.

Challenges: Adapting to new and updated medical device regulations, such as the EU MDR or FDA regulations, can be challenging for manufacturers due to the complexity and scope of the requirements. Ensuring compliance with MDRs, submitting timely and accurate regulatory submissions, and maintaining regulatory approval are key challenges in the medical device industry.

Customer Feedback

Customer feedback is information, opinions, and suggestions provided by healthcare providers, patients, users, or other stakeholders about the use, performance, or satisfaction with a medical device. Customer feedback can include complaints, compliments, suggestions for improvement, and other forms of communication that help manufacturers understand and address customer needs and expectations. Incorporating customer feedback into post-market surveillance and vigilance processes is essential for enhancing product quality, safety, and user experience.

Related Terms: User Experience, Satisfaction, Complaint Handling, Quality Improvement

Example: A medical device manufacturer conducts a user survey to gather feedback from healthcare providers about the usability and performance of a new device. Based on the feedback received, the manufacturer identifies opportunities for improvement, such as enhancing user interface design or providing additional training, to better meet customer needs and expectations.

Challenges: Collecting, analyzing, and acting on customer feedback effectively can be challenging for manufacturers due to the diversity of stakeholders, the volume of feedback, and the need for timely and meaningful responses. Establishing clear feedback mechanisms, processes, and communication channels is essential for incorporating customer input into product development and post-market surveillance.

Non-Conformity

Non-conformity refers to a deviation from specified requirements, standards, or expectations related to the design, manufacturing, distribution, or use of a medical device. Non-conformities can result from errors, defects, failures, or other issues that affect the quality, safety, or performance of the device. Identifying and addressing non-conformities promptly is essential for maintaining product quality, regulatory compliance, and patient safety.

Related Terms: Deviation, Non-Compliance, Corrective Action, Root Cause Analysis

Example: A medical device manufacturer identifies a non-conformity in the manufacturing process that has led to a defect in a batch of devices. The manufacturer initiates a corrective action to investigate the root cause of the non-conformity, implement immediate corrections, and prevent recurrence of similar issues in the future.

Challenges: Detecting, documenting, and resolving non-conformities effectively can be challenging for manufacturers due to the complexity and variability of quality issues, the impact on product safety, and the need for regulatory compliance. Establishing robust processes for non-conformity management, including root cause analysis and corrective actions, is essential for maintaining product quality and patient safety.

Corrective Action

Corrective action is a systematic process of identifying, investigating, and resolving issues, non-conformities, or discrepancies related to the design, manufacturing, distribution, or use of a medical device. Corrective actions aim to prevent recurrence of problems, improve product quality, and ensure compliance with regulatory requirements. Implementing timely and effective corrective actions is essential for maintaining

patient safety, product quality, and regulatory compliance.

Related Terms: Preventive Action, Root Cause Analysis, Non-Conformity, Quality Improvement

Example: A medical device manufacturer receives reports of device malfunctions that have resulted in patient injuries. The manufacturer initiates a corrective action to investigate the root cause of the malfunctions, implement immediate corrections, and prevent recurrence of similar incidents in the future through design modifications or process improvements.

Challenges: Implementing corrective actions in a timely and effective manner can be challenging for manufacturers due to the complexity of issues, the need for root cause analysis, and the impact on product safety. Coordinating cross-functional teams, tracking progress, and verifying the effectiveness of corrective actions are key challenges in corrective action management.

Root Cause Analysis

Root cause analysis is a systematic process of identifying, investigating, and addressing the underlying causes of issues, problems, or non-conformities related to the design, manufacturing, distribution, or use of a medical device. Root cause analysis aims to determine the fundamental reasons for failures, errors, or defects to prevent recurrence, improve product quality, and enhance patient safety. Conducting thorough root cause analysis is essential for effective corrective and preventive actions.

Related Terms: Problem Solving, Investigation, Corrective Action, Quality Improvement

Example: A medical device manufacturer conducts a root cause analysis to investigate the causes of a recurring device malfunction. The analysis reveals that the malfunction is due to a design flaw in the device components, leading the manufacturer to implement corrective actions, such as design modifications, to prevent similar incidents in the future.

Challenges: Conducting root cause analysis effectively can be challenging for manufacturers due to the complexity of issues, the need for multidisciplinary expertise, and the impact on product safety. Engaging stakeholders, collecting relevant data, and implementing sustainable corrective actions are key challenges in root cause analysis.

ISO 13485

ISO 13485 is an international standard that sets forth requirements for quality management systems in the design, manufacturing, distribution, and servicing of medical devices. ISO 13485 is based on the principles of ISO 9001 and is specific to the medical device industry, emphasizing regulatory compliance, risk management, customer satisfaction, and continuous improvement. Achieving ISO 13485 certification demonstrates a manufacturer's commitment to quality, safety, and regulatory compliance.

Related Terms: Quality Management System, Certification, Compliance, Audit

Example: A medical device manufacturer implements an ISO 13485-certified quality management system to ensure the consistent quality and safety of its products. The manufacturer undergoes a certification audit by

a notified body to verify compliance with ISO 13485 requirements and obtain certification to market its devices in the EU and other regions.

Challenges: Achieving and maintaining ISO 13485 certification can be challenging for manufacturers due to the complexity and scope of the standard, the need for ongoing compliance, and the impact on product quality. Establishing robust processes, training personnel, and conducting regular audits are key challenges in ISO 13485 certification.

Good Manufacturing Practice (GMP)

Good Manufacturing Practice (GMP) is a set of guidelines, standards, and requirements established by regulatory authorities to ensure the quality, safety, and consistency of medical devices throughout the manufacturing process. GMP covers all aspects of manufacturing, including facility design, equipment maintenance, personnel training, process control, quality assurance, and documentation. Adhering to GMP principles is essential for maintaining product quality, regulatory compliance, and patient safety.

Related Terms: Quality Control, Quality Assurance, Compliance, Audit

Example: A medical device manufacturer follows GMP guidelines to ensure the quality and safety of its products. The manufacturer establishes procedures for equipment calibration, process validation, personnel training, and quality control to meet GMP requirements and maintain regulatory approval for its devices.

Challenges: Implementing and maintaining GMP compliance can be challenging for manufacturers due to the complexity and rigor of the requirements, the need for continuous improvement, and the impact on product quality. Establishing robust quality management systems, conducting regular

Post-Market Surveillance and Vigilance

Post-Market Surveillance and Vigilance play a crucial role in ensuring the safety and effectiveness of medical devices after they have been placed on the market. This process involves monitoring the performance of devices, identifying and evaluating potential risks, and taking appropriate actions to address any issues that may arise.

Post-Market Surveillance (PMS)

Post-Market Surveillance (PMS) refers to the systematic collection, analysis, and interpretation of data related to the performance and safety of medical devices once they are on the market. The primary goal of PMS is to detect any potential issues or risks associated with the device and to take appropriate corrective actions to ensure patient safety.

Vigilance

Vigilance is the process of monitoring and reporting adverse events or incidents related to medical devices. It involves the collection, assessment, and reporting of information on the safety and performance of devices to regulatory authorities, manufacturers, and other stakeholders.

Adverse Event

An adverse event is any untoward medical occurrence associated with the use of a medical device, including but not limited to device malfunctions, user errors, or patient injuries. Adverse events must be reported to regulatory authorities as part of post-market surveillance efforts.

Device Failure

Device failure refers to the malfunction or breakdown of a medical device that results in the device not performing as intended. Device failures can lead to adverse events and may necessitate corrective actions by the manufacturer to prevent further incidents.

Risk Management

Risk management is the process of identifying, assessing, and mitigating risks associated with the use of medical devices. It involves evaluating potential hazards, estimating the likelihood of adverse events, and implementing strategies to reduce or eliminate risks to patients and users.

Signal Detection

Signal detection is the process of identifying potential safety issues or trends based on the analysis of data from post-market surveillance activities. Signals may indicate new risks, emerging trends, or patterns of adverse events that require further investigation.

Trend Analysis

Trend analysis involves tracking and analyzing data over time to identify patterns, changes, or anomalies related to the performance and safety of medical devices. Trend analysis can help detect potential issues early and inform decision-making in post-market surveillance efforts.

Complaint Handling

Complaint handling is the process of receiving, documenting, investigating, and resolving complaints related to the performance or safety of medical devices. Effective complaint handling is essential for identifying potential issues and taking appropriate corrective actions.

Field Safety Corrective Action (FSCA)

Field Safety Corrective Action (FSCA) is a term used to describe actions taken by manufacturers to address safety issues with medical devices that are already on the market. FSCAs may include recalls, software updates, labeling changes, or other measures to reduce risks to patients and users.

Recall

A recall is an action taken by a manufacturer to remove or correct a medical device that has been found to pose a risk to patient safety. Recalls may be initiated voluntarily by the manufacturer or mandated by regulatory authorities to protect public health.

Corrective and Preventive Actions (CAPA)

Corrective and Preventive Actions (CAPA) are systematic processes used to investigate and address non-conformities, deviations, or deficiencies in the quality management system. CAPA measures are essential for preventing recurrence of issues and improving overall product quality.

Post-Market Clinical Follow-Up (PMCF)

Post-Market Clinical Follow-Up (PMCF) is a process that involves collecting and analyzing clinical data on the performance and safety of medical devices in real-world settings. PMCF studies help assess the long-term efficacy and safety of devices after they have been approved for market use.

Medical Device Reporting (MDR)

Medical Device Reporting (MDR) is a regulatory requirement that mandates the reporting of adverse events, malfunctions, or other safety issues related to medical devices. Manufacturers, importers, and user facilities must submit MDRs to regulatory authorities to ensure patient safety.

Post-Market Surveillance Plan

A Post-Market Surveillance Plan is a document that outlines the strategies, processes, and responsibilities for monitoring and evaluating the safety and performance of medical devices after they have been commercialized. The plan helps ensure compliance with regulatory requirements and continuous improvement of devices.

Quality Management System (QMS)

A Quality Management System (QMS) is a set of policies, procedures, and processes designed to ensure that products meet quality standards and regulatory requirements. QMS principles are essential for maintaining product quality, safety, and compliance throughout the product lifecycle.

ISO 13485

ISO 13485 is an international standard that sets out the requirements for a quality management system specific to the medical device industry. Compliance with ISO 13485 demonstrates a manufacturer's commitment to producing safe and effective medical devices that meet regulatory requirements.

Regulatory Authority

A regulatory authority is a government agency responsible for overseeing and enforcing regulations related to the safety, efficacy, and quality of medical devices. Regulatory authorities set standards, review applications, and monitor compliance to protect public health and ensure patient safety.

Notified Body

A Notified Body is an independent organization designated by a regulatory authority to assess the conformity of medical devices with regulatory requirements. Notified Bodies conduct audits, reviews, and

certifications to ensure that devices meet safety and performance standards before they can be placed on the market.

European Database for Medical Devices (EUDAMED)

The European Database for Medical Devices (EUDAMED) is a central repository of information on medical devices marketed in the European Union. EUDAMED provides a platform for exchanging data, tracking devices, and monitoring safety issues to enhance post-market surveillance and vigilance efforts.

Unique Device Identification (UDI)

Unique Device Identification (UDI) is a system for uniquely identifying and tracking medical devices throughout their lifecycle. UDIs consist of a series of numeric or alphanumeric codes that allow for easy identification, traceability, and monitoring of devices for post-market surveillance purposes.

Post-Market Clinical Studies

Post-Market Clinical Studies are research studies conducted after a medical device has been approved for market use to gather additional data on its safety, efficacy, and performance. These studies help manufacturers assess real-world outcomes and address any potential issues that may arise post-approval.

Device Tracking

Device tracking is the process of monitoring and tracing the movement of medical devices from production to distribution to use. Tracking devices allows for better inventory management, recall effectiveness, and post-market surveillance efforts to ensure the safety and quality of devices.

Advisory Notice

An advisory notice is a communication issued by a regulatory authority or manufacturer to inform healthcare providers, patients, and users about safety issues, recalls, or other important information related to medical devices. Advisory notices help raise awareness and facilitate appropriate actions to address risks.

Compliance Monitoring

Compliance monitoring involves assessing whether manufacturers, importers, and distributors of medical devices are meeting regulatory requirements and quality standards. Monitoring compliance helps ensure that devices are safe, effective, and of high quality for patient use.

Post-Market Data Analysis

Post-Market Data Analysis involves the review and interpretation of data collected through post-market surveillance activities to identify trends, patterns, or signals related to the safety and performance of medical devices. Data analysis informs decision-making and risk management strategies for continuous improvement.

Post-Market Surveillance Reporting

Post-Market Surveillance Reporting is the process of documenting and communicating findings from post-market surveillance activities to regulatory authorities, stakeholders, and internal teams. Reporting ensures transparency, accountability, and timely action to address safety issues and enhance patient safety.

Compliance Audit

A compliance audit is an independent assessment of a manufacturer's adherence to regulatory requirements, quality standards, and internal processes related to medical devices. Audits help identify gaps, non-compliances, or areas for improvement to ensure ongoing compliance and product quality.

Risk Assessment

Risk assessment is the process of identifying, evaluating, and prioritizing potential risks associated with the use of medical devices. It involves assessing the severity, likelihood, and impact of risks to determine appropriate mitigation strategies and preventive measures for patient safety.

Post-Market Surveillance Team

A Post-Market Surveillance Team is a multidisciplinary group of professionals responsible for coordinating, implementing, and overseeing post-market surveillance activities within an organization. The team collaborates on data collection, analysis, reporting, and risk management efforts to ensure device safety and compliance.

Device Registration

Device registration is the process of submitting information on medical devices to regulatory authorities for market approval or clearance. Registration requirements vary by country and region but typically include details on device specifications, intended use, and safety data for review and authorization.

Health Hazard Evaluation

A health hazard evaluation is an assessment conducted to determine the potential risks or health effects associated with the use of a medical device. Evaluations may involve clinical data analysis, risk assessment, and consultation with experts to identify and address safety concerns for patient protection.

Compliance Checklist

A compliance checklist is a tool used to ensure that manufacturers, importers, and distributors of medical devices meet regulatory requirements and quality standards. Checklists outline key criteria, documentation, and processes for compliance monitoring, audits, and inspections to maintain product quality and safety.

Post-Market Surveillance Strategy

A Post-Market Surveillance Strategy is a comprehensive plan that outlines the objectives, methods, and resources for monitoring and evaluating the safety and performance of medical devices post-approval. The strategy guides surveillance activities, data collection, analysis, and reporting for continuous improvement and risk management.

Periodic Safety Update Report (PSUR)

A Periodic Safety Update Report (PSUR) is a document submitted to regulatory authorities that provides an overview of safety data, adverse events, and risk management activities related to a medical device. PSURs help regulators assess device safety, effectiveness, and compliance with post-market surveillance requirements.

Quality Audit

A quality audit is a systematic examination of a manufacturer's quality management system, processes, and procedures to ensure compliance with regulatory requirements and industry standards. Audits may be conducted internally or by external parties to assess product quality, safety, and performance.

Complaint Investigation

A complaint investigation is a process conducted to determine the root cause of a reported issue, incident, or adverse event related to a medical device. Investigations involve collecting data, analyzing evidence, and identifying corrective actions to prevent recurrence and ensure patient safety.

Post-Market Surveillance Database

A Post-Market Surveillance Database is a centralized system for storing, managing, and analyzing data on the safety and performance of medical devices post-commercialization. The database facilitates data collection, trend analysis, and reporting to support risk management and regulatory compliance efforts.

Risk Mitigation

Risk mitigation is the process of implementing measures to reduce or eliminate potential risks associated with the use of medical devices. Mitigation strategies may include design changes, labeling updates, training programs, or other interventions to enhance device safety, effectiveness, and compliance.

Adverse Event Reporting System

An Adverse Event Reporting System is a mechanism for healthcare providers, patients, and users to report incidents, malfunctions, or adverse events related to medical devices. Reporting systems help capture safety data, facilitate early detection of issues, and support post-market surveillance and vigilance activities.

Post-Market Surveillance Dashboard

A Post-Market Surveillance Dashboard is a visual tool that displays key performance indicators, metrics, and trends related to the safety and performance of medical devices. Dashboards provide real-time data insights, facilitate decision-making, and enhance communication within organizations for effective risk management.

Regulatory Compliance

Regulatory compliance refers to the adherence to laws, regulations, and standards governing the design,

manufacture, distribution, and use of medical devices. Compliance ensures that devices meet safety, efficacy, and quality requirements to protect patient health and maintain public trust in the healthcare system.

Compliance Reporting

Compliance reporting involves documenting and communicating activities, findings, and outcomes related to regulatory compliance efforts for medical devices. Reporting provides transparency, accountability, and evidence of adherence to regulatory requirements to demonstrate product quality, safety, and effectiveness.

Post-Market Surveillance Process

The Post-Market Surveillance Process is a structured approach to monitoring, evaluating, and managing the safety and performance of medical devices after they have been released to the market. The process includes data collection, analysis, reporting, and risk management activities to ensure ongoing compliance and patient safety.

Regulatory Compliance Officer

A Regulatory Compliance Officer is a professional responsible for overseeing and ensuring compliance with regulatory requirements, quality standards, and industry guidelines for medical devices. Compliance officers develop strategies, policies, and procedures to maintain product quality, safety, and regulatory compliance.

Post-Market Surveillance Coordinator

A Post-Market Surveillance Coordinator is a role responsible for managing, coordinating, and overseeing post-market surveillance activities within an organization. Coordinators work with cross-functional teams to collect data, analyze trends, and implement risk management strategies to enhance device safety and compliance.

Device Labeling

Device labeling is the information provided on the packaging, instructions for use, and accompanying materials of a medical device. Labeling includes details on device specifications, intended use, warnings, precautions, and instructions for proper use to ensure safe and effective use by healthcare professionals and patients.

Regulatory Compliance Training

Regulatory Compliance Training is education provided to employees, stakeholders, and partners on regulatory requirements, quality standards, and best practices for medical devices. Training programs help ensure awareness, understanding, and adherence to compliance obligations for maintaining product quality, safety, and regulatory compliance.

Compliance Management System

A Compliance Management System is a framework of policies, procedures, and tools designed to oversee,

monitor, and ensure compliance with regulatory requirements and quality standards for medical devices. Management systems help identify, assess, and mitigate risks to maintain product quality, safety, and regulatory compliance.

Post-Market Surveillance Audit

A Post-Market Surveillance Audit is an examination of an organization's post-market surveillance activities to assess compliance with regulatory requirements, quality standards, and internal processes. Audits help identify gaps, opportunities for improvement, and areas for corrective actions to enhance device safety and compliance.

Regulatory Compliance Plan

A Regulatory Compliance Plan is a document that outlines the strategies, objectives, and actions for ensuring compliance with regulatory requirements and quality standards for medical devices. The plan includes risk assessments, monitoring activities, and corrective actions to maintain product quality, safety, and regulatory compliance.

Compliance Monitoring System

A Compliance Monitoring System is a set of tools, processes, and controls used to track, evaluate, and manage compliance with regulatory requirements and quality standards for medical devices. Monitoring systems help identify non-compliances, gaps, or deviations to address issues and maintain product quality, safety, and compliance.

Regulatory Compliance Framework

A Regulatory Compliance Framework is a structured approach to managing and ensuring compliance with regulatory requirements and quality standards for medical devices. The framework includes policies, procedures, controls, and monitoring mechanisms to maintain product quality, safety, and regulatory compliance throughout the product lifecycle.

Compliance Audit Report

A Compliance Audit Report is a document that outlines the findings, observations, and recommendations from an audit of an organization's compliance with regulatory requirements and quality standards for medical devices. Audit reports provide insights, feedback, and action plans to address non-compliances and improve product quality and safety.

Post-Market Surveillance Checklist

A Post-Market Surveillance Checklist is a tool used to ensure that organizations are following the necessary steps, processes, and activities for monitoring, evaluating, and managing the safety and performance of medical devices post-commercialization. Checklists help maintain compliance, consistency, and effectiveness in post-market surveillance efforts.

Regulatory Compliance Review

A Regulatory Compliance Review is an assessment conducted to evaluate an organization's adherence to regulatory requirements, quality standards, and industry guidelines for medical devices. Reviews help identify gaps, risks, and opportunities for improvement to enhance product quality, safety, and regulatory compliance.

Compliance Monitoring Report

A Compliance Monitoring Report is a document that summarizes the results, findings, and outcomes of monitoring activities related to regulatory compliance for medical devices. Monitoring reports provide insights, trends, and recommendations for addressing non-compliances, gaps, or deviations to ensure ongoing product quality, safety, and regulatory compliance.

Regulatory Compliance Assessment

A Regulatory Compliance Assessment is an evaluation conducted to determine the level of adherence of an organization to regulatory requirements, quality standards, and industry guidelines for medical devices. Assessments help identify strengths, weaknesses, and areas for improvement to maintain product quality, safety, and regulatory compliance.

Compliance Monitoring Dashboard

A Compliance Monitoring Dashboard is a visual tool that displays key performance indicators, metrics, and trends related to regulatory compliance efforts for medical devices. Dashboards provide real-time data insights, facilitate decision-making, and enhance communication within organizations for effective compliance management.

Post-Market Surveillance Dashboard

A Post-Market Surveillance Dashboard is a visual tool that displays key performance indicators, metrics, and trends related to the safety and performance of medical devices. Dashboards provide real-time data insights, facilitate decision-making, and enhance communication within organizations for effective risk management.

Regulatory Compliance Dashboard

A Regulatory Compliance Dashboard is a visual tool that displays key performance indicators, metrics, and trends related to regulatory compliance efforts for medical devices. Dashboards provide real-time data insights, facilitate decision-making, and enhance communication within organizations for effective compliance management.

Compliance Monitoring Tool

A Compliance Monitoring Tool is a software application or platform used to track, assess, and manage compliance with regulatory requirements and quality standards for medical devices. Monitoring tools help

automate processes, streamline data collection, and ensure accuracy in compliance monitoring efforts to maintain product quality, safety, and regulatory compliance.

Regulatory Compliance Software

Regulatory Compliance Software is a technology solution designed to support organizations in managing, monitoring, and ensuring compliance with regulatory requirements and quality standards for medical devices. Compliance software helps streamline processes, centralize data, and facilitate reporting for effective compliance management and risk mitigation.

Compliance Monitoring Platform

A Compliance Monitoring Platform is a centralized system or interface used to oversee, track, and manage compliance with regulatory requirements and quality standards for medical devices. Monitoring platforms provide visibility, transparency, and control over compliance activities to maintain product quality, safety, and regulatory compliance.

Post-Market Surveillance Platform

A Post-Market Surveillance Platform is a centralized system or interface used to collect, manage, and analyze data related to the safety and performance of medical devices post-commercialization. Surveillance platforms support data collection, trend analysis, and reporting for effective risk management and compliance with regulatory requirements.

Regulatory Compliance System

A Regulatory Compliance System is a comprehensive framework of policies, procedures, and tools used to ensure adherence to regulatory requirements and quality standards for medical devices. Compliance systems help manage risks, monitor activities, and address non-compliances to maintain product quality, safety, and regulatory compliance.

Compliance Monitoring Solution

A Compliance Monitoring