
Mastering Strategies for Risk Management in Medical Device Safety: Integrating Clinical Expertise and Comprehensive Approaches Across the Product Lifecycle

ADVANCED METHODS TO ENSURE DEVICE SAFETY AND COMPLIANCE

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Disclaimer

- Information within these slides represent personal opinion and points of view from over two decades of personal and professional experience in both Clinical and Corporate scenarios, inclusive, but not limited to Health Institutions and/or Corporations I have practiced in and/or been employed at.
- This does not necessarily express the opinion of my previous or current employer.

Presentation Agenda Overview

- Integrating Clinical Expertise Into Medical Device Risk Assessment
- Effective Post-Market Surveillance for Mitigating Safety Risks
- Regulatory Compliance and Cross-Functional Collaboration for Global Product Safety
- Leveraging Clinical Trial Support and Risk Assessment Throughout the Medical Device Lifecycle

Integrating Clinical Expertise Into Medical Device Risk Assessment



Utilizing Clinical Input During Hazard Identification and Risk Analysis

Early Clinical Expertise

Involving clinical experts early uncovers risks that engineering alone might overlook, enhancing hazard identification.

Improved Risk Analysis

Clinical input adds relevance and thoroughness to risk analysis by providing unique healthcare perspectives.





Bridging the Gap Between Engineering Teams and Healthcare Professionals

Collaboration Importance

Close teamwork between engineers and clinicians ensures medical devices meet real-world clinical requirements effectively.

Aligning Device Design

Device design must align with clinical practices to reduce risks and improve patient safety outcomes.

Risk Assessment Integration

Integrating clinical insights into risk assessments helps identify and minimize potential safety hazards.

Real-World Evidence and Feedback to Enhance Risk Assessment Accuracy



Real-World Data Collection

Collecting data from actual device usage reveals authentic performance and user behavior patterns. Inclusive of patient perspective.

Risk Model Refinement

Integrating real-world data helps improve the accuracy of risk prediction models.



Anticipating Safety Issues

Insights from real-world evidence enable proactive identification of potential safety concerns. Predictive analytics?

Effective Post-Market Surveillance for Mitigating Safety Risks



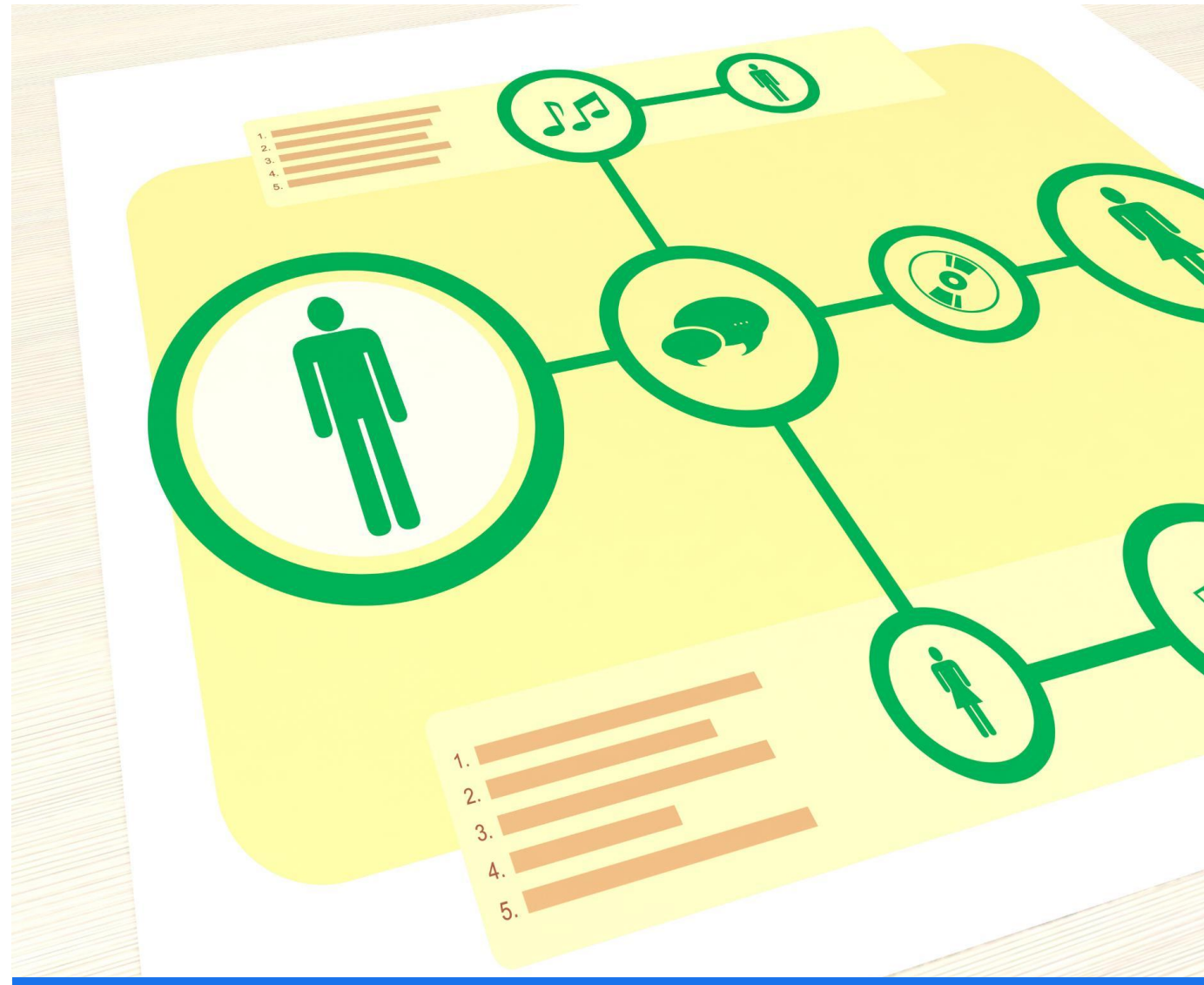
Building Robust Post-Market Surveillance Systems and Feedback Loops

Systematic Monitoring

Implementing structured monitoring processes captures safety data effectively and consistently.

Feedback Mechanisms

Feedback **loops** enable timely communication and action on identified hazards. Connected risk management through the lifecycle of the product. Think **LOOP**.



Data Collection, Adverse Event Reporting, and Trend Analysis

Comprehensive Data Collection

Gathering detailed adverse event data is crucial for identifying safety issues early and accurately.

Adverse Event Reporting

Timely reporting of adverse events helps monitor patient safety and regulatory compliance.

Trend Analysis for Safety

Analyzing data trends enables detection of patterns signaling potential safety concerns requiring intervention.



Proactive Risk Mitigation Based on Post-Market Insights

Surveillance Insights Utilization

Post-market surveillance provides critical data to identify potential risks early and guide corrective actions effectively.

Corrective Actions Implementation

Timely corrective actions based on insights help address design flaws and improve product safety proactively.

Minimizing Patient Safety Risks

Proactive improvements reduce risks before they affect patients, enhancing overall safety and care quality.



Regulatory Compliance and Cross-Functional Collaboration for Global Product Safety

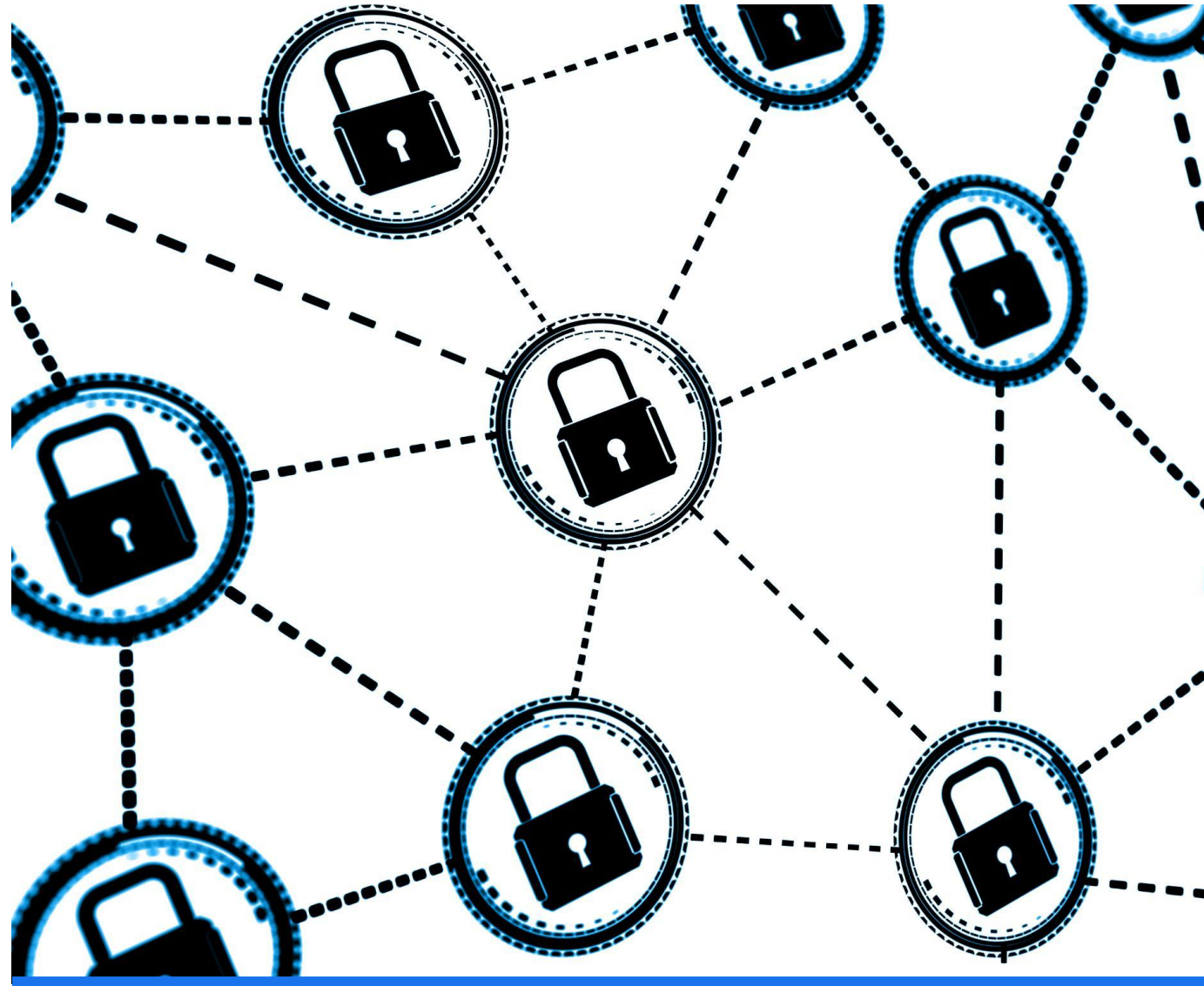
Navigating International Regulations and Standards

Global Regulatory Compliance

Adhering to international regulations ensures products meet legal requirements for market entry worldwide. Creation of a common “regulatory language”.

Safety Standards Assurance

Meeting safety benchmarks safeguards consumers and maintains product reliability across regions.



Establishing Cross-Functional Safety Teams: Clinical, Regulatory, Engineering



Diverse Expertise Collaboration

Cross-functional teams bring clinical, regulatory, and engineering experts together for comprehensive safety solutions.



Robust Risk Management

Integrating diverse perspectives enhances risk assessment and ensures thorough safety decisions.



Aligned Safety Objectives

Unified safety goals promote consistent standards across clinical, regulatory, and engineering departments. Clear purpose.

Global Harmonization of Safety Practices and Documentation

Standardized Safety Processes

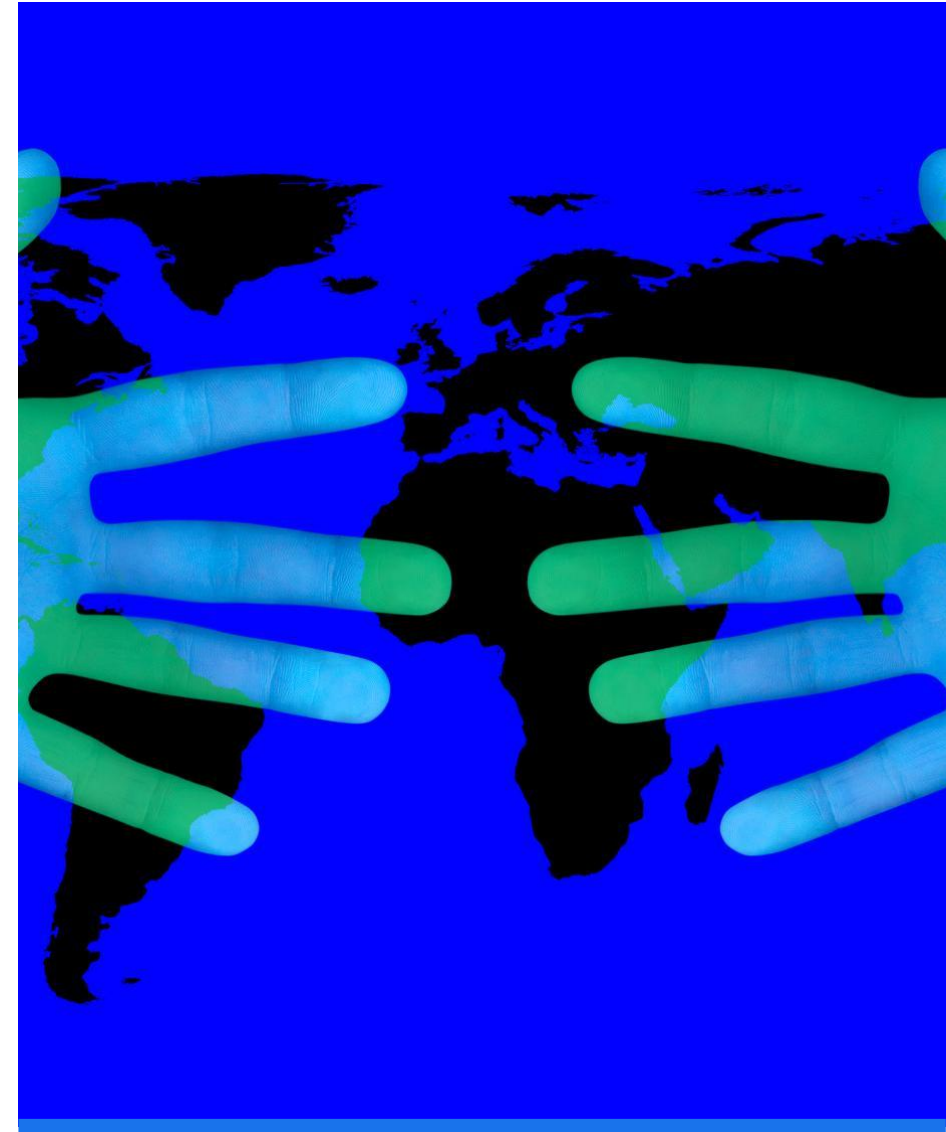
Harmonizing safety procedures ensures consistent compliance with regulations worldwide.

Efficient Documentation

Unified documentation enhances clear communication and reduces errors internationally.

International Market Compliance

Global harmonization supports seamless compliance across diverse international markets.



Leveraging Clinical Trial Support and Risk Assessment Throughout the Medical Device Lifecycle





Designing Clinical Trials to Identify and Address Safety Risks

Safety-Focused Trial Design

Designing trials with safety endpoints ensures early identification of potential risks associated with medical devices. Escalate / terminate as needed.

Early Risk Detection

Early detection of device risks helps prevent adverse events and protects patient health during trials.

Risk Mitigation Strategies

Proactive risk mitigation during trials improves device safety and ensures regulatory compliance before market release.

Continuous Risk Assessment From Development to Post-Market Phases



Ongoing Risk Evaluation

Continuous risk assessment detects new hazards throughout the device lifecycle effectively and promptly. **LOOP**

Development Phase Focus

Early identification of potential risks during development minimizes future safety issues and compliance challenges. **LOOP**.

Post-Market Monitoring

Post-market risk management ensures timely detection and mitigation of hazards after device release. **LOOP**.

Integration of Clinical Trial Data Into Lifecycle Risk Management Strategies

Clinical Trial Data Utilization

Clinical trial findings provide crucial evidence to inform and enhance risk management throughout product lifecycle.

Safety Assurance Enhancement

Incorporating trial data strengthens safety monitoring and helps prevent adverse effects in real-world use.

Regulatory Compliance Support

Aligning risk management strategies with clinical data ensures adherence to regulatory standards and guidelines.



Conclusion

Clinical Expertise Integration

Incorporating clinical knowledge is essential for identifying and mitigating medical device risks effectively.

Post-Market Surveillance

Ongoing monitoring after product release ensures early detection and management of safety issues. **LOOP**.

Regulatory Compliance

Adhering to regulations ensures devices meet safety standards and legal requirements.

Collaborative Lifecycle Approach

A unified approach across all product stages maximizes safety and success for patients and manufacturers.

Thank you

- Q&A