Operationalizing Post Market Surveillance in a Global Company

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Post Market Surveillance – Regulations and Requirements

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1. US Regulations and Guidance
2. EU Requirements and Guidance
3. Other Regions
4. Future Considerations

US FDA Post-Market Surveillance

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Current FDA Post-Market Surveillance Efforts

The FDA's Center for Devices and Radiological Health (CDRH) has traditionally relied on several approaches in its post-market surveillance program:

Passive:

- Medical Device Reporting (MDR)
- Medical Product Safety Network (MedSun)

Active:

- Post-Approval Studies (Condition of Approval for some Class III devices)
- Post-Market Surveillance Studies ("Section 522" Studies)
- Literature Searches / Systematic Reviews
- FDA Discretionary Studies (using registries, databases, etc.)

Quality System-Based Inspections

- Primary Focus on Complaint Handling

US Regulations Specific to Post-Market Surveillance

- Complaint handling (21 CFR 820.198)
- MDR reporting (21 CFR 803)
- Reports on Accidental Radiation Occurrences or Device Defects (21 CFR 1003.10 and 1002.20)
- Medical Device Tracking as ordered by FDA (21 CFR 821)
- Reports on Corrections and Removals (21 CFR 806)
- Post-Market Surveillance for Class II and Class III medical devices (21 CFR 822 – FDCA §522 – "Section 522 Studies")
- Post-Approval Studies – conditions of PMA, HDE, PDP approval, such as participation in a registry (21 CFR 814.82)

US FDA CDRH Guidance on Post-Market Surveillance

- Section 522 Guidance – April 2006
- Post-Approval Studies Guidance – June 2009
- Draft Recalls and Enhancements Guidance – February 2013
- Draft MDR Guidance – July 2013
- Balancing Premarket and Post-Market Data Collection for Devices subject to Premarket Approval – April 2014

EU Post-Market Surveillance and Vigilance

Post-Market Surveillance – preventive systems that monitor the market
Vigilance – reactive systems activated in case of adverse events

Current system for medical devices defined by:
European Medical Device Directive 93/42/EEC (including annexes and amendments)*
-Sets the harmonized standards to be met (e.g. ISO 14971)
MEDDEV 2.12-1 Rev8 "Guidelines on a Medical Devices Vigilance System"
MEDDEV 2.12-2 Rev2 "Post-Market Clinical Follow-up (PMCF) Studies"

* IVD and AIMD have similar legislation; all are transposed to national legislation

ISO Standards for Post-Market Surveillance

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ISO 13485:2012 - Medical devices -- Quality management systems -- Requirements for regulatory purposes

-Procedures to collect information from various sources such as users, service personnel, training personnel, incident reports and customer feedback

ISO 14971:2012 - Medical devices — Application of risk management to medical devices

-Methods of obtaining relevant post-production information

- Established quality management system procedures (for example ISO 13485:2003)
- Risk Management Plan should also define what type of post-market surveillance is appropriate for the device
  - Reactive surveillance
  - Proactive studies

Similarities and Differences Between Four Device Post-Market Surveillance Systems

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System Features	US	EU	Japan	China
Transparency	Premarket data and PMS study status for high-risk devices publicly available. Public databases for reported adverse events and recalls.	Basis for device approval and any post marketing commitments largely unknown. EU-wide adverse event data not accessible, though individual countries post PMS events in non-systematic manner	Public posting of approvals, adverse event data, and notices	Public website listing all approved devices including labeling, but clinical data and collected adverse event data not public
Formal re-examination	Product performance reports may be submitted from PMS studies registries, but no formal process for renewing approval for specific indications	Clinical evaluation reports summarize PMS data but are not consistently produced and are not used to evaluate renewal of CE marking	Statutorily-required formal reexamination period for selected devices	Statutorily-required formal reexamination period for selected devices
Central versus local control	Device regulation centralized at FDA; individual states may not impose stricter standards on manufacturers for marketing	EU provides guidance but directives are interpreted by national Competent Authorities and private Notified Bodies	Centralized process organized by Ministry of Health, Labor and Welfare and its Pharmaceutics and Medical Devices Agency	Central CFDA provides oversight for provincial authorities, however opportunities for local initiatives exist

Kramer DB, Tan YT, Sato C, Kesselheim AS (2013) Postmarket Surveillance of Medical Devices: A Comparison of Strategies in the US, EU, Japan, and China. PLoS Med 10(9): e1001519. doi:10.1371/journal.pmed.1001519
http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1001519

Future Considerations – US FDA

Limitations of Current PMS:

-"Numerator" dependent

-Collection is inefficient and incomplete

-Not timely

Future Vision Outlined:

-"Strengthening Our National System for Medical Device Post-Market Surveillance"

- September 2012 and revision April 2013

-2013 and 2014 CDRH Strategic Priorities

Future Considerations – US FDA

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FDA Plans for Improving Device Post-Market Surveillance:

- Establish a multi-stakeholder Medical Device Post-market Surveillance System Planning Board
- Establish a unique device identification (UDI) system and promote its incorporation into electronic health information
- Promote the development of national and international device registries for selected products
- Modernize adverse event reporting and analysis; and
- Develop and use new methods for evidence generation, synthesis, and appraisal

Vehicles:

- UDI will make individual device model identifiable
- Sentinel initiative – full implementation for Medical Devices
- MDEpiNet, and collaborations with providers, academic centers
- Enhanced technology for data mining and extraction (eMDR, FAERS, access to EHRs)

Future Considerations – EU

Updated regulations on medical devices being adopted:

- European Commission desires better coordinated information exchange between national competent authorities
- Device traceability system in planning
- Stricter requirements for clinical evidence
- More accountability for Notified Bodies in certifying devices, and in post market follow-up
  - -Heightened expectations for NB performance from EC and national Competent Authorities
  - -Increase in NB scrutiny of manufacturers and devices

Components of Effective Post-Market Surveillance Systems

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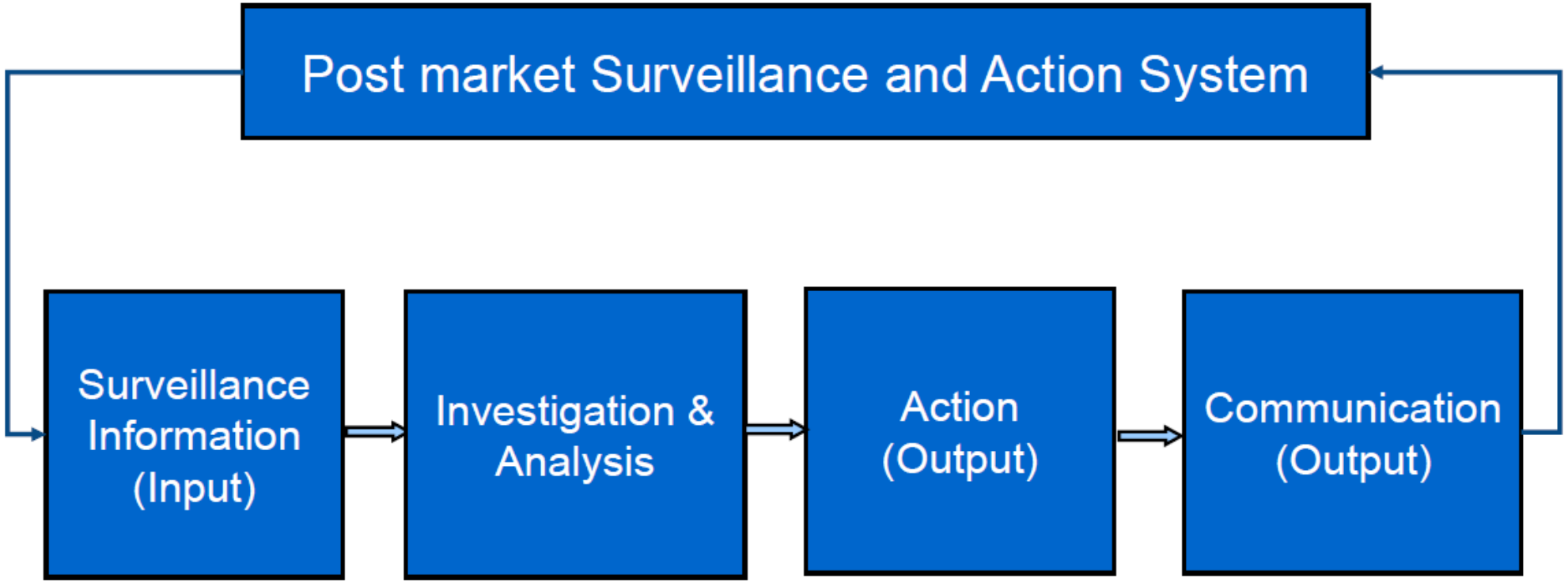

Goal of PMS system is to take appropriate action to protect public safety and improve product performance