Operationalizing Post Market Surveillance in a Global Company

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Agenda

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- Components of an effective Post market surveillance System
  - Surveillance information sources
  - Investigation and Analysis
    - Risk Analysis
  - MDR Challenges
  - Vigilance Challenges
  - Action System and Outputs
  - Management Reviews & Dissemination
- Monitoring Health of Post market surveillance system
- Best Practices
- Case Studies

What is Post market Surveillance?

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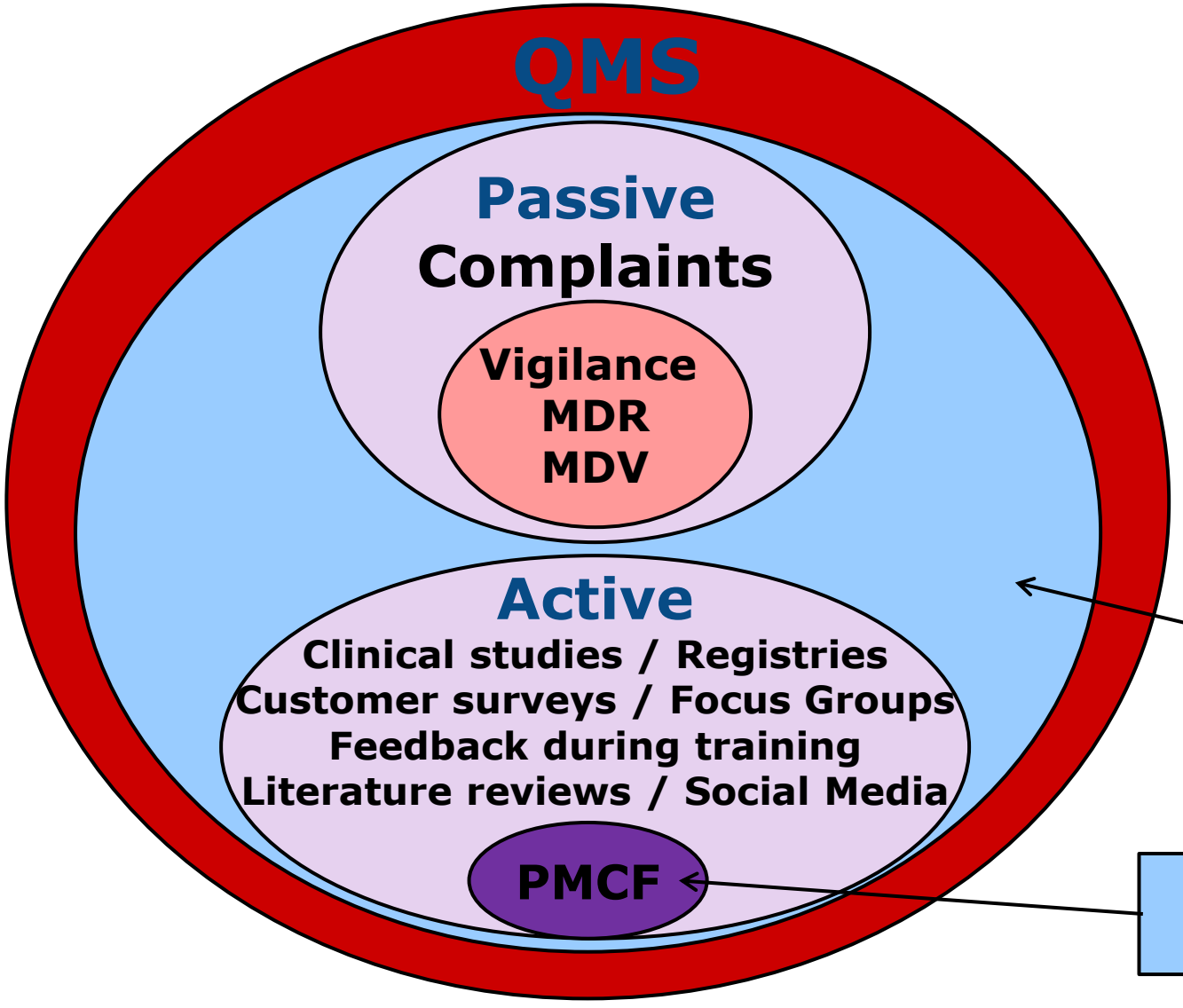
Comprehensive set of Passive (Reactive) and Proactive activities to identify and action signals on patient safety and product quality post market



Passive PMS – Always required

Active PMS – Required, but level and type of activity dependent upon product risk

Post market Surveillance

Post market Clinical Follow-up

Post market Surveillance Components

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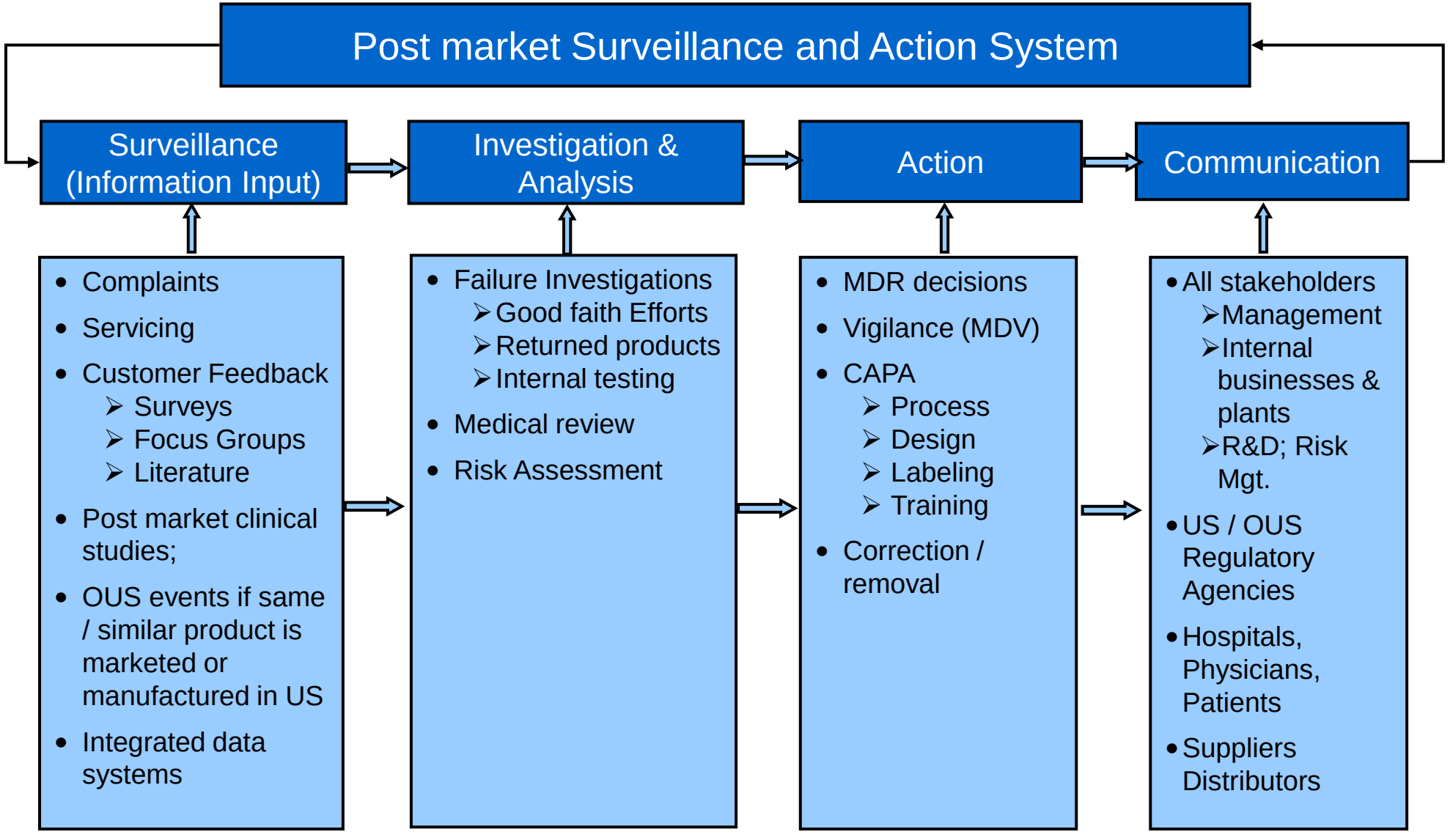

Goal of PMS system is to take appropriate action to protect public safety and improve product performance

Surveillance Information Sources

- Customers, Sales Force, Field Service, Affiliates, Distributors; 3rd parties
  - Are roles, responsibilities, accountabilities for reporting complaints in a timely fashion, undertaking the necessary follow-up; when req'd; parts returns etc. clearly understood and documented by all parties?
  - Training
    - Do all employees know where and how to report complaints?
    - Complaint handlings staff trained on the products, use, and the regulation.
    - Document complaints so that they are easy to follow and understand – internal and external uses.
    - Training records for company employees service; sales force; documenting they have been appropriately trained in complaint handling.
  - Quality agreements between Manufacturing sites and Complaint handling unit; Quality agreements with Affiliates and Distributors.

Organizational Alignment

- Consider how is the company structured?
  - Multiple manufacturing sites, businesses, divisions
  - Call centers
  - Complaint processing site vs. Investigation site
  - Distributors, affiliates, 3'rd parties
    - Clear definition roles & responsibilities
- Who are the designated complaint handling units
- Reporting – Central team; Regulatory Affairs; Local Units
- Electronic systems and flow of information
  - Service Systems
  - Complaint Handling Systems; Electronic vs. paper
  - Time zones; Local language and provisions for translation
  - Record availability

Surveillance Information Sources

- Field Service reports **must** be reviewed for complaint information and MDR reportability *21 C.F.R. § 820.200(c)*
  - Train field service staff to recognize and report complaints
  - Distributors and 3'rd parties providing service
- Establish process for capturing and reviewing service records
  - Unplanned service; Corrective Repairs
    - Out of Box vs. post-installation failures
  - Service reports for routine service requests (*e.g.* general maintenance) typically are not complaints and do not require same level of investigation.
  - Open vs. closed service records; review of incremental information added to service records
  - Quality of information received and required follow-up
  - Trending of service records; component replacement – feeders into the complaint system.

Investigation & Analysis

Must be both Patient- and Product-Centric

Patient–Related Questions

- What was the patient's condition prior, during, and after the use of the device?
- Did or would the patient require medical or surgical intervention related to an issue associated with the use of the device?
- What medication did the patient require prior to and subsequent to the adverse event?
- Did the patient require return visits to a physician or health care provider to monitor healing after the adverse event?

Product-Related Questions

- How and why was Company made aware of this event?
- What other experience has Company learned about the use of this device in the same or similar circumstances?
- What have past Company investigations revealed about the use of this device?
- What is the severity and frequency of reported complaints associated with this device?
- Has there been any change to the manufacturing of, or materials used in the manufacturing of, the device, even ones meant to improve quality?

Investigation & Analysis

- Accurate, complete, and timely information exchange
  - Between complaint handling unit, investigating site, and local site
  - Request for follow-up information; Privacy issues
  - End users, customers, regulatory authorities
- Make it easy for auditors to read and understand complaint files, investigations, and reporting decisions
  - Record structure – goal is complaint file should be stand-alone;
  - Complaint summary and record closure
  - Periodic audits of complaint files
  - Reviews of source documentation e.g. service records, and outputs e.g. associated CAPAs, field actions etc.
  - Actions taken consistent and aligned with the objective data
- Sample and Device returns
  - Consistent policy on when to request device for investigation
  - Make it easy for customers and field to return device

Risk Analysis

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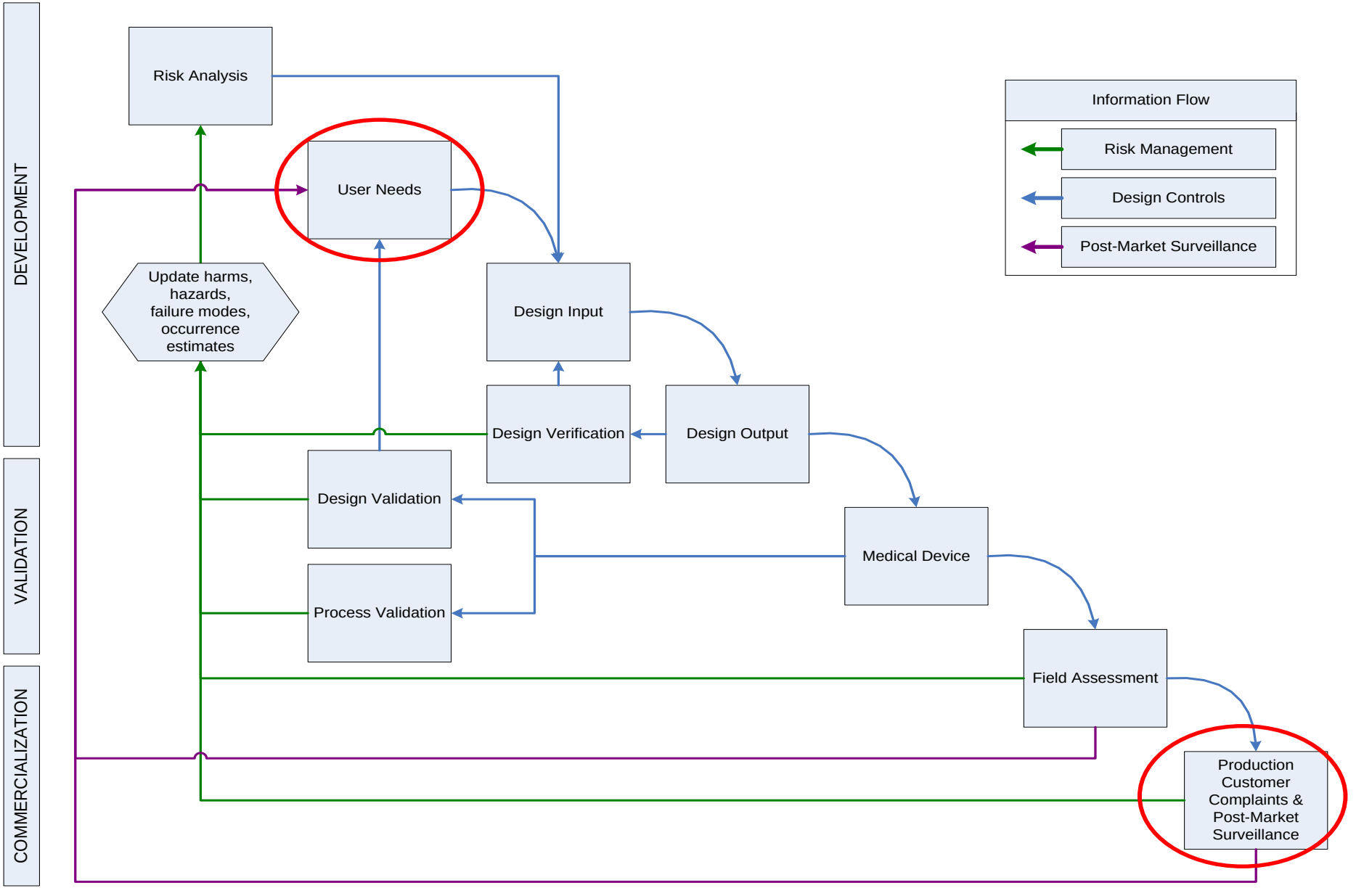

MDR Reporting Challenges

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- Conducting robust and timely investigations
- Timely reporting
- MDR Reportability
  - Adverse Events Occurring Outside the U.S.
  - Events from clinical trials
  - Events that are the result of user error; off-label use; abnormal use
  - Events that are within labeled frequency
  - Discontinued product
- Clear, consistent documentation

Vigilance Reporting Challenges

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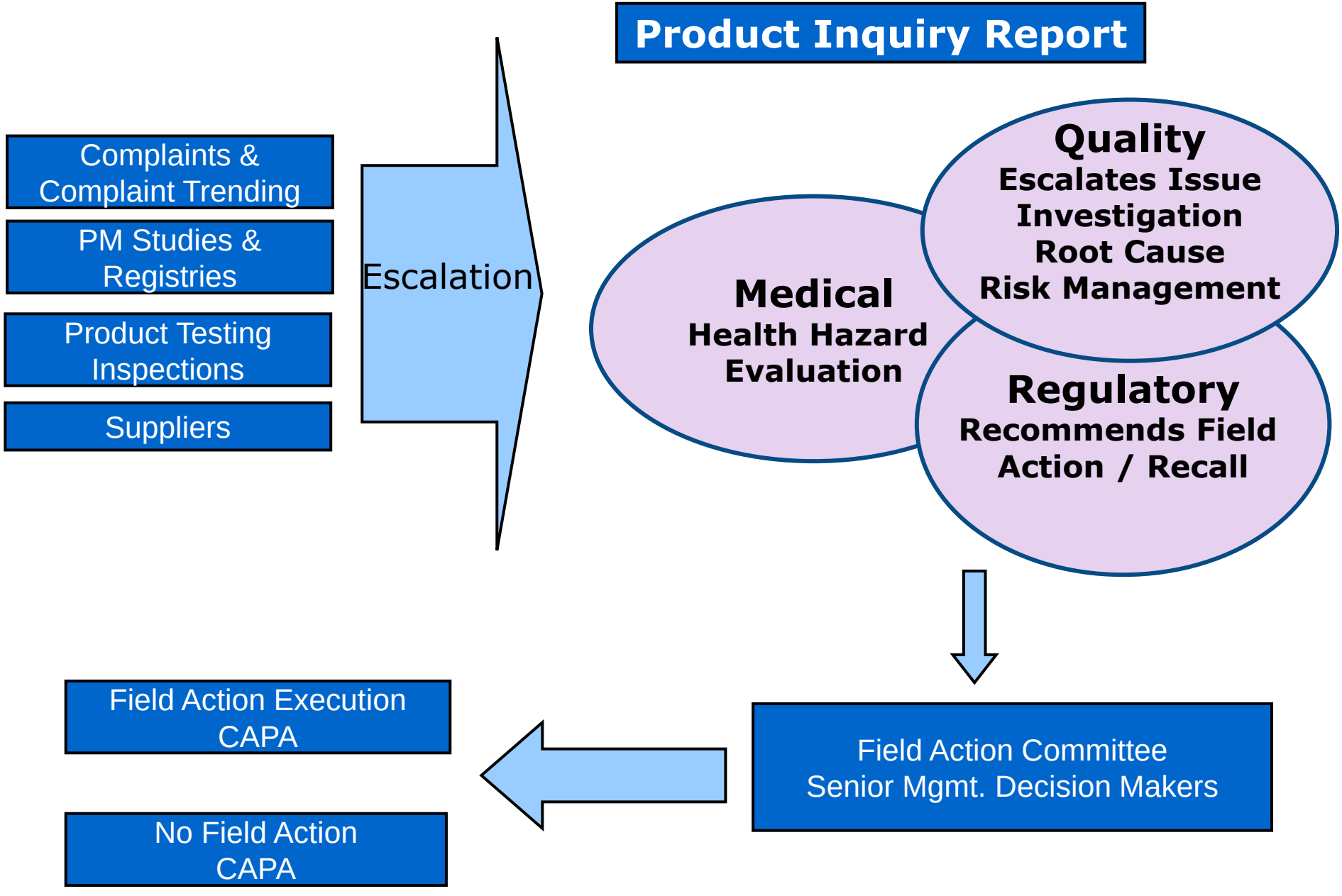
Challenges:

- Differing global regulatory requirements
- Timeframes for reporting differ by country and / or region
- Implementing MDD / EU / MEDDEV Requirements
- Field actions - Reliance on Affiliates, Distributors, 3'rd parties
- Maintaining accurate install base and product listing

Solutions:

- Use country-specific Decision trees and standard forms documenting reporting decision
  - Be aware of current and emerging regulations
  - Establish process for updating decision matrices and electronic systems
- Clarify authority to make reportabilty decisions at local / country level and ensure local / country personnel are adequately trained
- Local language and provisions for translation
- Ensure consistent record content

Action System & Outputs



Dissemination & Management Reviews

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Timely & Accurate information Exchange

Internal & External stakeholders:

- Site, Business Unit, Regional and Exec Management Reviews
- Local, Regional & Corporate quality boards
- Businesses; Manufacturing plants; R&D; Risk Mgt.
- Hospitals, Physicians, Patients
- US & Outside US Regulatory Agencies
- Suppliers, Distributors, other 3rd parties

Typical information disseminated/discussed:

- Serious AE; Reportable events; Trends
- System performance efficiency and effectiveness metrics
- Relevant CAPAs; Projects/initiatives
- Complaint investigations Status & Aging
- Industry trends and new/changing regulations
- User feedback
- Procedural changes/improvements

Post market surveillance System Monitoring

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Institute a systematic process for reviewing post market surveillance system and provide timely feedback

- System Efficiency Metrics
  - Late Regulatory Reports & Late Entered Complaints
    - Feeder to CAPA / NCE process
  - Complaint and Investigation Cycle Times vs. Targets
  - Complaint and Investigation Aging
  - Total Complaints & Investigations Entered and Closed
- System Effectiveness Metrics
  - Independent Review of Complaint Files and Documentation
    - Review MDR / MDV reportable and non-reportable decisions
    - Use queries and filters to identify files with high risk of incorrect decision e.g. patient harm codes with non-reportable decisions; MDV with no MDR;
    - Monitor results to identify if need for systemic fixes or additional training required
- Product Performance Metrics
  - Top 10 As Reported and As Analyzed Codes
  - Top Complaint Products
  - Unfavorable Trends

Best Practices - Effective Post market Surveillance

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1. *Establish procedures and systems to assure complaint information from all sources are entered into the complaint handling system within defined timeframes.*
   - Establish procedures and train all company employees and agents to recognize and report complaints within a defined timeframe

2. *Develop Tools to facilitate collection and documentation of comprehensive complaint information (e.g. product specific complaint questionnaires)*
   - Balance Patient-centric vs. Product-centric information collection

3. *Ensure MDR / MDV procedures and processes fully comply with regulatory requirements in all regions where products are marketed*
   - Balance information needed to report with timely decision-making; If in doubt report on-time and supplement when additional information is available.
   - Use decision trees and examples to facilitate consistent decision-making; What objective evidence supports the "non-reporting" decision?
   - Medical review and escalation process for safety issues and serious events & Assessment of various clinical scenarios: e.g.
     - Treatment/Therapy not achieved
     - Significance of delay in treatment
     - Medical Intervention
   - Leverage Risk Management information to aid in assessment and making reporting decisions.

QUESTIONS & DISCUSSION