Managing Product Risk from Cradle to Grave

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Learning Objectives

- Risk management basics
- A 5 element risk management strategy
- Various risk management concepts and techniques
- What we are learning
- Real life product recalls – Preventable?
  A look at two recent cases

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Background

World Leader - Market Driven Innovation & Science

Diverse Industries

Positioned to Help Solve Worlds Biggest Problems

Regulated Products

Risk Management Basics

Hazard Potential source of a Harm

- Texting while driving (TWD)

Harm Injury to people; Damage to property

- Auto accident; bodily injury

Risk Probability of harm X Severity of harm

- A near miss (no collision) vs. death

Accident resulting from TWD

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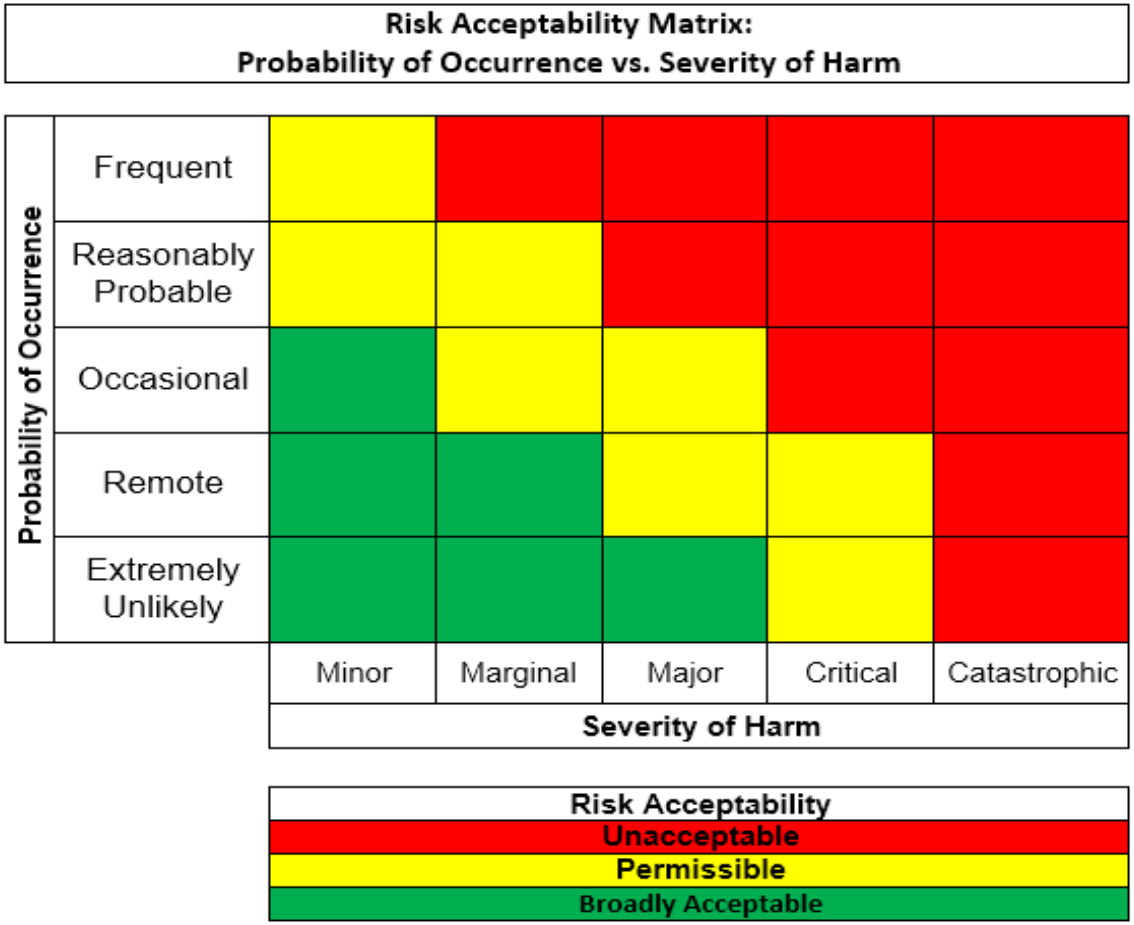
Risk Management Basics

Probability of Occurrence vs. Severity of Harm



Murphy's Law

Deceleration sled
Edwards Air Force Base 1949

"If anything can go wrong, it will"

Named after Capt. Edward A, Murphy, and engineer working on Air Force Project MX981 (a project designed to see how much sudden deceleration a person can stand in a crash).
http://www.murphys-laws.com/murphy/murphy-true.html

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Murphy's Law & Risk Management

"If anything can go wrong, it will"

Probability of occurrence

Potential hazards that can result in harm

A Risk Management Strategy

5 Element Risk Management

Product	• Product Development
Process	• Supply Chain
Business	• Worst Case Scenarios
Product Stewardship	• Safety, Health & Environment
Post Market	• Performance Indicators

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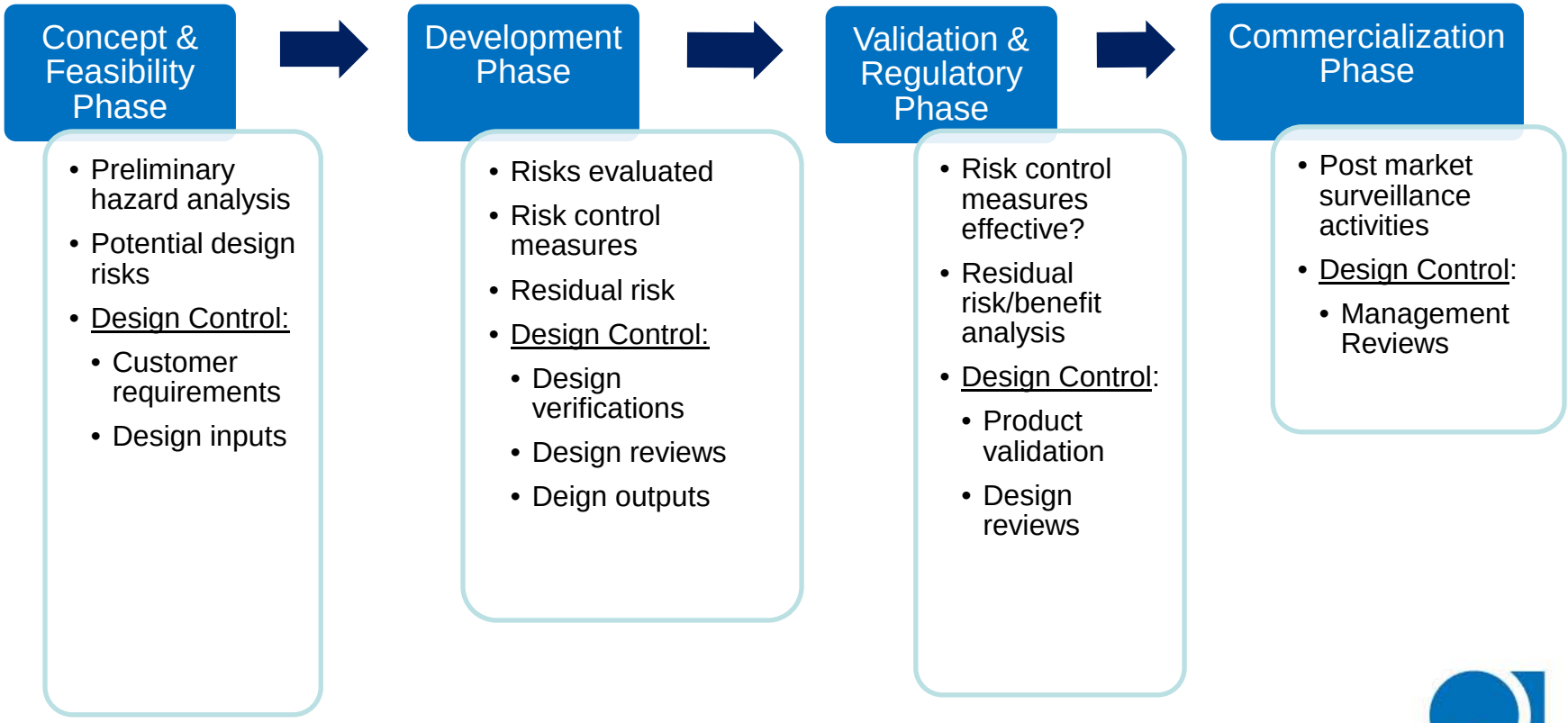
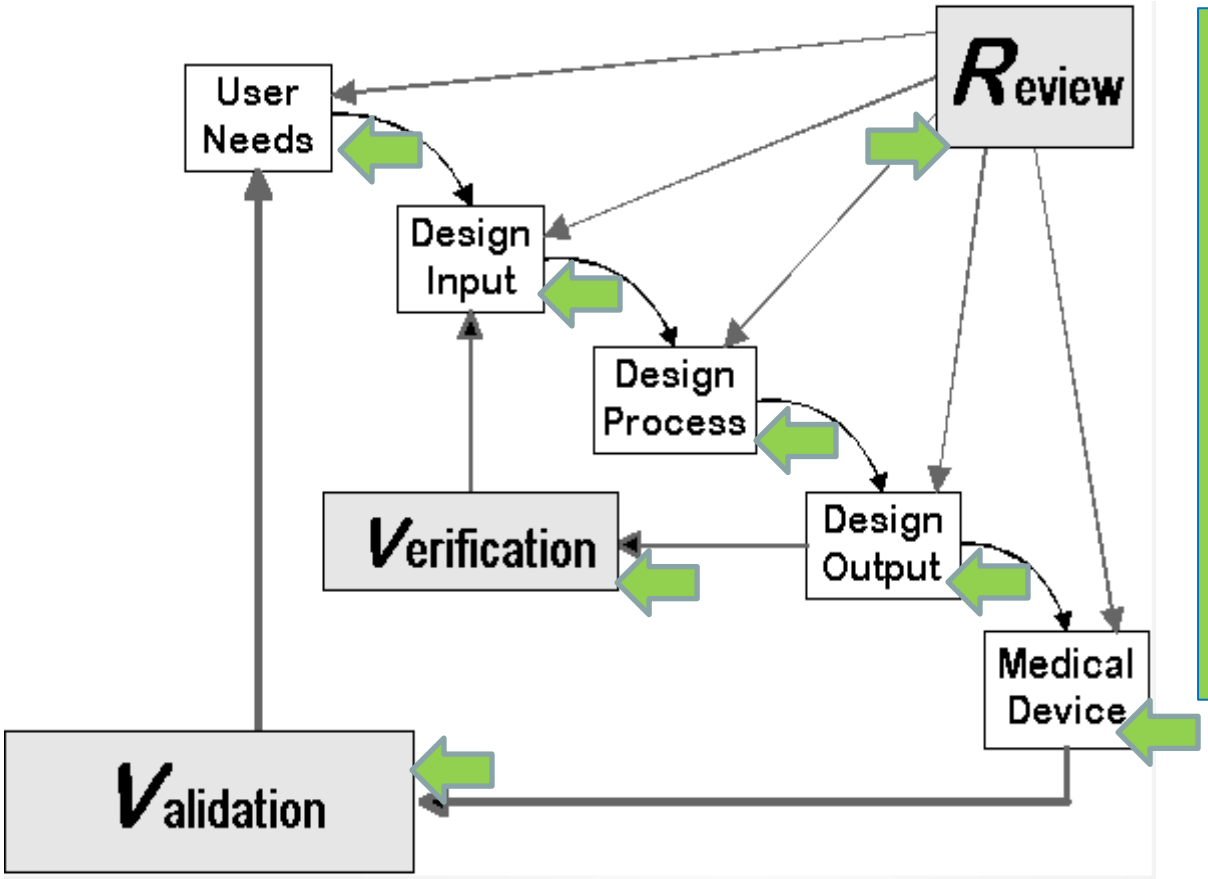
Product Risk Management

Stage/Phase gated product developed process utilized
Risk Mgt. workflow shows key RM and Design Control activities



Application of Risk Mgt.

Design Control Guidance For Medical Device Manufacturers



Potential Hazard

- identification
- analysis
- evaluation

applies during all phases of design control

This Guidance relates to FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001 March 11, 1997

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Risk Mgt. Tools Utilized

Potential Hazards Checklists	• Thought provoking queries • Used to identify potential design risks
Preliminary Hazard Analysis Checklists	• Identify, e.g. biological, energy, environmental, incorrect use, etc.
Preliminary Hazard Analysis Worksheets	• Potential failure modes? • Likely causes? System level effects? • Potential risk control measures?
Failure Modes & Effects Analysis	• Probability vs. Severity (SPN) • Detectable (RPN)

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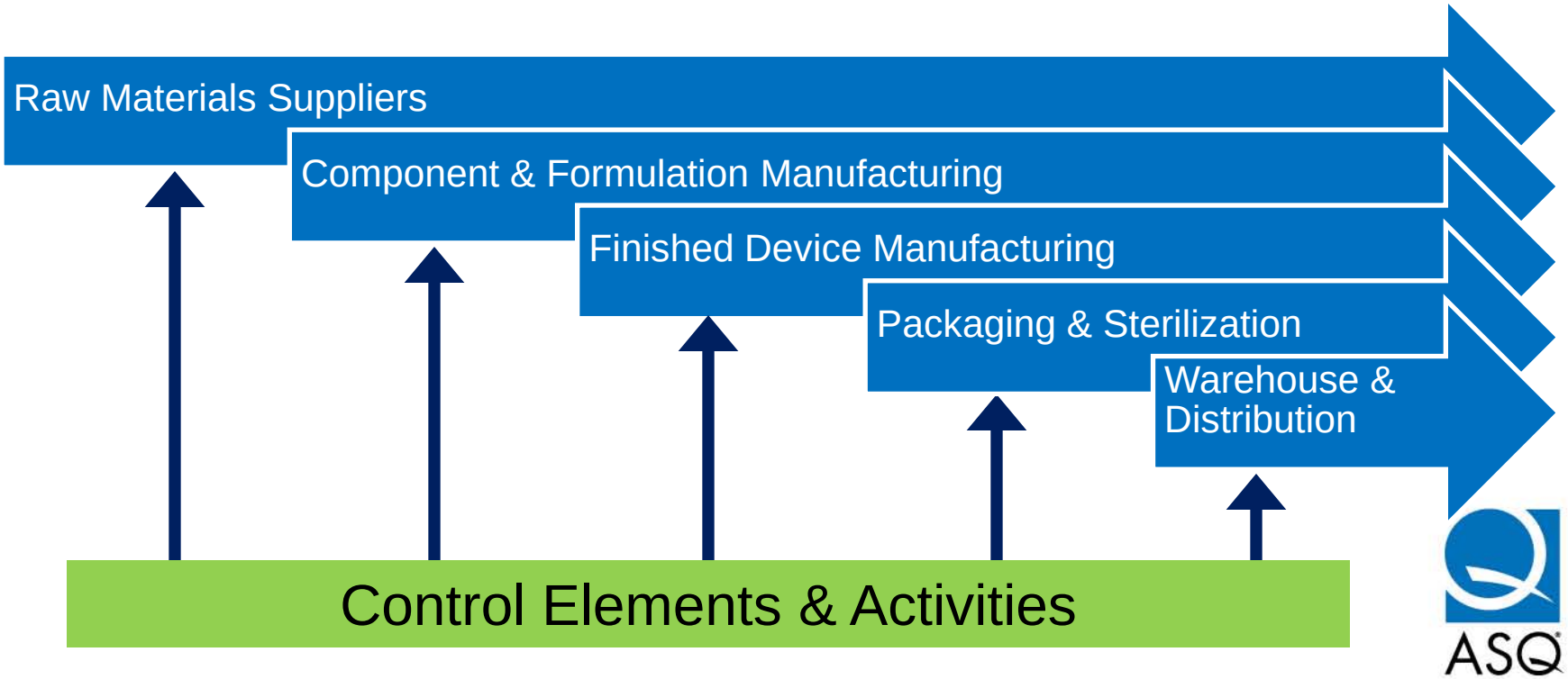
Process Risk Management

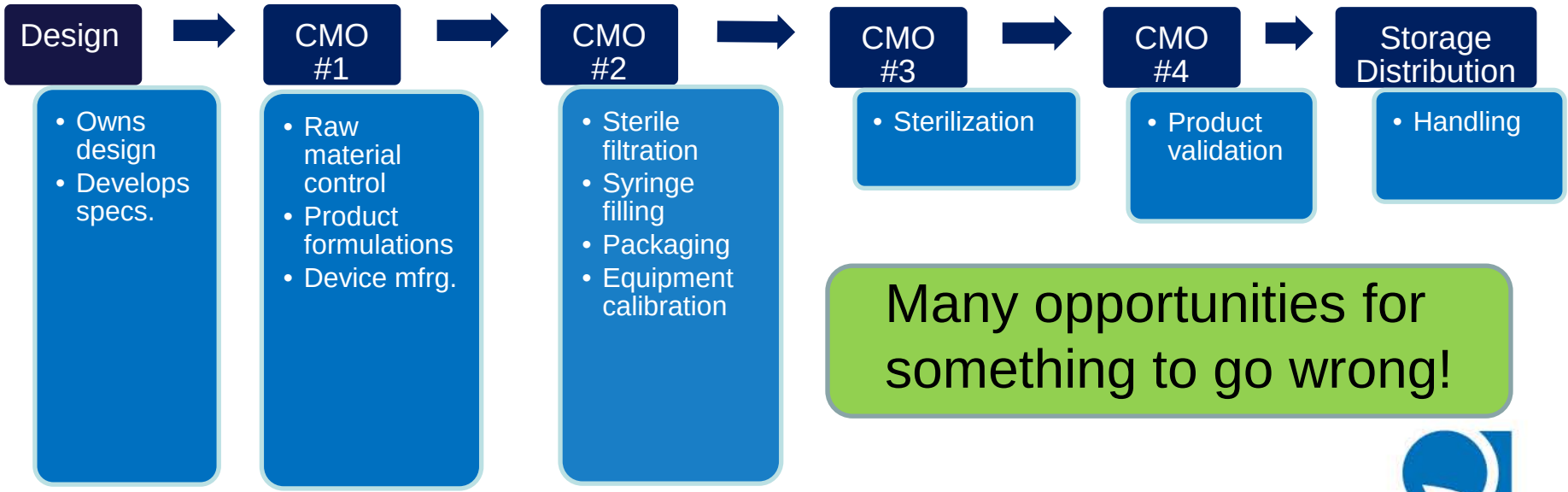
- Consider supply chain from raw materials to customer (and everything in between)
- All manufacturing in company owned plants/facilities?
- All production at contract manufacturing organizations?



Process Risk Management

A supply chain example:

- ✓ Product designed and developed by small start-up
- ✓ Manufacturing outsourced to Contract Mfrg. Orgs.
- ✓ Small start-up needs to ensure I/O to CMOs controlled



Many opportunities for something to go wrong!

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Business Risk Management

Consists of:

- Scenario planning: Identification and assessment
- Provide awareness of risks
- Likelihood of occurrence
- Degree of potential impact on strategic objectives
- Identification of mitigation and control actions

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Business Risk Management

Examples of scenario contingency planning

Risk Category	Scenario Planning
Product Development	• Unable to meet requirements • Final product too expensive vs. business plan
Supply Chain	• Single source suppliers • Unable to meet sustainability requirements • Out of spec product not detected by QA/QC
Registration & Compliance	• Delays in country specific registrations • Clinical trials shows product unsafe and ineffective • Unable to obtain quality system certifications
Marketing & Sales	• Increased competition • Product liability claims

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Business Risk Management

Qualitative analysis of various scenarios

Likelihood of Occurrence (Remote → Probable)	Impact ($) → ($$$$)	Exposure	Priority Risk	Response	Risk Response Details
Very Low Low Medium High Very High	Very Low Low Medium High Very High	Low Medium High	No Yes	Reduce Accept	Actions indicated for each scenario.

Exposure = Impact X Likelihood of Occurrence.

Priority Risk and Response determined by management and project teams

All scenarios reexamined throughout product development

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Product Stewardship Risk Management

Product Stewardship is:

- Management of product throughout its life cycle
- Focus on health, safety and environmental issues
- Requires good communication among all team members
- Work with customers to develop risk management actions
- Address emerging needs, e.g. training, web

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Product Stewardship Risk Management

Considerations throughout the lifecycle of a medical device

Examples of Product Stewardship Considerations
• Product trail
• New hazard identification & characterization
• Product composition
• Physical hazards
• Human toxicity hazards & effects
• Environmental effects & impact
• Shipping & storage requirements
• Import & export controls
• Packaging & labeling concerns

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Post Market Surveillance

Examination of commercial product performance

A regulatory requirement for medical devices

A key element of continual improvement practices

PMS assessment outputs:

- Discussed at Management Reviews
- Compared against previous risk assessments
- Mitigation actions effective? (Y/N)
- New or potential hazards identified? (Y/N)

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Post Market Surveillance

Examples of Sources (Input) to PMS Reviews Include:
• Follow-up actions from earlier PMS reviews
• Known manufacturing problems
• Product quality improvements
• Changes to risk analysis
• Knowledge of changing performance trends
• Feedback on indications of use; instructions for use
• Feedback on customer satisfaction
• Vigilance reports
• Knowledge of ways in which is misused
• Feedback on continuing market viability

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What Are We Learning?

- Risk Management is a continuous process (Post Market Surveillance)
- Significant time in early stages required to design out potential hazards
- Unintended events (harms) will occur
- Risk Management • • • ••• • • • • • [1]
- Competing, overlapping risks identified among the 5 elements in this strategy

[1]The Growth of Risk Management

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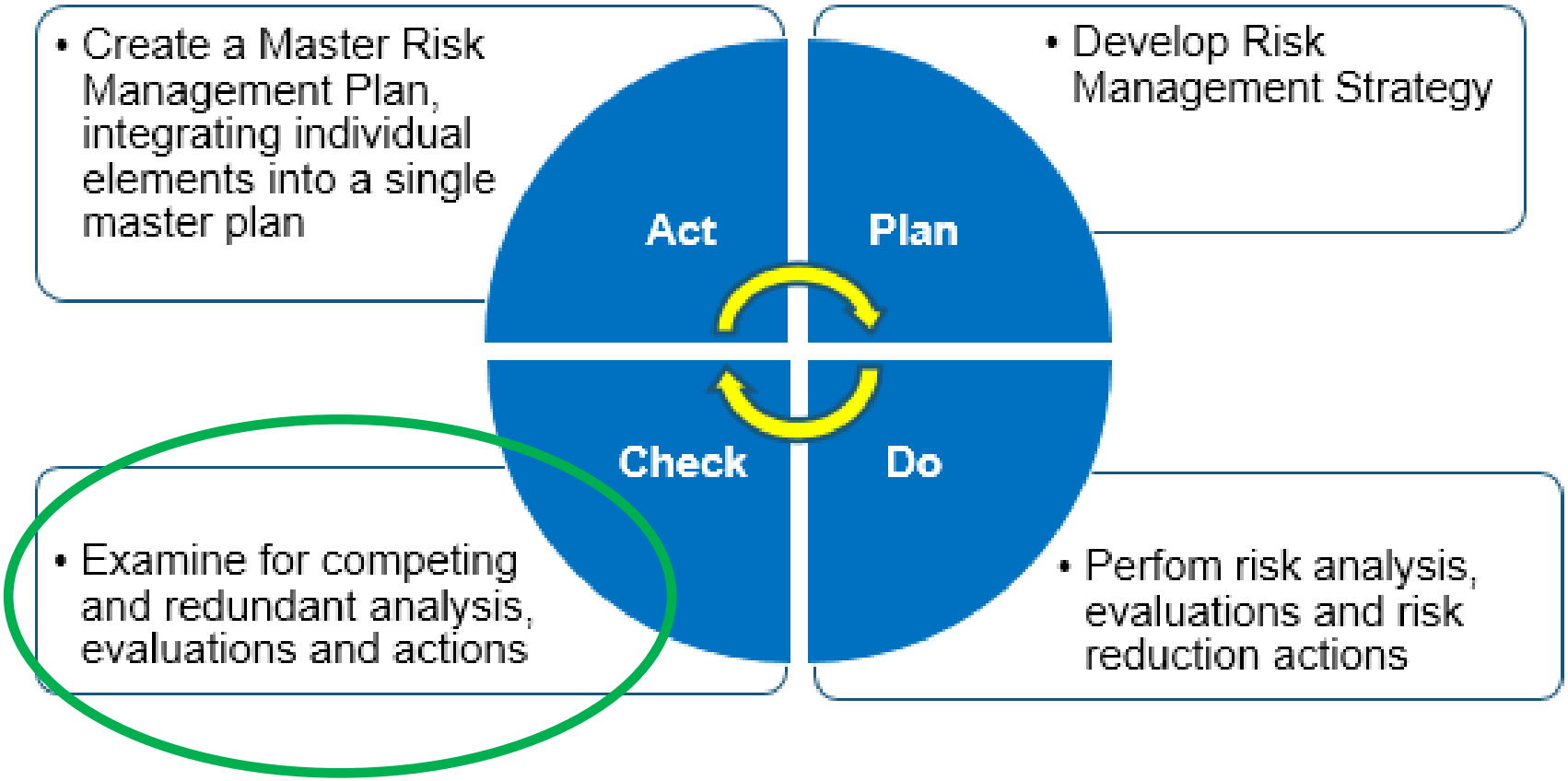
Check: Where to Improve?



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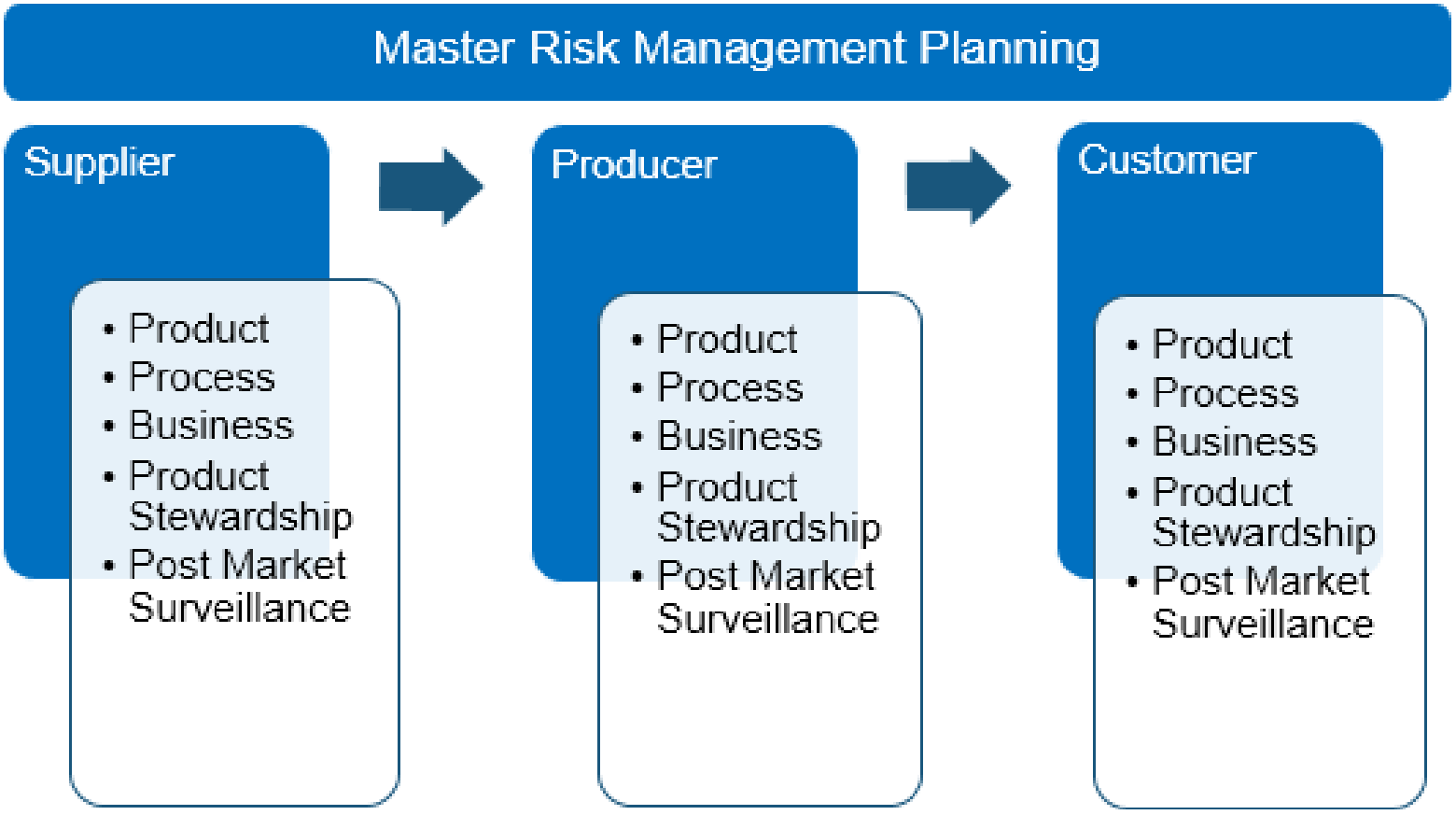
Act: Process Improvements

- Create a Master Risk Management Plan
- Integrate 5 elements into each supply chain operation
  - ✓ To eliminate redundant, overlapping, competing analysis



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Real Life Product Recalls

Two recent cases

Were they preventable?

You decide! (Monday morning risk management)

Sources:

U.S. Food and Drug Administration (FDA)
Recalls, Market Withdrawals & Safety Alerts
http://www.fda.gov/Safety/Recalls/default.htm

For Further Information ….

Please see technical paper available on the 2014 WCQI web site and in the ASQ Knowledge Center

Managing Product Risk from Cradle to Grave;
Application of Risk Management in the Development of Medical Devices

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Summary

A Risk Management strategy was developed for a DuPont business dedicated to the development of medical devices. This strategy took into consideration five different forms of risk: Risk associated with product development, risk associated with the manufacturing process, risk associated with business scenarios, risk associated with stewardship of the product and risk associated with post-market surveillance.

Keywords

Risk management; Product development; ISO 14971:2007; ISO 13485:2003; Medical devices

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Questions?

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