Risk Management
Current Thinking and Experiences

Medical Device Industry 2011

Orla Connaughton connaughton.orla@gmail.com

Current Thinking

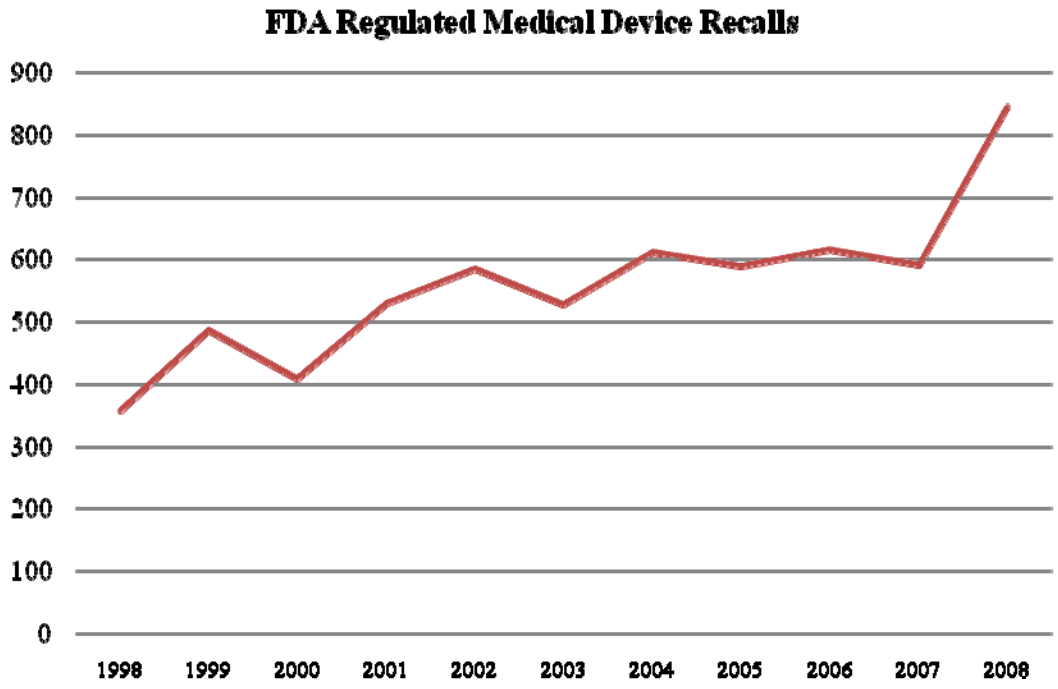
- **Sastri (2005) specified that a "structured, flexible new product development process that facilitates speed to market, reduces product development cycle times, *manages risks*, and delivers products that meet the requirements of customers and the market place enhances the probability of product launch success".**
- **Brown (2010) suggests that "Effective risk management is your best shield from lawsuits". ..."Effective risk management saves money in at least three ways: It reduces corporate liability insurance costs, reduces failure rates, and improves your customer satisfaction".**

Current Thinking

- As well as adhering to ISO 14971, Narayan and Prutow (2010) recognize that robustness in other fundamental areas are key to "maximize benefit and minimize risk"
  - Integrated processes: links to (CAPA) and management review processes, systems, and procedures. Such integration allows companies to prioritize continuous improvement activities, improve customer satisfaction, and sustain long-run profitability—maximizing results while minimizing risk.
  - Robust governance: Management must also play a strong role in ensuring the proper governance of risk management processes and drive company-wide risk control measures; ... establish and monitor sensible metrics to measure process effectiveness.
  - Cross-functional involvement
  - Adequate and appropriate resources and tools

Current Thinking

- **There are ~ 85,000 device problems reported to the FDA annually (FDA, 2010).**



Current Thinking

- **The three primary reasons for device problems and recalls are:**
  - **design defect**
  - **manufacturing defect**
  - **misuse of the device**
- **Numerous studies and publications show that these three root causes were directly linked to poor risk analysis. James (2008).**
- **FDA has dramatically increased its scrutiny of the product risk management practices, demanding adherence to the current standard, ISO 14971. (Brown 2010)**

Data Source

Research Thesis for Masters in Science Degree in Technology Management

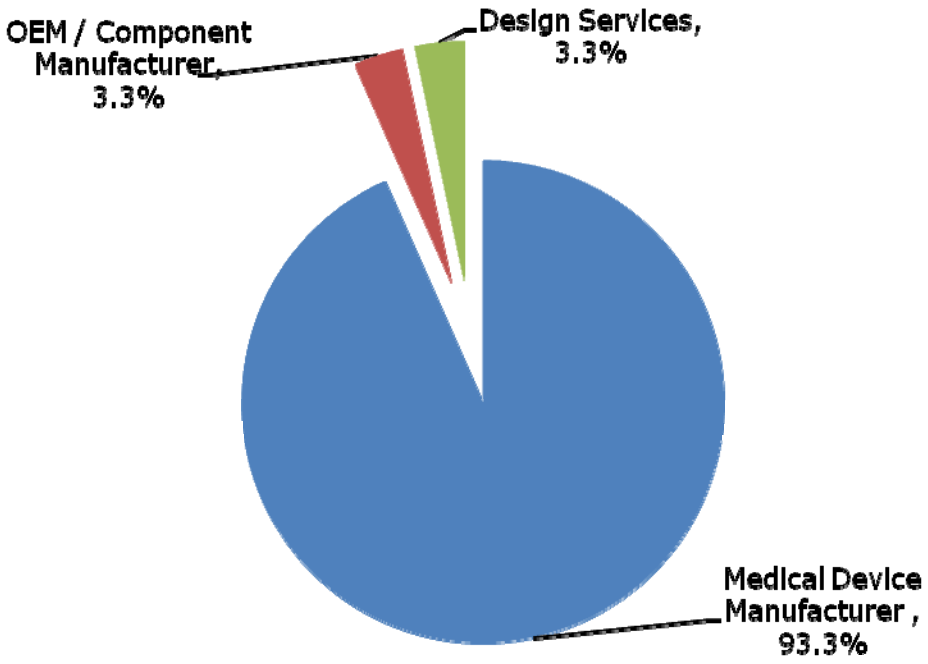
by Caitriona Conneely

“Assessing the Use of Risk Management in the New Product Development of Medical Devices”

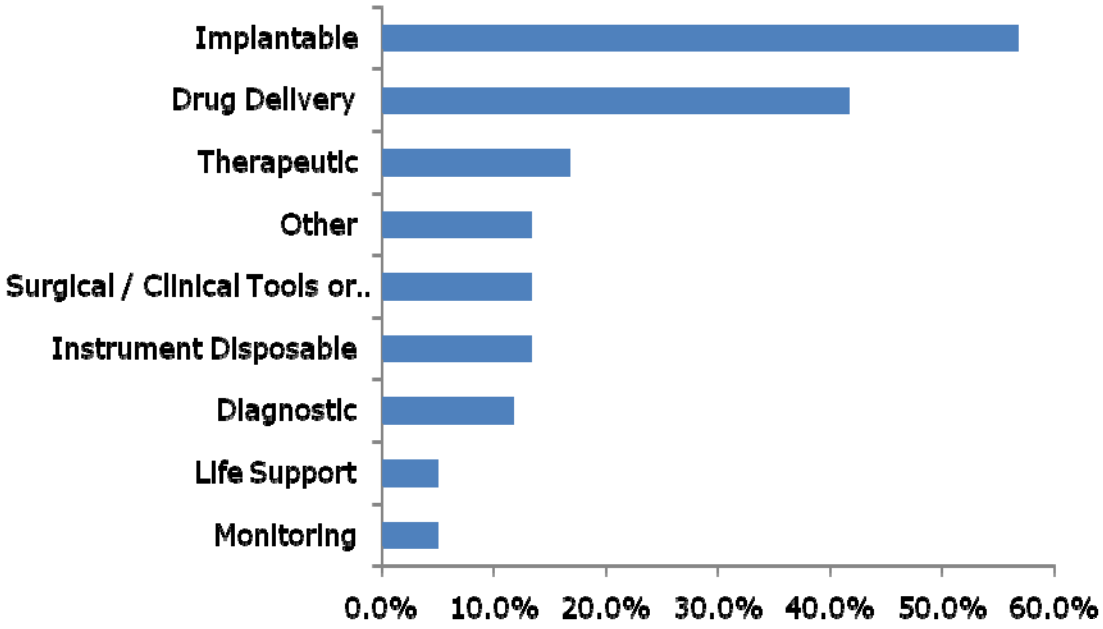
Scope of Research

- **16 medical device companies participated:**
  - **Small (<50 employees): 6**
  - **Medium (50-250 employees): 4**
  - **Large (250+ employees): 6**
- **60 participants responded from the 16 companies**
- **10 follow up interviews were conducted**
- **Diverse range of functional groups responded:**
  - **Engineering**
  - **R&D; product and process**
  - **Quality including Design Assurance**
  - **Regulatory and Clinical**
  - **Manufacturing and Operations**

Type of Company



Nature of Device



Research Questions

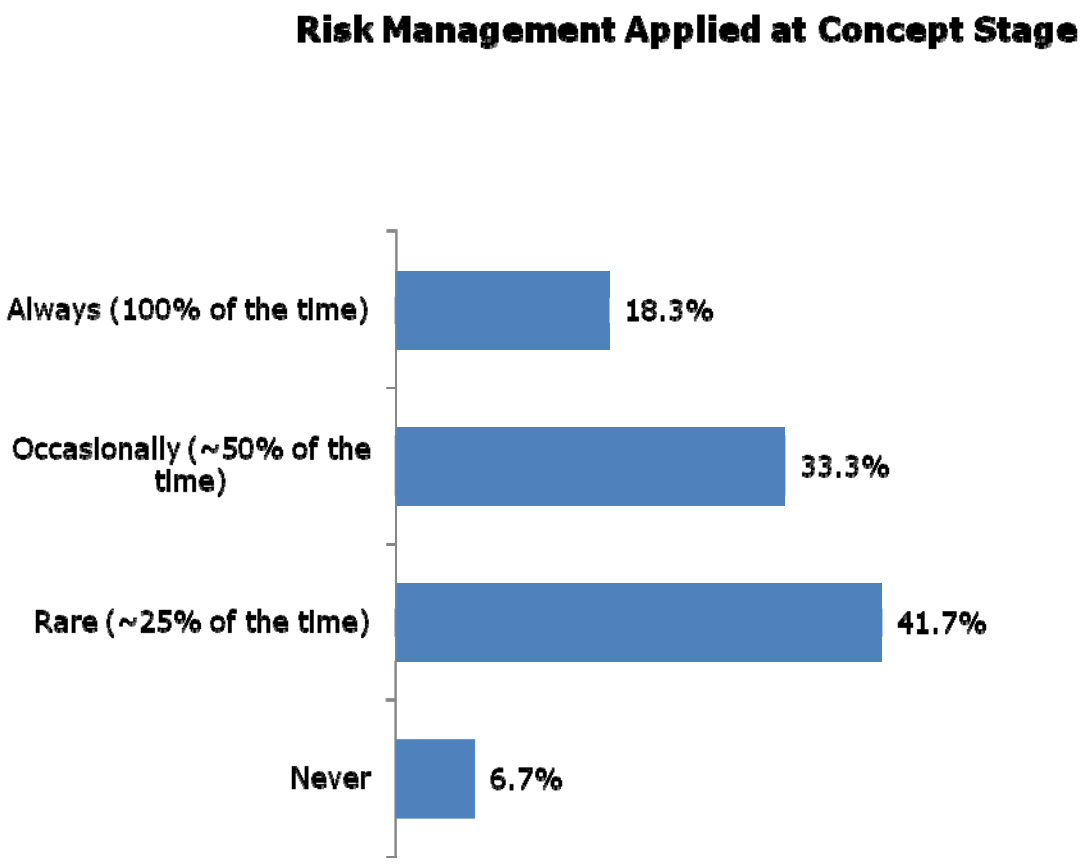
- **Four primary research questions**
  - **Level of compliance with ISO 14971**
  - **Factors which influence the level of risk management activities**
  - **Risk Management: Best Practice**
  - **Risk Management: Views, Perception, Culture and Leadership**

- **All organisations were operating to ISO 14971**

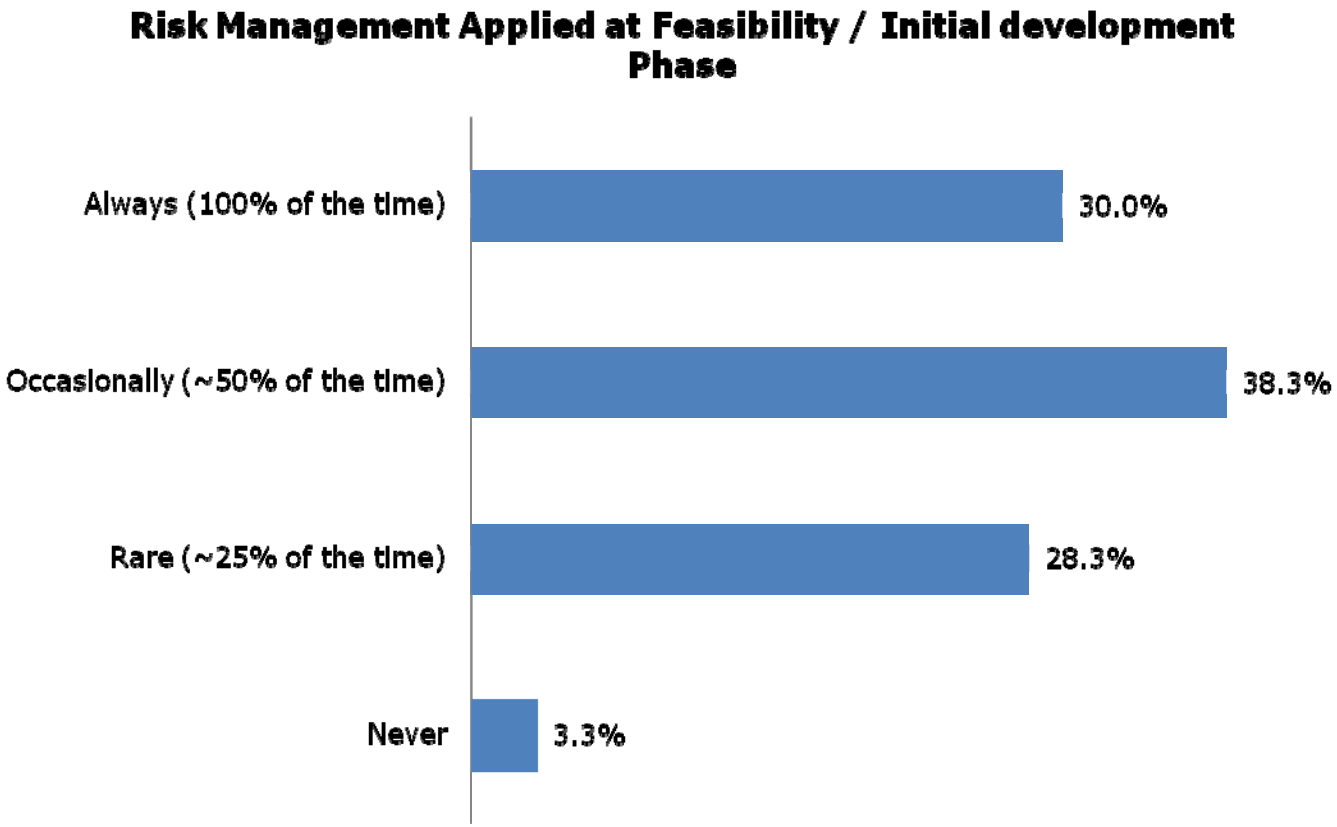
Compliance to ISO 14971

- What level of RM is being applied at each stage of the NPD process?
- Is RM used for root cause analysis?
- Is RM used to determine patient/user risk when assessing customer complaints?
- Are RM documents being kept alive? – updated immediately upon recognition of a new hazard, risk etc?
- Are RM activities being performed by a cross functional team?
- What RM tools are being used to assess risk?

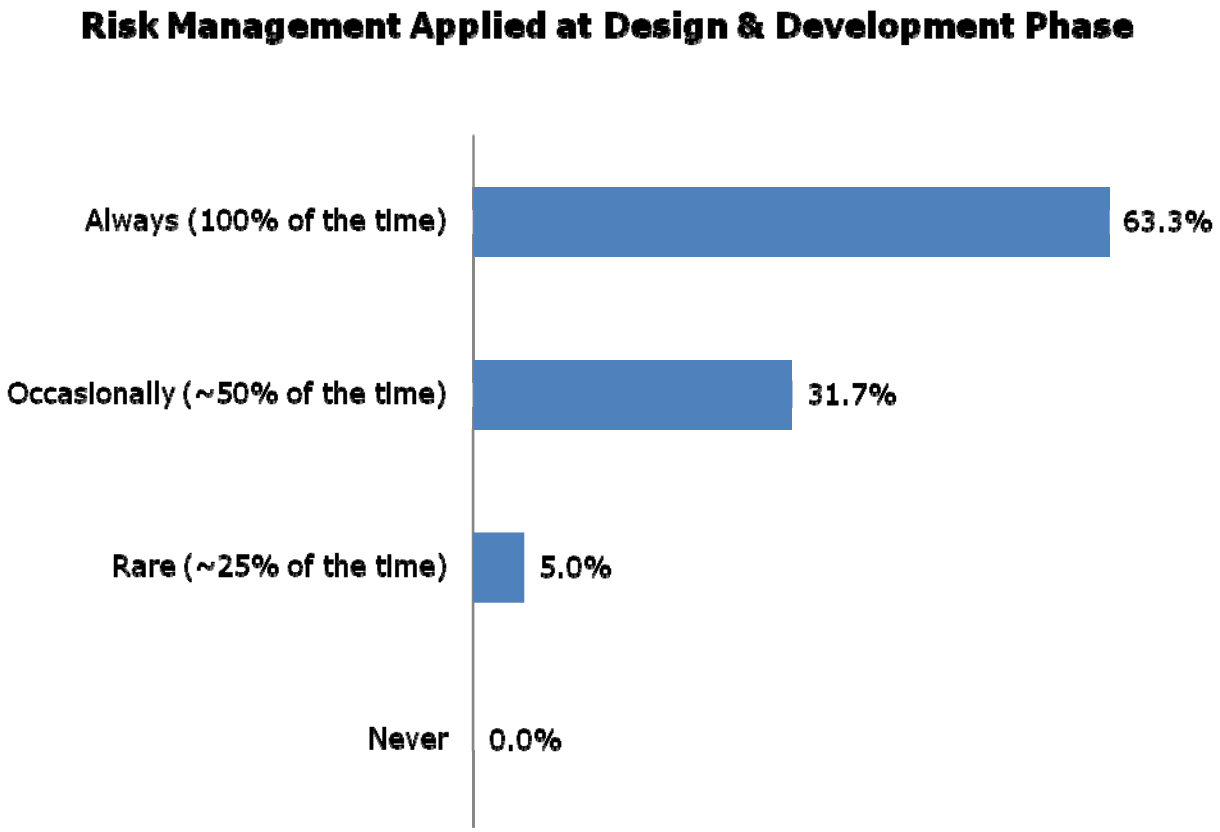
Concept Phase



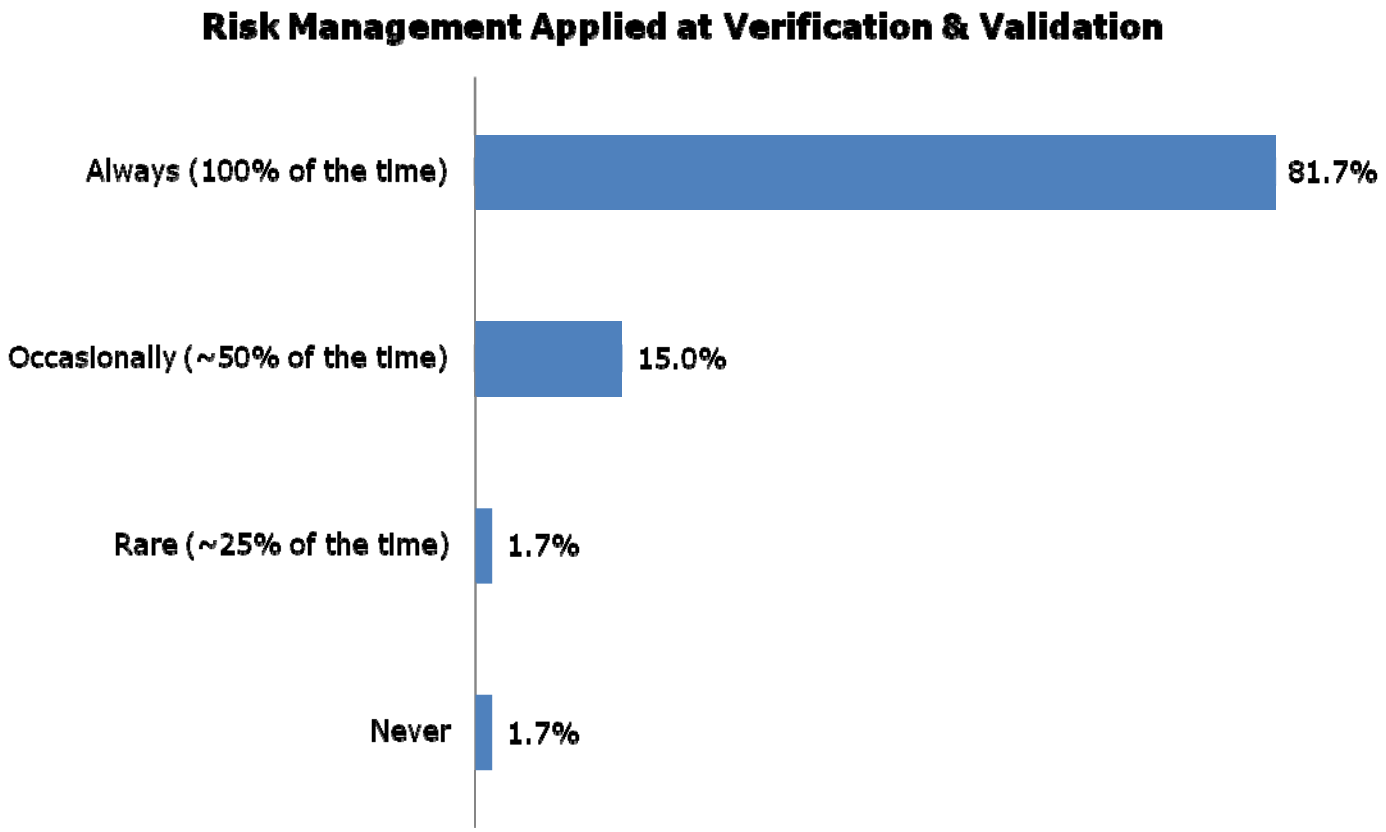
Feasibility Phase



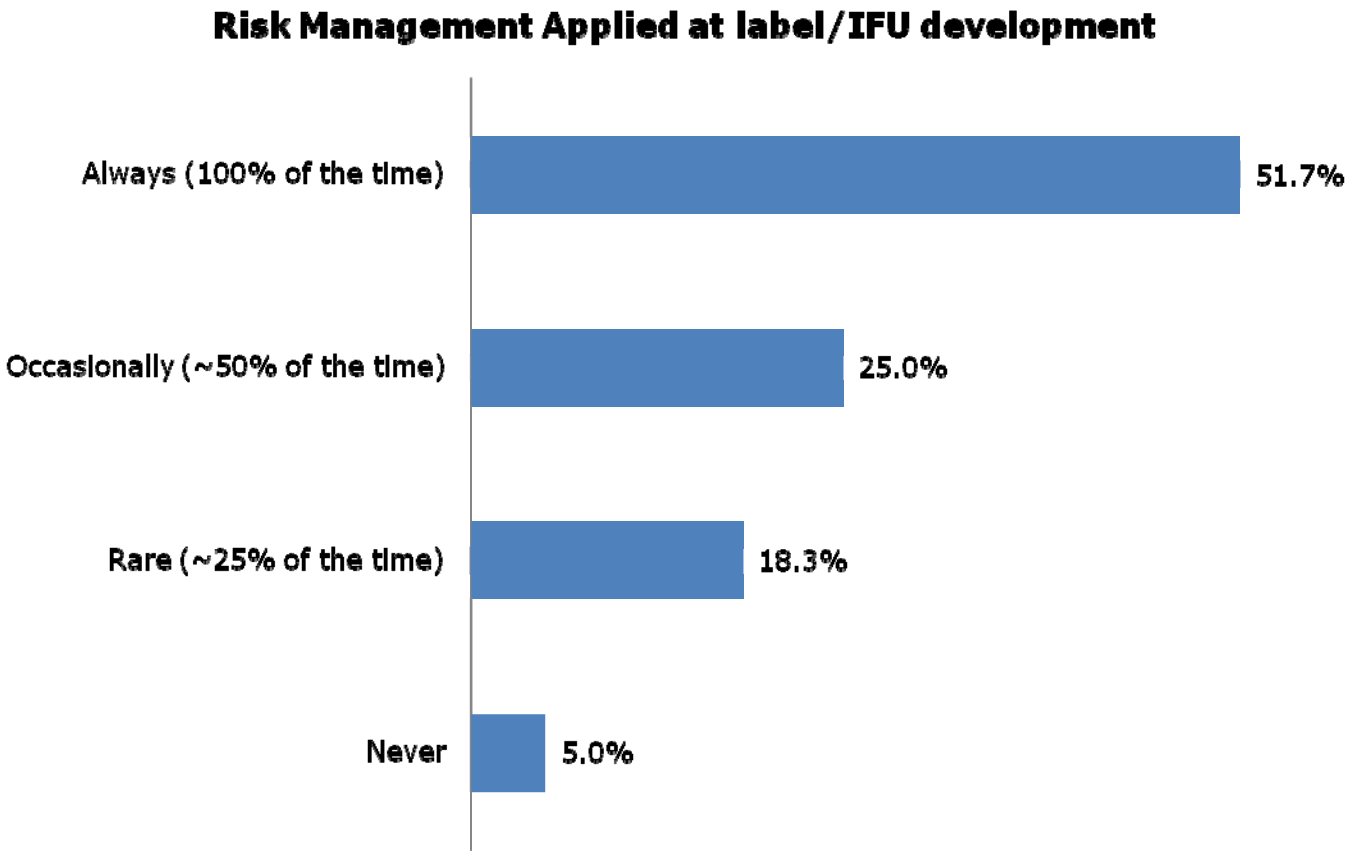
Design Development Phase



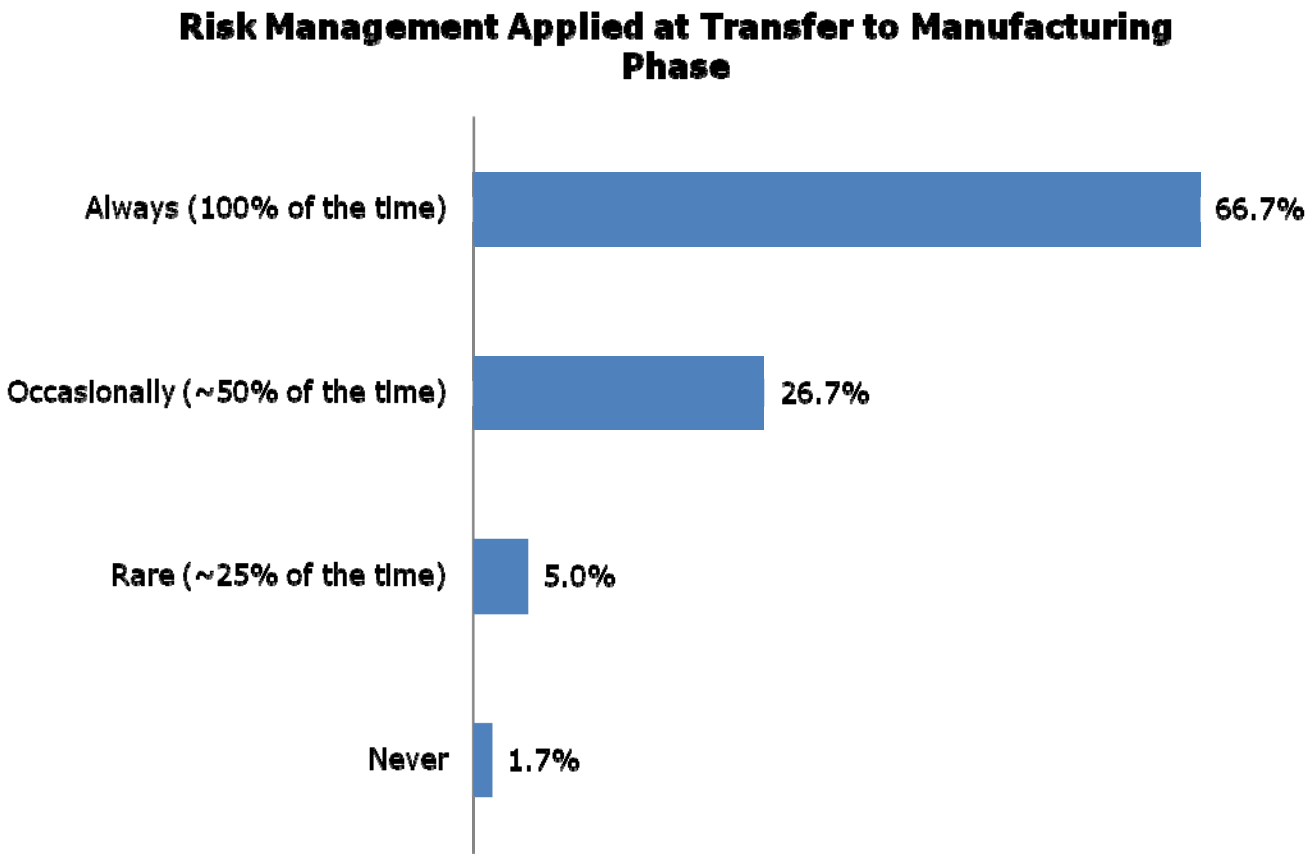
Verification / Validation Phase



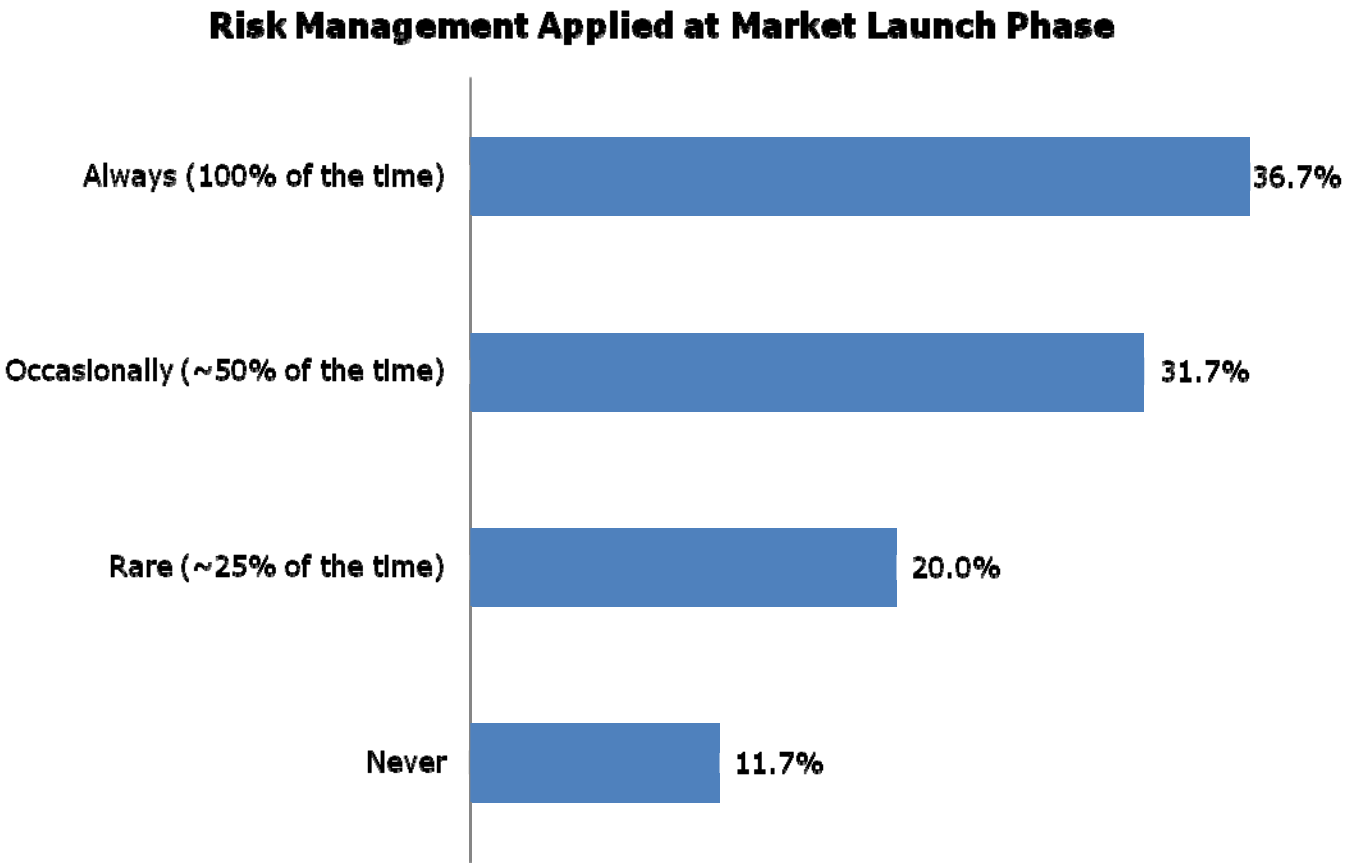
Label Design Phase



Transfer to Manufacturing Phase

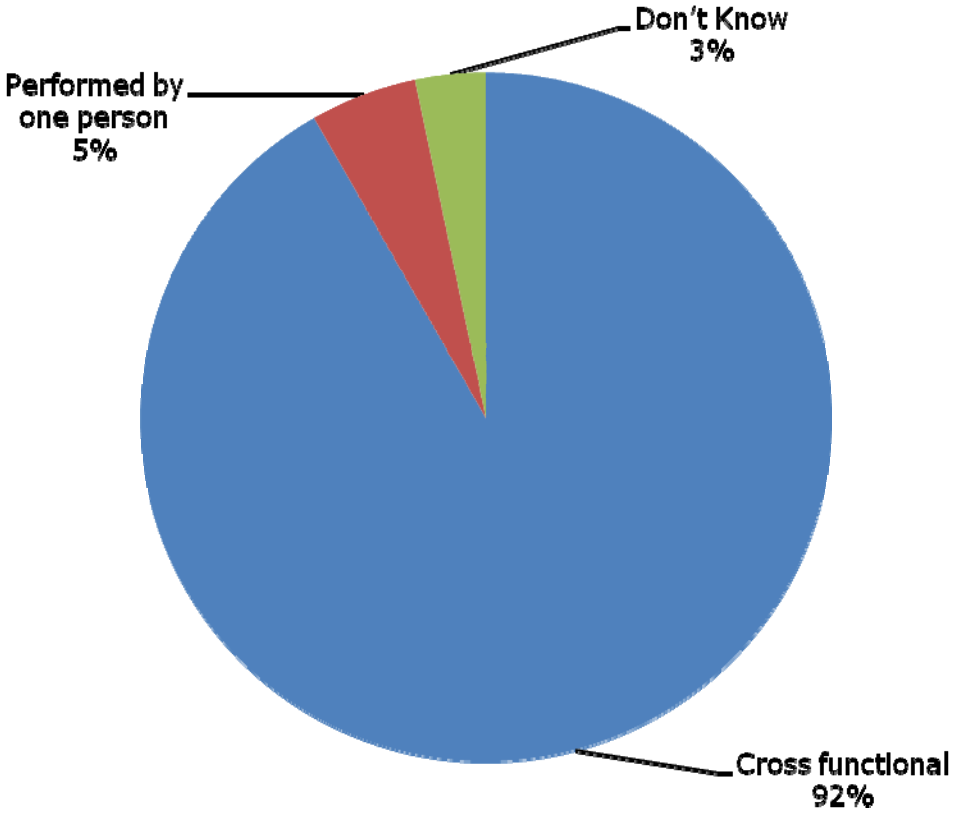


Market Launch Phase

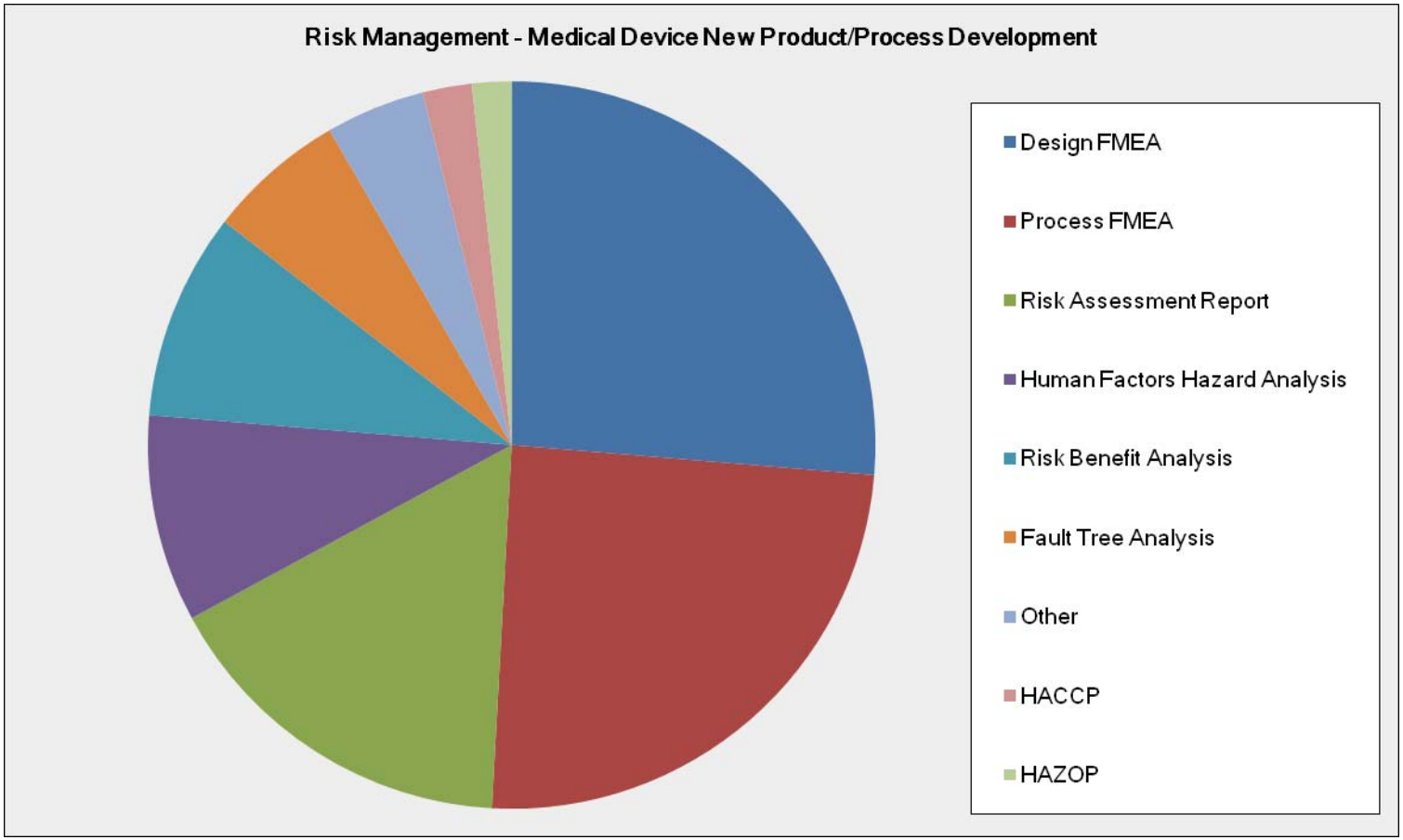


Live Documents?

Who performs RM?



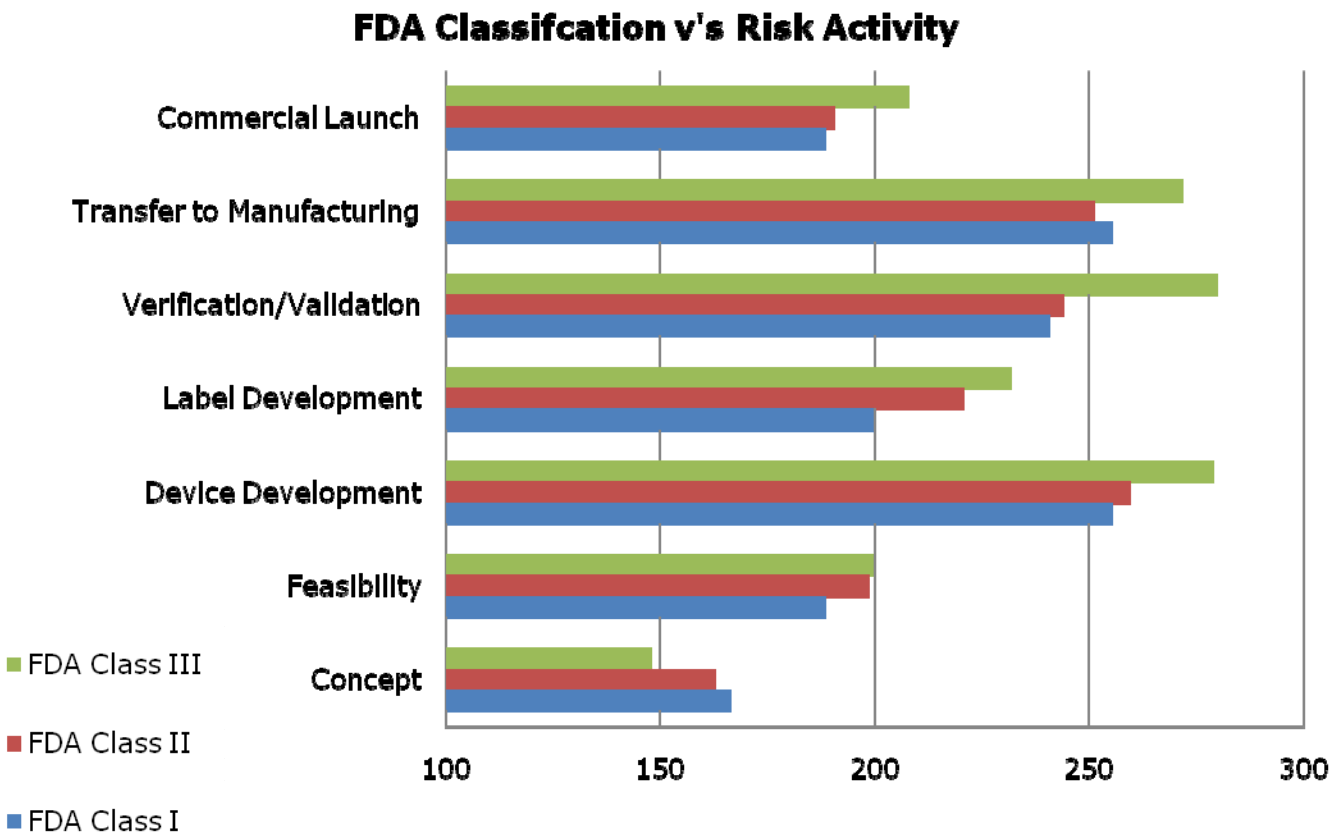
Most common RM Tools



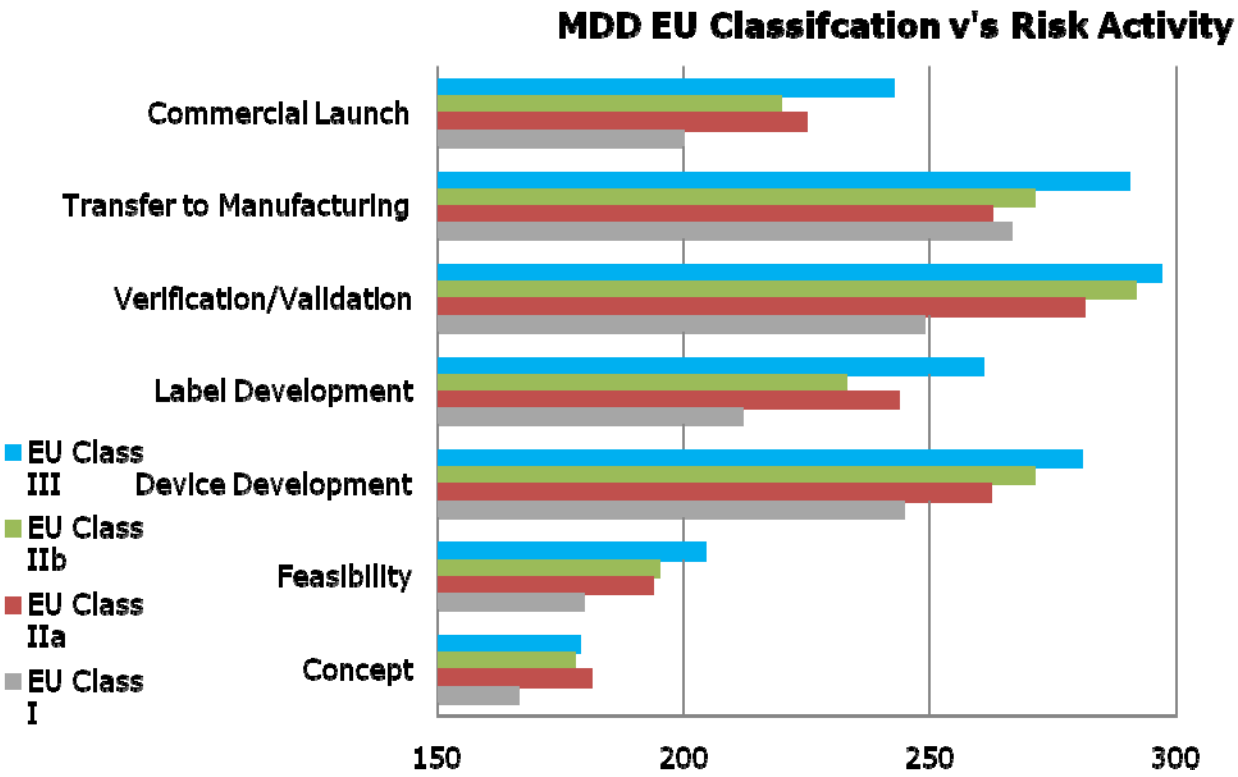
Factors Influencing Level of RM Activities

- **Is the level of RM activities dependent on the following factors?**
  - **Device Classification**
  - **Company Demographics**
  - **New product v Modification of existing device**
  - **Device user competence**
- **Is there a relationship between the rate of customer complaints and the level of RM applied to that product?**

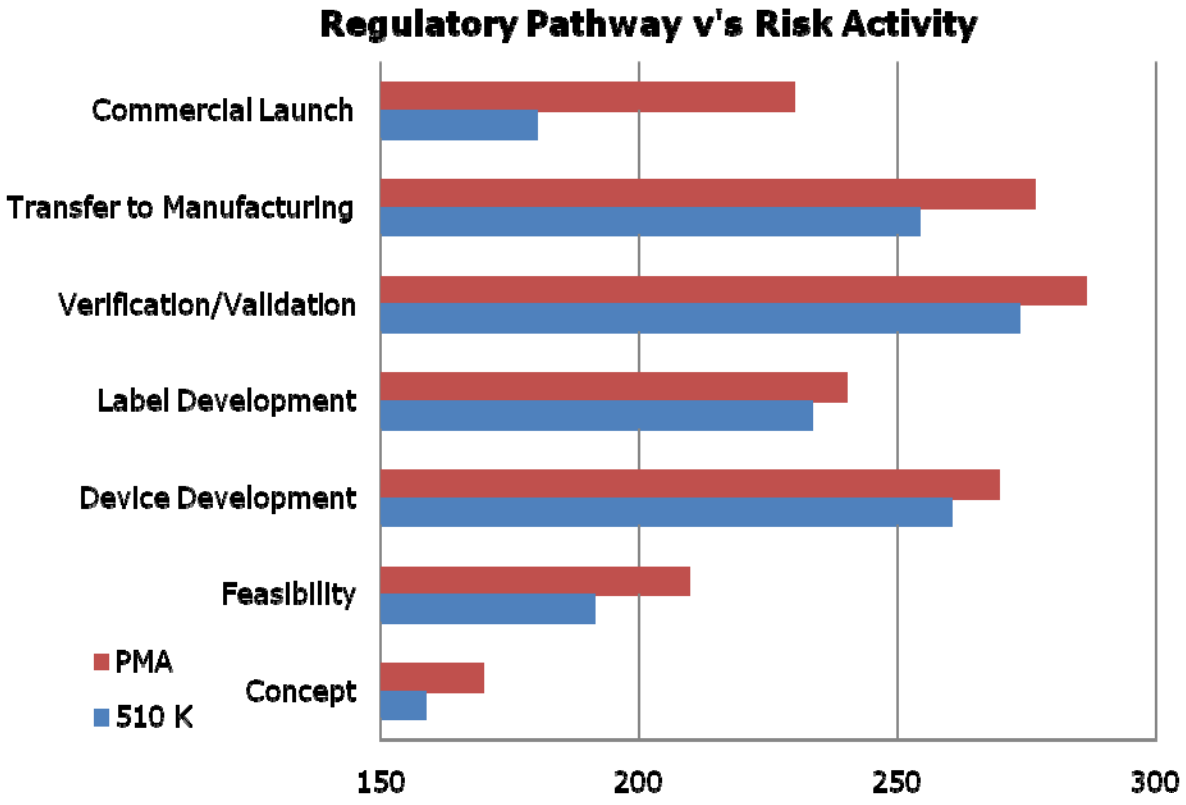
FDA Regulatory Class of Device



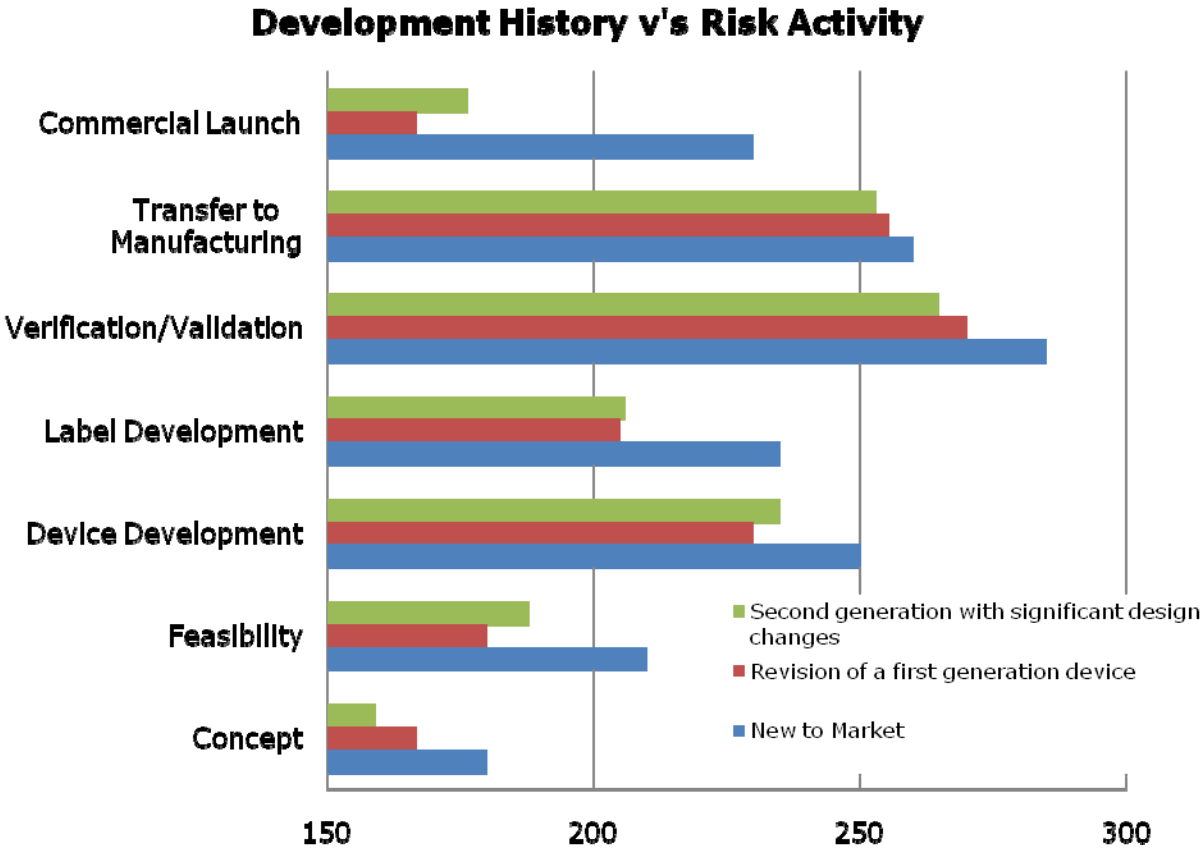
EU Regulatory Class of Device



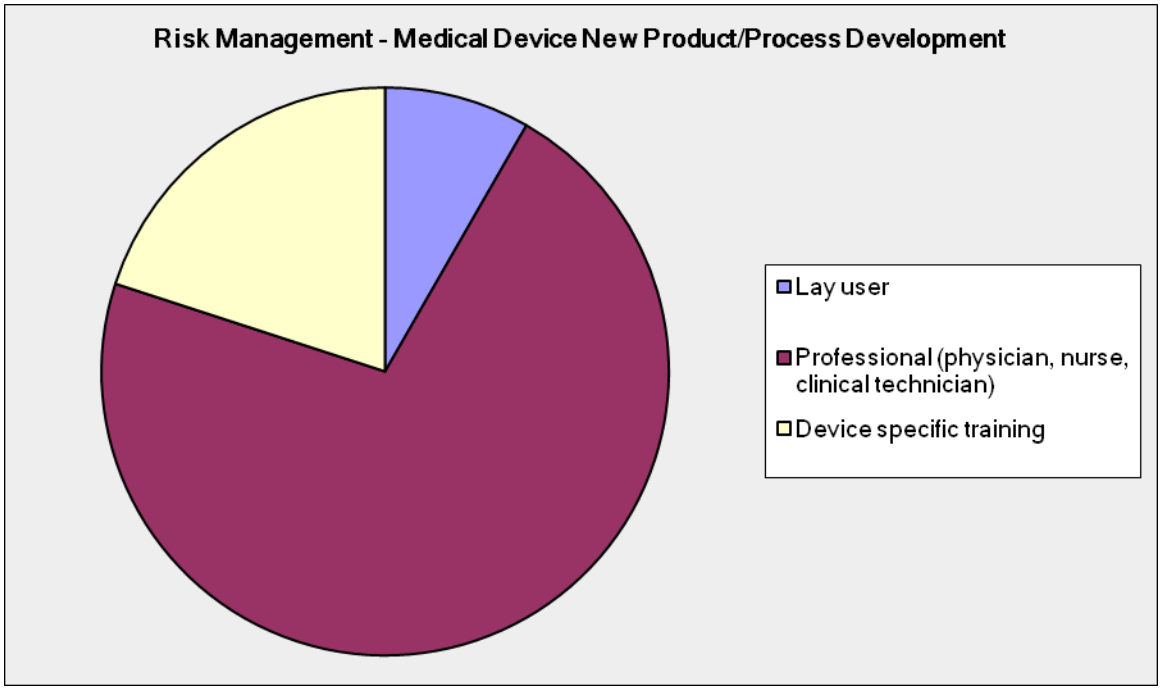
Regulatory Pathway



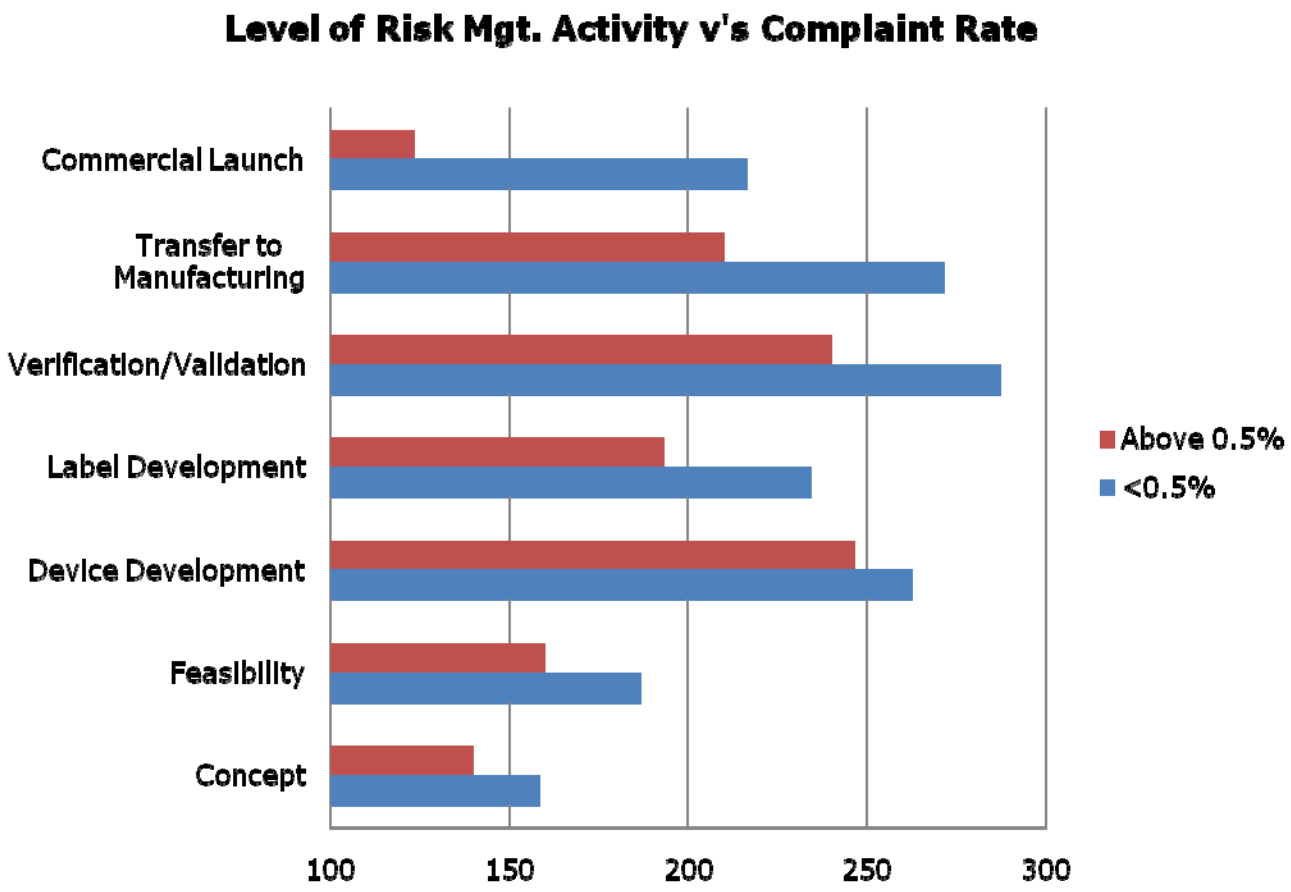
Stage of Product Lifecycle current product is at



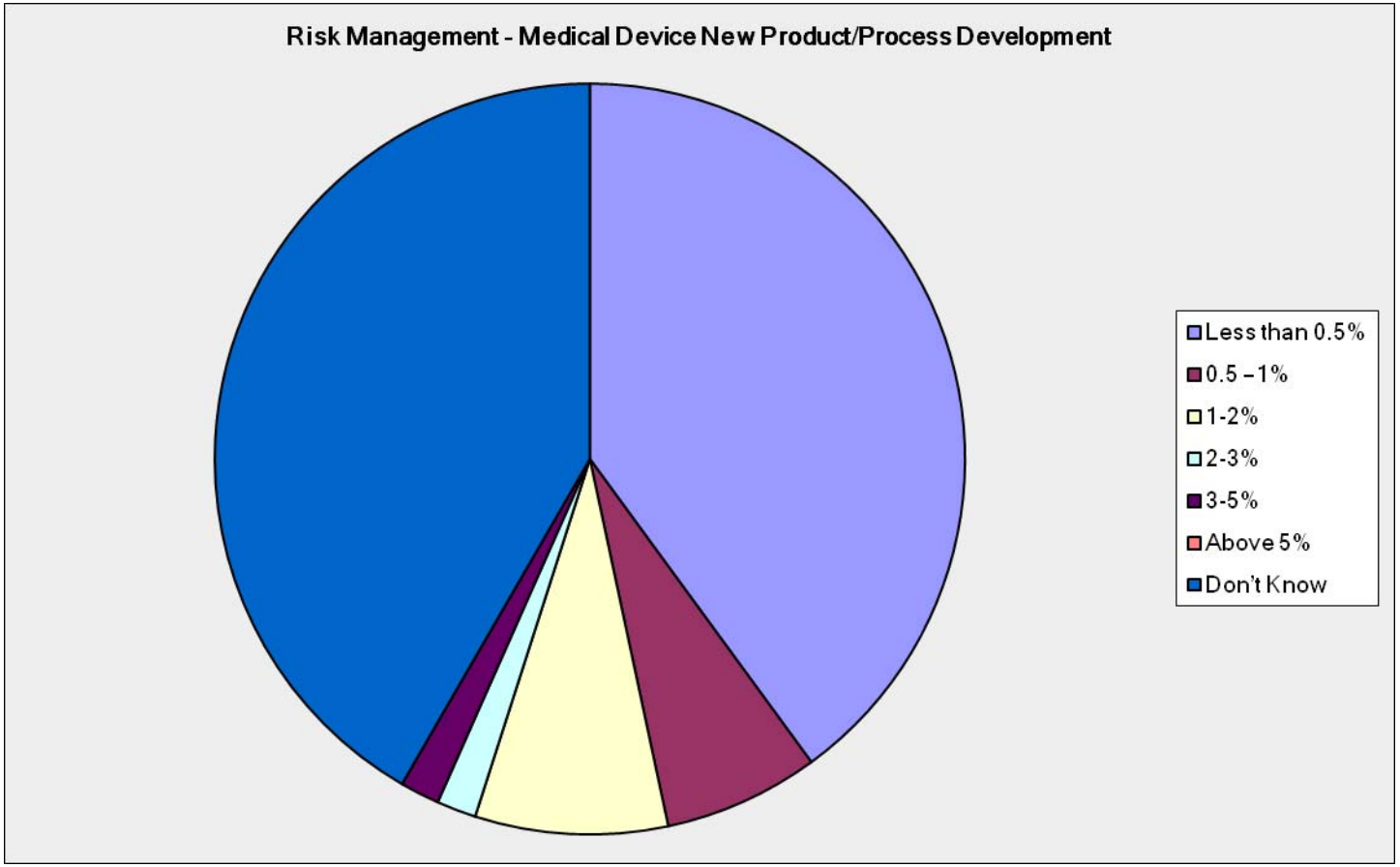
Device User Competence



Link to Customer Complaint Rate



What is the customer complaint rate for this product?

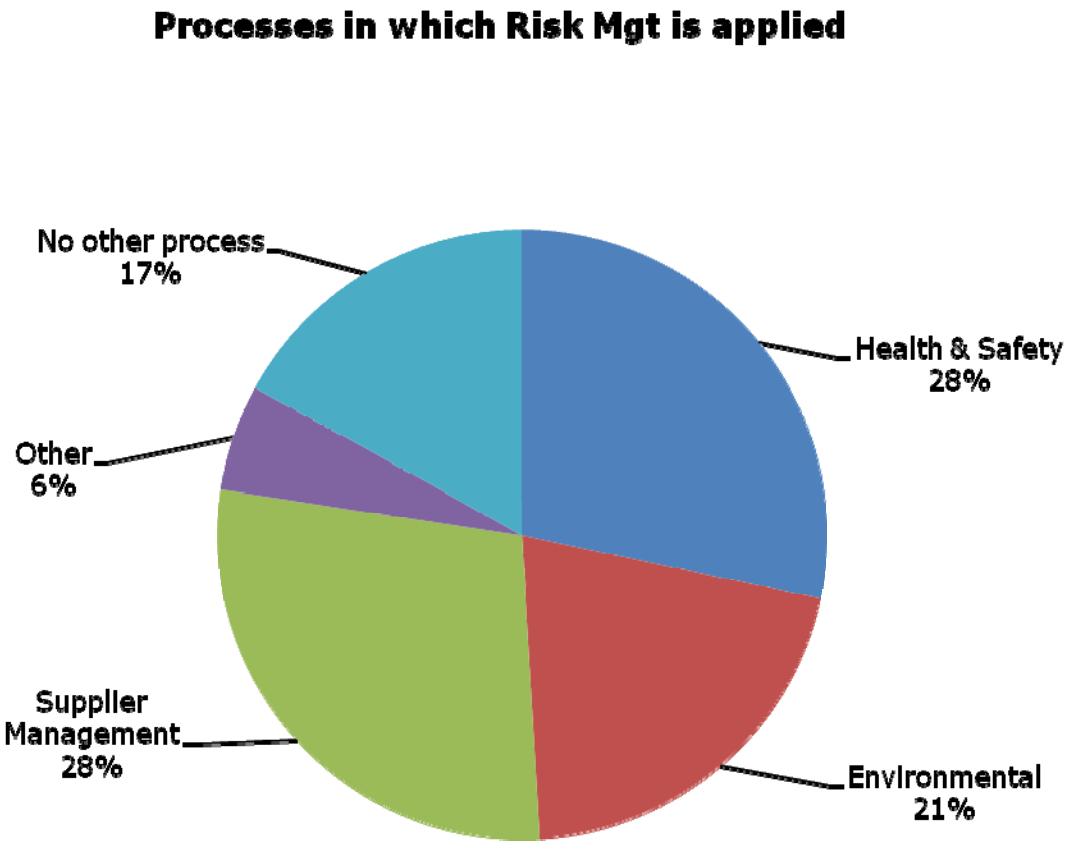


Best Practice

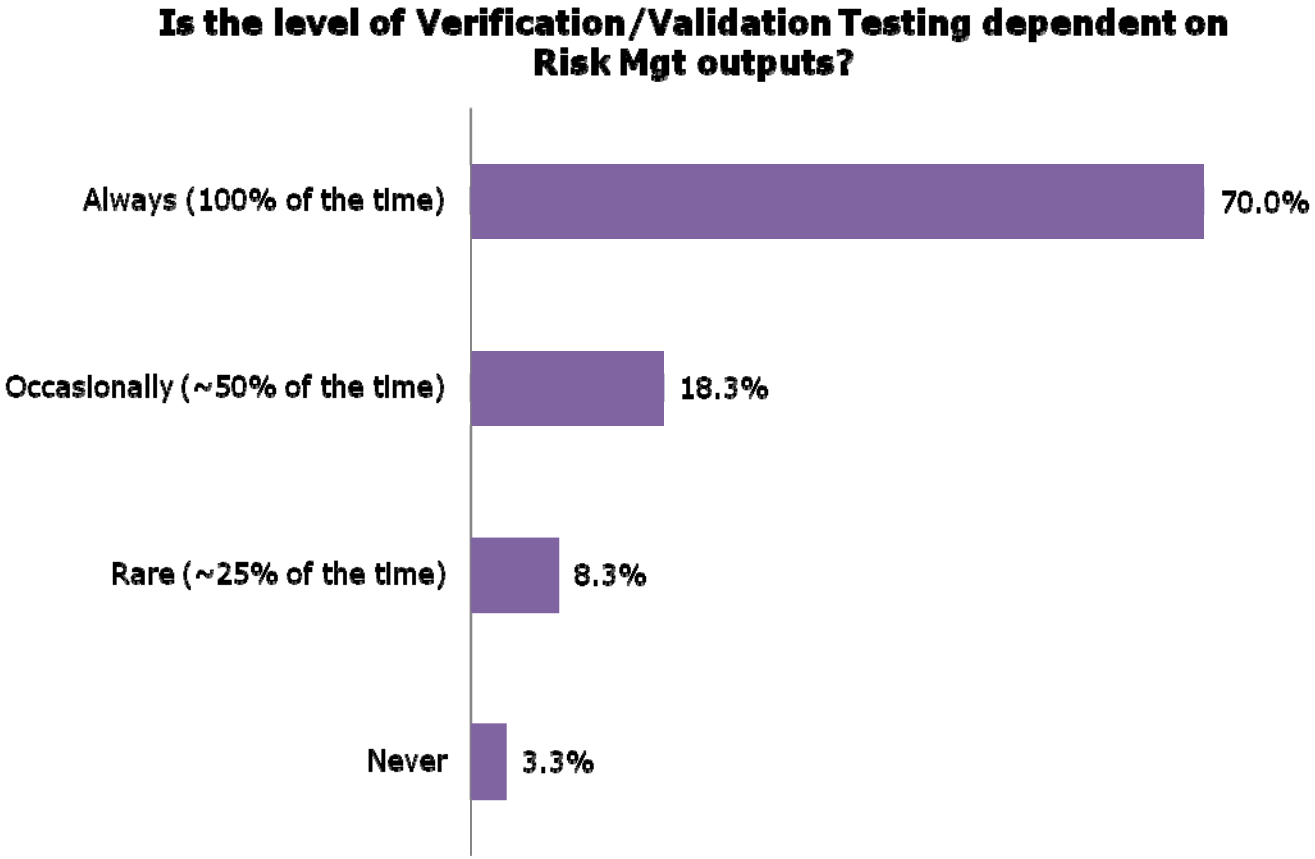
- Who leads RM Activities?
- Is RM being applied outside of the product or process life cycle? E.g. Health and Safety, Supplier Management, Environmental Control?
- Is the level of verification or validation testing determined by risk management?
- Is the sample size for testing determined by risk management?
- Are design or process changes as a result of RM activities?

Who Leads RM Activities?

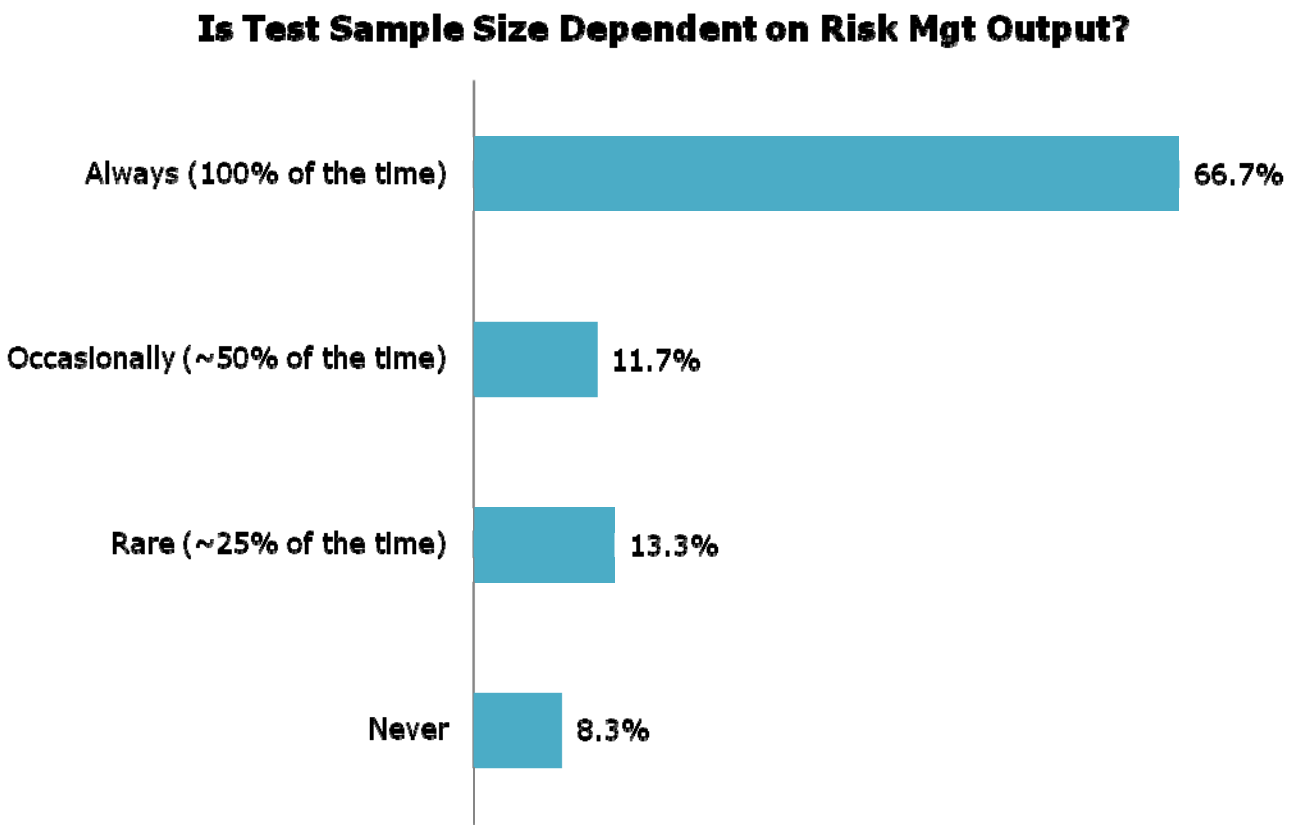
Other Processes?



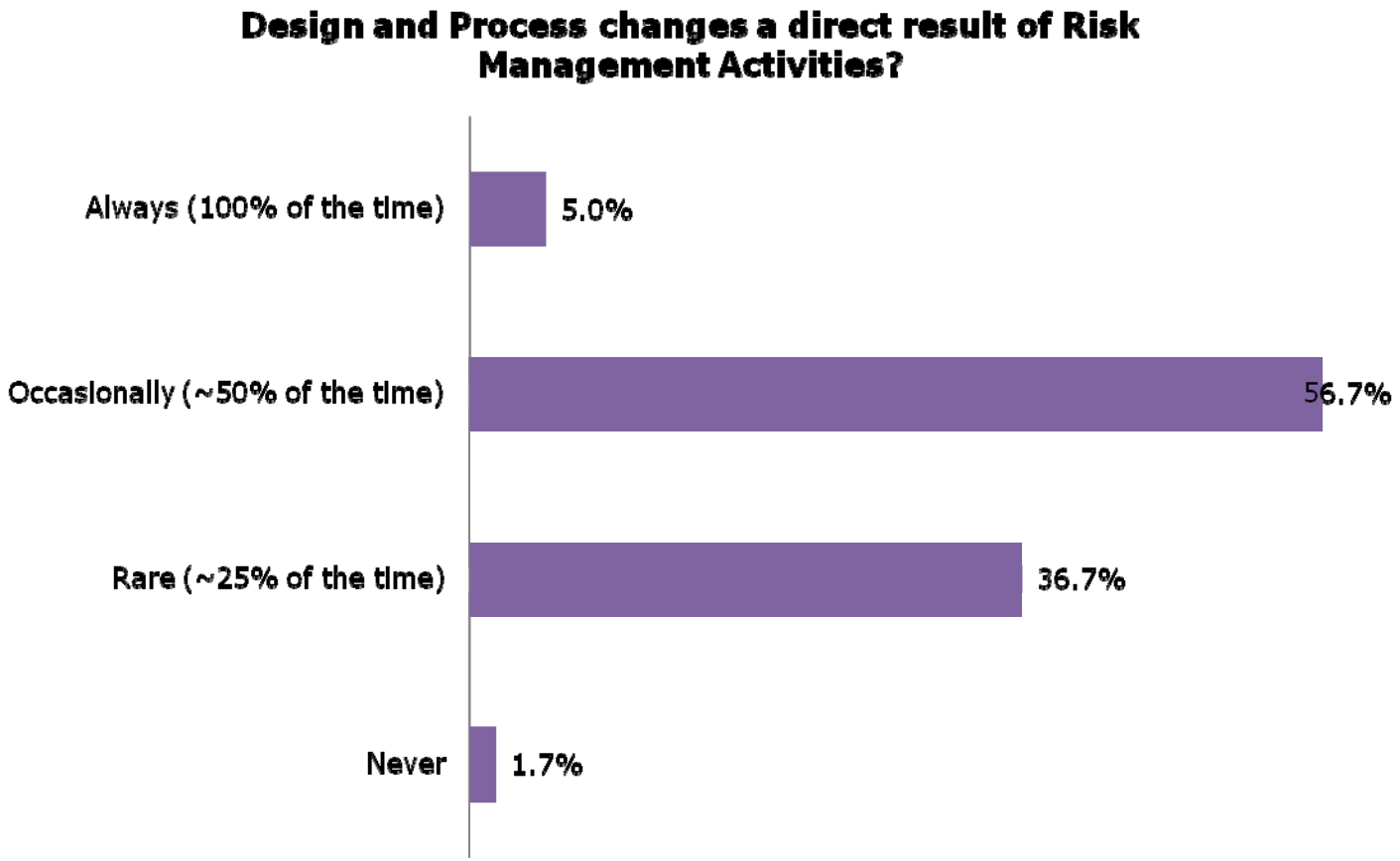
RM Drive Level of Testing



RM output Drive Test Sample Size



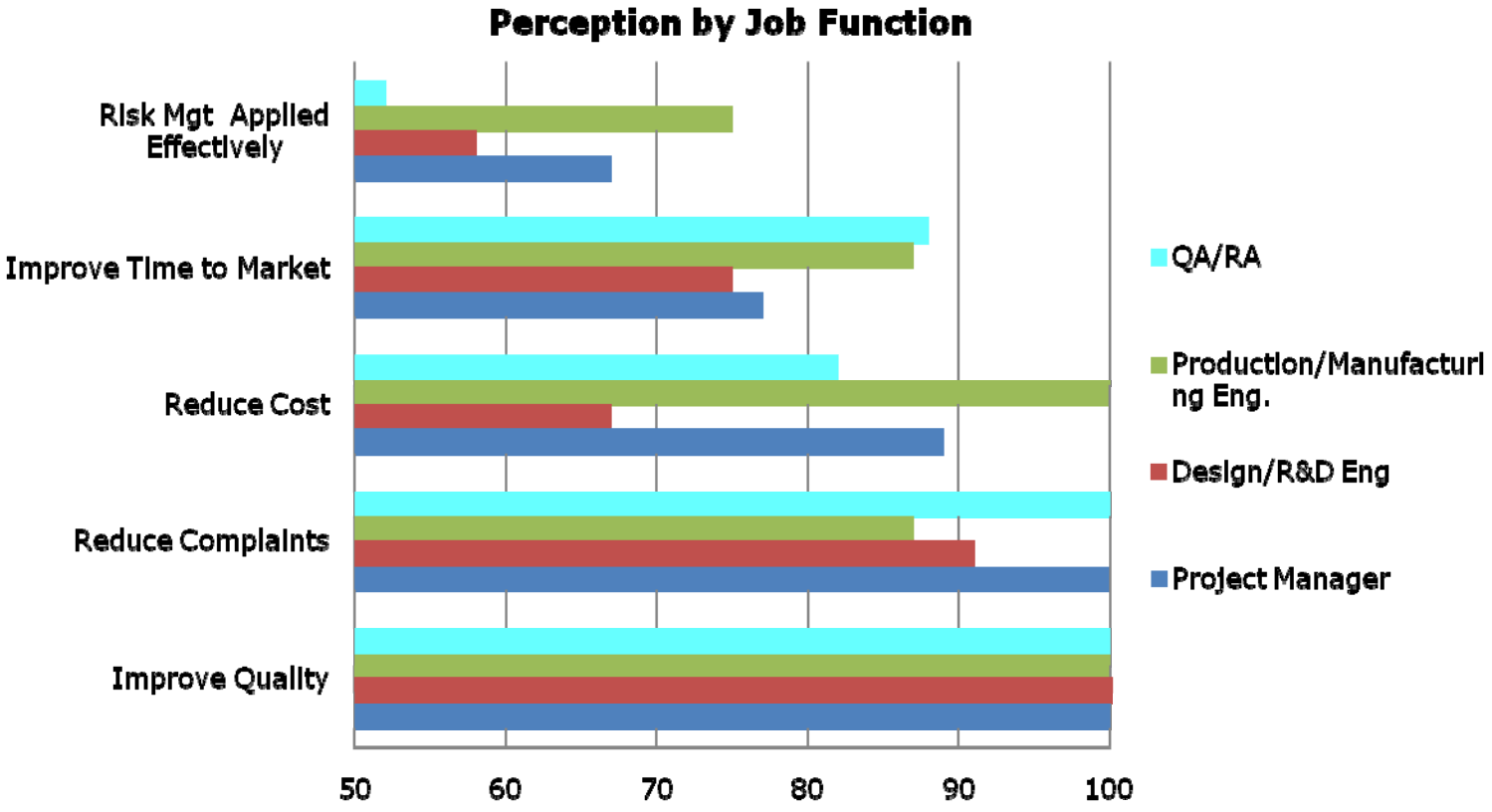
RM Drive Change?



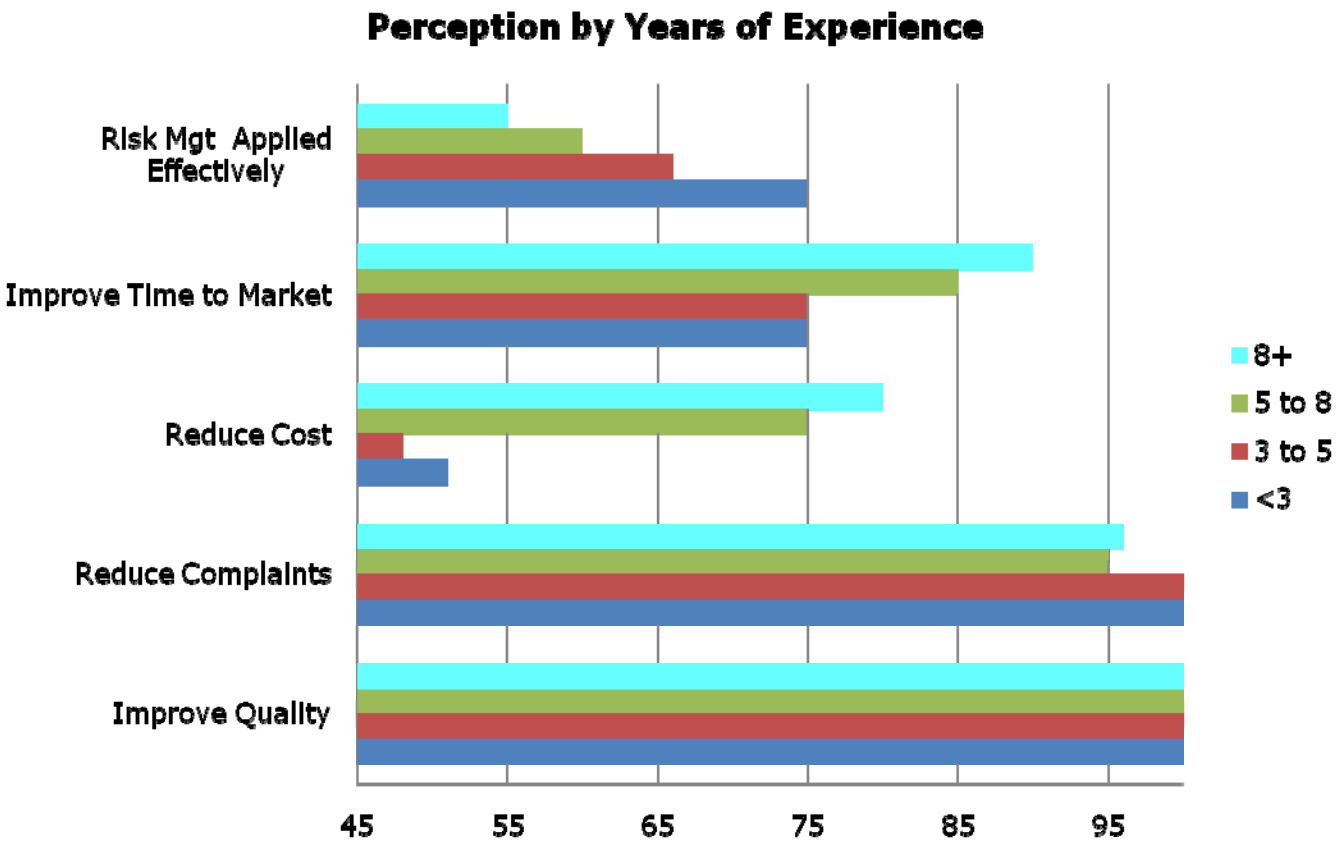
Culture & Leadership

- Are views, perception and understanding influenced by
  - Job function?
  - Level of training received?
  - Years of experience?
- What are the perceived benefits to the organisation of a robust risk management system?
- Does a risk management culture exist in the organisation?
- Do individual's feel that risk management is being applied effectively in their organisation?

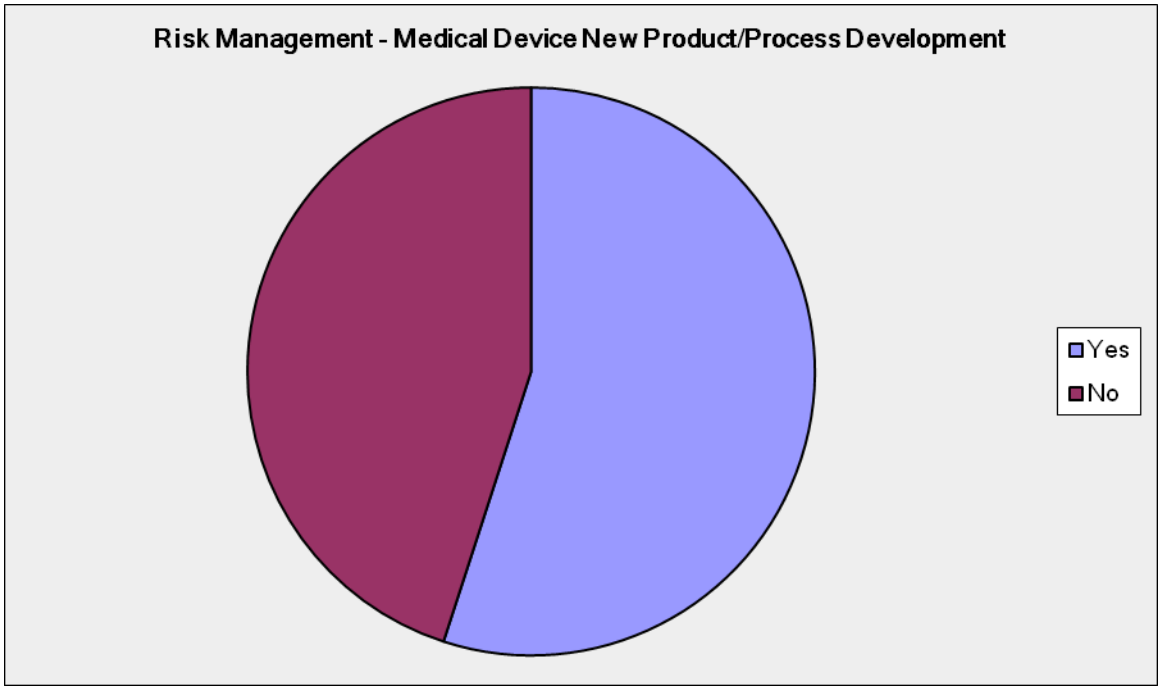
Culture & Leadership



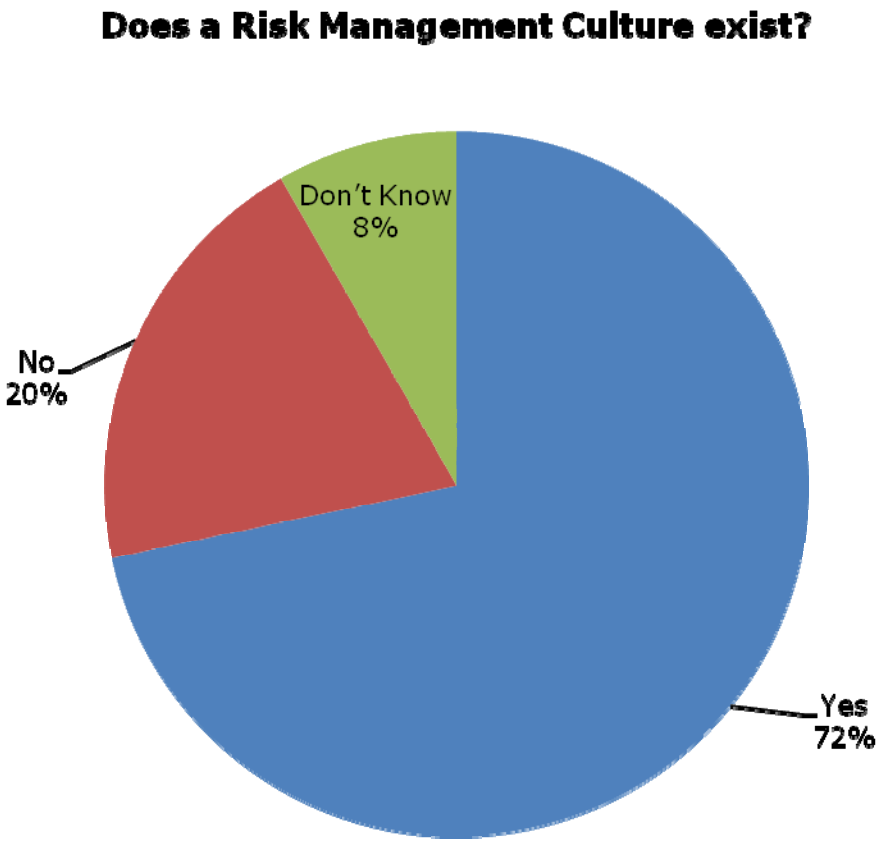
Culture & Leadership



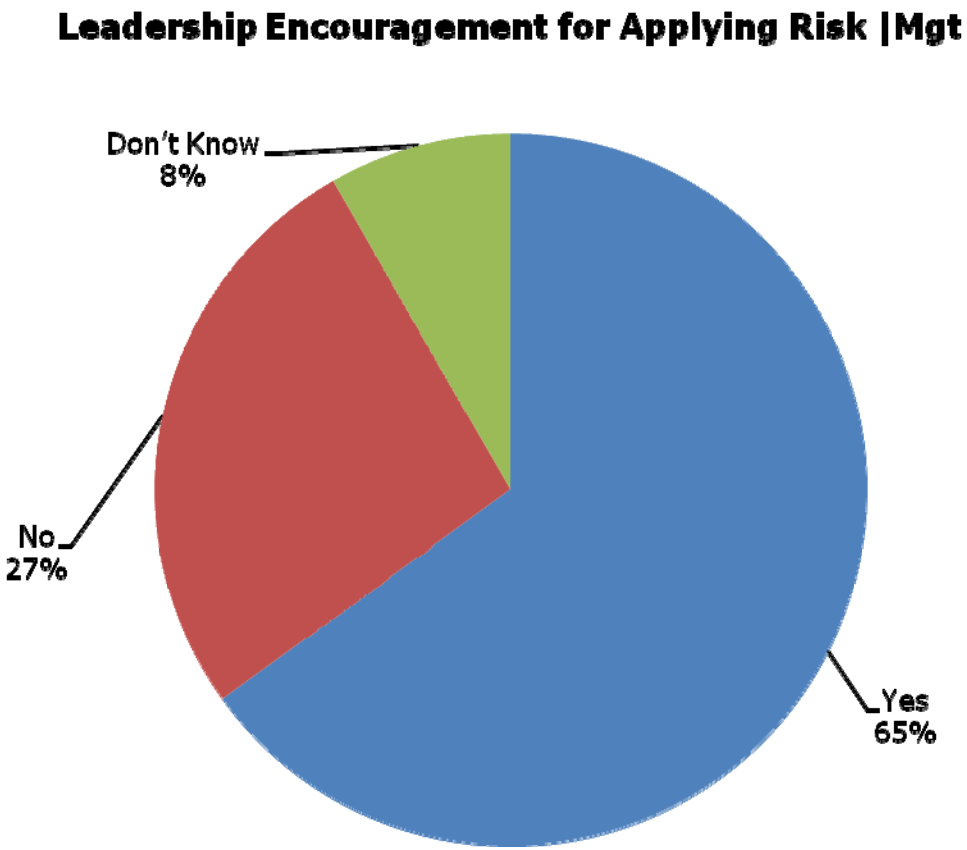
Have you received formal training in ISO 14971?



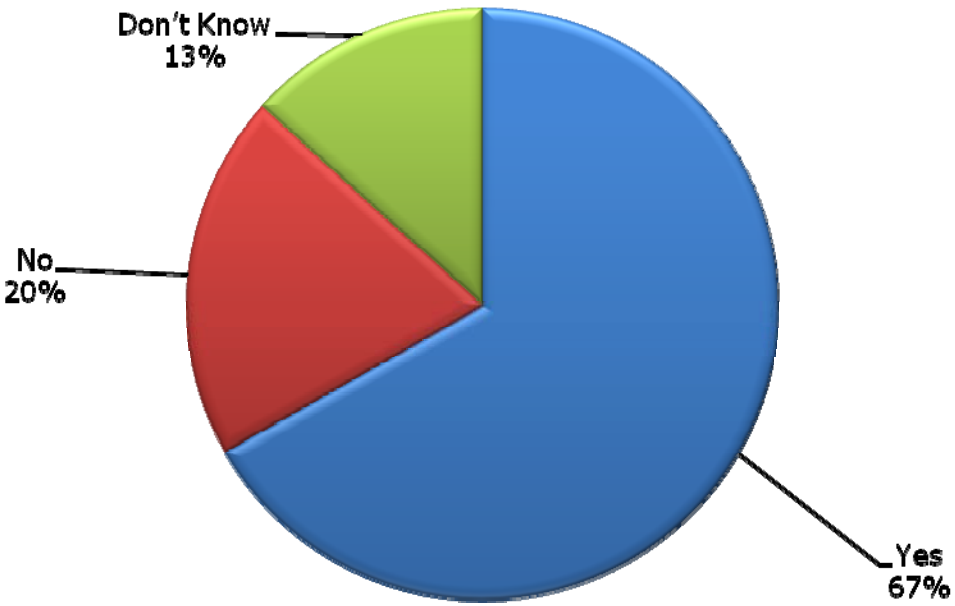
Culture & Leadership



Culture & Leadership



Is Risk Mgt / ISO 14971 being applied effectively?



Conclusion from Research

- Risk Management is being applied at all stages of the NPD process; mostly in the development, testing and transfer to manufacturing stages.
- The RM tools recommended by ISO 14971 are being applied; most popular being FMEA.
- 30% of participants stated that they do not use RM to assess patient risk when notified of a customer complaint; not linking in the post-market surveillance aspect.
- A higher regulatory classification of device generally means a higher level of RM activity.
- A significantly higher level of RM activity is applied when a product is a new design, rather than a modification.

Conclusion from Research

- **Companies who applied a higher level of RM during the NPD process had lower complaint rates (<0.5%) versus companies who applied a lower level of risk management (>0.5%).**
- **Almost all RM activity is led by the Quality function.**
- **RM is applied to other functional areas, outside of NPD by 83% of the participants.**
- **The majority of participants (88%) use the output of the RM activity to drive the testing sample size for verification and validation testing.**

Conclusion from Research

- **Participants of greater than 5 years experience in the medical device industry, across all functions, view the benefits of a RM process to be:**
  - **Improved product quality**
  - **Reduced level of customer complaints**
  - **Improved NPD project timelines**
  - **Reduced overall NPD cost.**
- **The majority of participants (~70%) believe that there is a culture of RM and it is strongly linked to management leadership.**