

# RISK MANAGEMENT AND DESIGN CONTROL



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# OBJECTIVES

1. Present a brief overview of Risk Management and its key elements
2. Discuss Risk Management and Design
3. How to determine risk benefit and its link to profitability
4. How to use risk management in design transfer
5. Share some “trips to avoid”

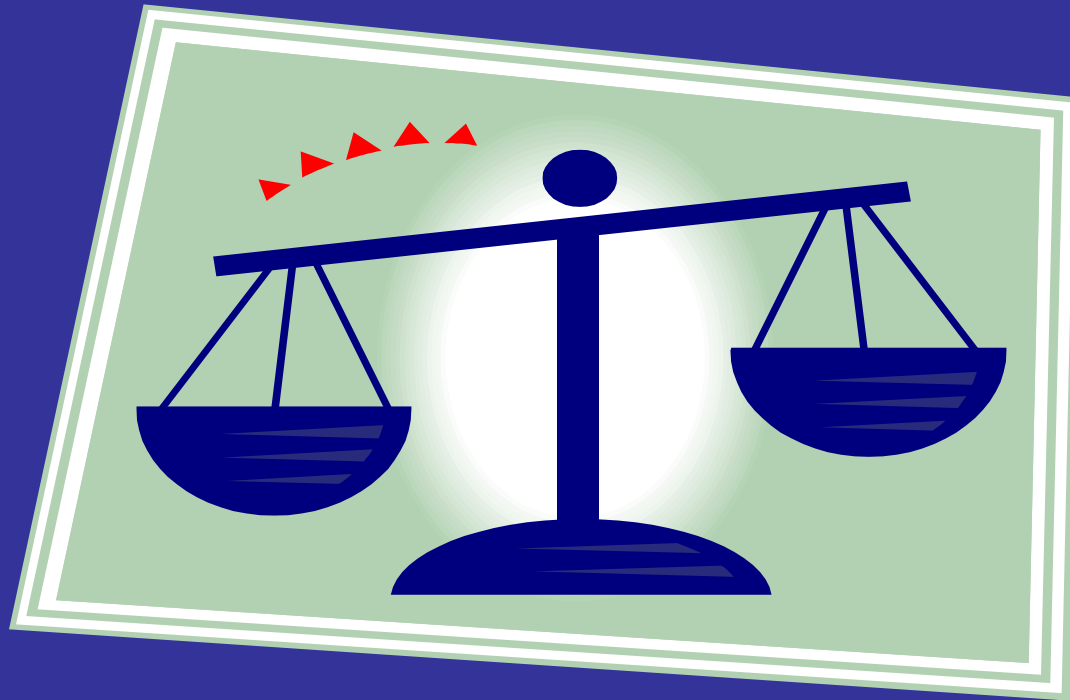


# CHALLENGES

“...each stakeholder places a different value on the probability of harm occurring and on the detriment that might be suffered on exposure to a hazard.”



# BALANCE



**RISK**

**BENEFIT**

**SOCIETY vs. ECONOMIC**



# BASIC DEFINITIONS

Safety – **freedom** from unacceptable risk

Harm – **physical** injury or damage to **people** or damage to **property** or **environment**

Hazard – **source** of harm

Hazardous Situation

- Medical action delayed
- Inappropriate therapy given
- Operator injured
- Unintended shock given to patient
- Medical action/therapy not given



# KEY TERMS & DEFINITIONS

Risk analysis – **systematic** use of information to identify hazards and estimate risk

Risk evaluation – risk which is **determined acceptable** has been achieved in a given context based on the **current values of society**

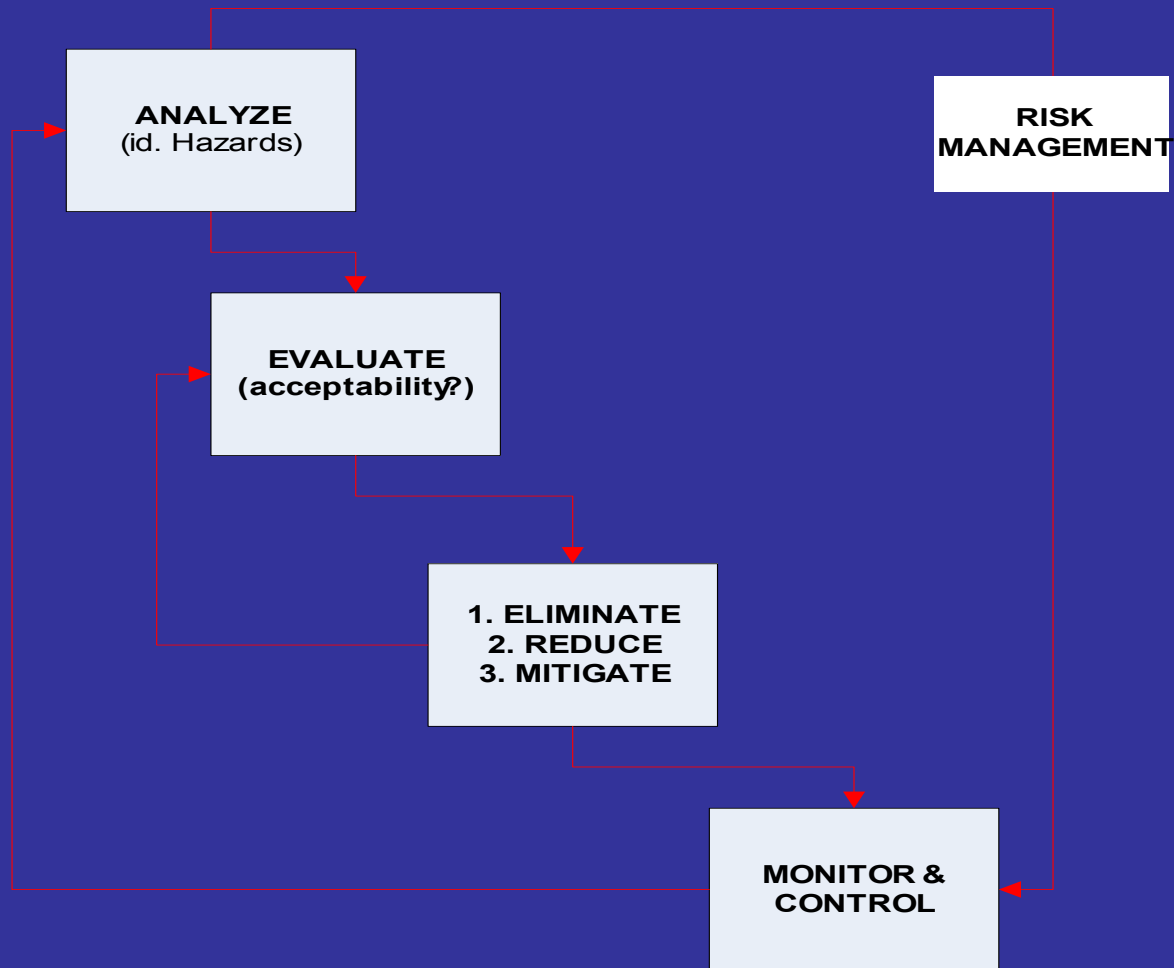
Risk control – process in which decisions reaches and protective measures implemented to

- **eliminate** risk
- **reduce** risk
- **maintain** risk

Risk management – **systematic application**



# PROCESS



# CHALLENGES

the **probability** of occurrence of harm

+ the **consequences** of that harm (severity)

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**ACCEPTABILITY OF RISK**



# BUSINESS ADVANTAGES

1. Asset for Marketing strategies
2. Asset for reimbursement strategies
3. Asset for Sales campaigns
4. Use as cost containment tools
5. Expedite product approval
6. Used in determining insurance profiles for medical device manufacturers; level of effective application
7. Lower or contain Cost of Quality; proactive



# VALUABLE LINKS

1. Choice of design features
2. Choice of warranty claims
3. Choice of advertising & promotion content
4. Choice of packaging
5. Choice of supply chain
6. Price
7. Complaint Management
8. Choice of sample plan types & levels
9. Approach to process validation



# STATE OF THE ART

How **proactively** defined???

- through MAUDE
- product monographs
- through your internal complaint database
- through 'edge of failure studies'
- through reliability studies
- through clinical studies
- through M&M reports/statistics
- comparison testing with competitors actual or similar product

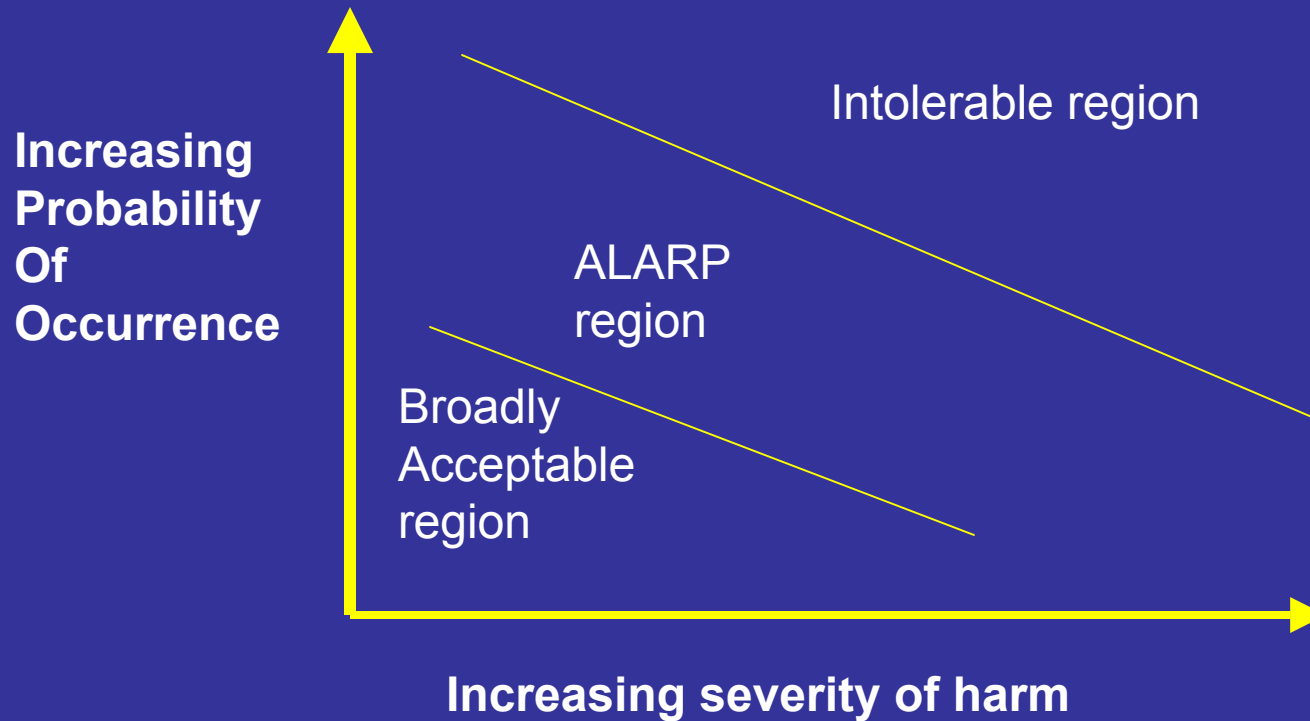


# SEVERITY DESCRIPTION

Catastrophic (10)	Potential death
Critical (7)	Potential of serious injury or potential field action
Marginal (4)	Potential of non-serious injury or potential malfunction
Negligible (1)	No potential of injury or potential



# PLAN

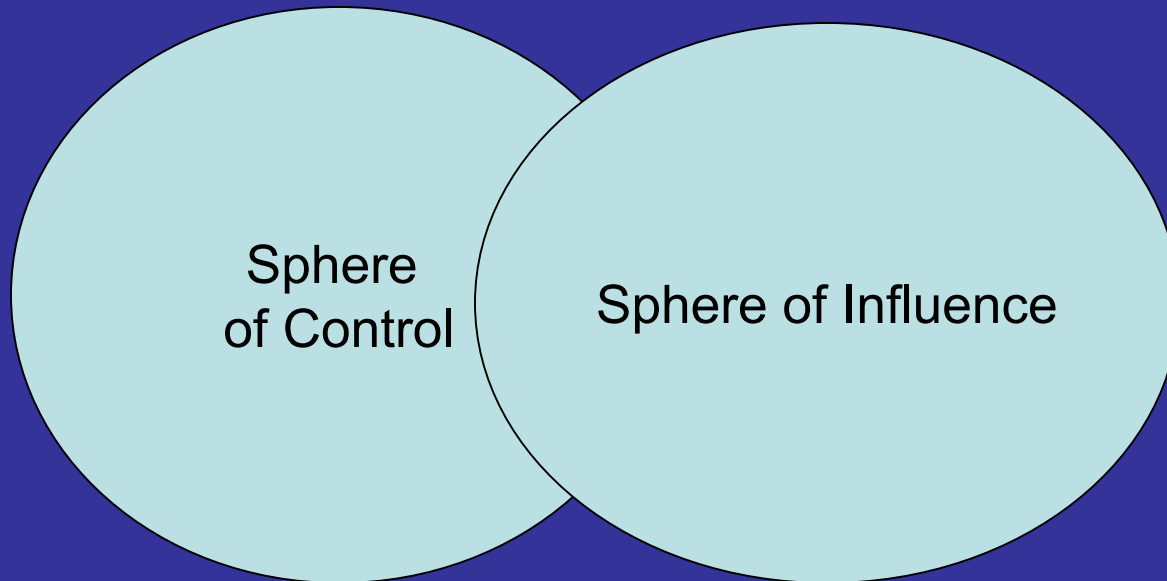


# DESIGN PHASES

Feasibility	Project Charter	Development Phase	Design Phase	Transfer Phase	Release & Post Market
Customer needs (general)  <b>Hazard Id.</b> <b>Preliminary Risk estimation</b>	Customer inputs  Design input  <b>Risk Mgmt. plan</b>	Clinical & Regulatory plan  Supplier plan  Mfg. plan  <b>Risk Analysis</b>	Design verification  Design validation  Process qualification  <b>Risk analysis update</b>	Reports •Clinical •Design validation •Process validation  <b>Risk analysis plan final update</b>  <b>Linked control plans for risk mgmt.</b>	CAPA  Change control impacting design (includes process)  <b>Post market review (includes more than complaint mgmt.)</b>



# INFLUENCES



# DESIGN

## PARTNERSHIP WITH SALES & MARKETING

- Determining criteria for inclusion
  - Develop key product performance deliverables and assign a weight & ROI
    - Marketplace competitive assessment
    - Prioritization of design performance features
    - Price (fully loaded) of each feature



# TYPES OF QUESTIONS TO BE ANSWERED

- Stand alone or to be used as part of another system?
- Can be exchanged into another manufacturer's system? Exclusive?
- Same product type such as aortic catheters or blood draw tubes & accessories?
- Novel; first of its kind? (Bare metal stents now drug coated)
- Use with other common medical equipment & accessories & their interactions



# MARKETING & SALES DECISION MATRIX

Feature	Priority	Competitive Cost Profile	Internal Cost	ROI	Negotiable
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# DESIGN PLAN

Category	Sales & Marketing	Hazard	Failure Mode (s)	Cause	Severity	Occurrence
Risk	Elimination or Mitigation Method	Severity	Occurrence	Residual Risk	Design Control	Process Control



# MEDIATION

Driven by risk/benefit ratio

Driven by severity of risk or degree of harm

Mediation steps

- Change design (poke yoke, remove feature)
- Change level of control within the user's sphere of influence (height of a control for an adult vs. a child)



# MEDIATION

Driven by your risk analysis and original design inputs associated with environment, culture, level of user sophistication, reading comprehension (ESL & average American has a 6<sup>th</sup> grade reading level)



# RISK CONTROL

Goal is to reduce risk to acceptable levels which you have pre-determined by policy and SOP

Design and process changes must be evaluated to determine if there is a potential for an increase or decrease in the overall risk for the product  
(new hazards, change to rate of occurrence)

Residual risk must be evaluated against potential benefit of the device



# RISK TABLE & ACTIONS

Likelihood	Severity			
	Negligible	Marginal	Critical	Catastrophic
<b>Incredible</b>	Broadly acceptable	Broadly acceptable	Broadly acceptable	ALARP
<b>Improbable</b>	Broadly acceptable	Broadly acceptable	ALARP	ALARP
<b>Remote</b>	ALARP	ALARP	ALARP	Intolerable
<b>Occasional</b>	ALARP	ALARP	ALARP	Intolerable
<b>Probable</b>	ALARP	ALARP	Intolerable	Intolerable
<b>Frequent</b>	ALARP	Intolerable	Intolerable	Intolerable



# DESIGN TRANSFER

Determinations made by:

- Predetermined statistical criteria
  - High importance = performance at 95%/99.9% confidence interval
  - Medium importance = performance at 95%/95%
  - Minor importance = performance at 95%/90%
- Can't meet by design translation into specifications
- Can't meet by design performance (bench top testing or from Clinicals)



# DESIGN TRANSFER

Can't meet Sales & Marketing criteria

- Discuss with Sales & Marketing and determine product positioning impact
- Based on cost impact (sales impact, development, timeline to market) change
- If can't change, reconfigure market positioning and launch plans
- Other considerations to warranty, overall price, reimbursement



# RISK MANAGEMENT & DESIGN VALIDATION

Under Design Control the user validates the final design.

Risk management is a key player in that activity.

The post production period will prove that all design elements and their acceptable risk management levels are acceptable to the user community.



# OVERALL RISK EVALUATION

After all control measures are in plan the questions must be asked,

“Do the final criteria meet the original plan????”

If yes, then evaluate in terms of risk/benefit and document.



# POST MARKET INFORMATION

Sources of information should be reviewed to ensure that:

- no unanticipated hazards exist
- the original risk assessment is still valid (this information is the validation of the original risk management process)



# POST MARKET INFORMATION

This is more than Complaint Management!

- focus groups
- periodic testing of finished & aged product back to its design level where predetermined based in risk level of product (process & user drift)
- servicing requests
- technical requests



# RE-EVALUATION OF RISK

## HOW?

Usually through change control and post market activities.

Change control is addressed by going back to the design files and revisiting controls, risk/benefit ratios and material & process interactions & controls



# ANNUAL PRODUCT REVIEW DESIGN CONSIDERATIONS

- Required for pharmaceuticals
- Required for devices by PMA but still dissimilar to drugs
- Should it be used for devices?



# ANNUAL PRODUCT REVIEW

Considerations include:

- Get out in the field!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!
- Review of stability results to reflect full shelf life of product
- Review of design related product complaints (lagging indicator)
- Review of literature and Marketing focus panels
- Review of Sales inputs (done in webcast/forum not questionnaires)



# “TRIPS TO AVOID”

- Be reasonable
- FMEA = frame your rate of occurrence to a lot, exp. date, etc.
- You own the data/info.
- Revisit hazards & harms on a set frequency



# CONCLUSIONS

- Sales & Marketing must play! Do not proceed without more detailed input from them.
- Use tools as illustrated here or Quality Function Deployment
- Covers product use from cradle to grave.
- Addresses initial design features and tradeoffs as well as user drift.



# QUESTIONS

????????????



# Thank You

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