

# RISK MANAGEMENT



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# **PROGRAM**

**RISKY BUSINESS IN RISK-FREE (?) SOCIETY**

**WHY WORRY?**

**RISK ANALYSIS**

**RISK MANAGEMENT**

**Q & A**

**TAKE HOME IDEAS**

## **RISKY BUSINESS IN RISK-FREE (?) SOCIETY**

- Reality of the situation from customer view-point
- Reality from manufacturer/supplier view-point
- Minimize risk to ALARP level
- Assess, mitigate and manage risk
- Legal consequences
- **DO IT FOR EXCELLENCE**

## **WHY WORRY?**

- Risk management by FORD/FIRESTONE
- Risk assessment by Hyundai
- Impacts safety of REAL PEOPLE
- Make a REAL COMMITMEN
- It simply makes good business sense

## RISK ANALYSIS & MANAGEMENT

- To identify hazards and to estimate risk
- EN 1441:1997 Medical Devices – Risk Analysis
- ISO 14971-1:1998 Application of Risk Analysis
- HACCP – Hazard Analysis and Critical Control Points
- FDA Guidance July 2000 – Medical Device Use – Safety: Human Factors ...

### Types of Risks:

- Design/product risk
- Process risk
- User/use risk

## RISK ANALYSIS (contd.)

- FMEA/FMECA – Failure Mode Effect and Criticality Analysis
- FTA – Fault Tree Analysis
- HACCP – Hazard Analysis and Critical Control Points

### FTA

- “Top-down”
- Starts from a postulated undesired consequence, deduces possible fault mode of the next lower functional system level to eventually component level.

### FMEA

- “Bottom-up approach”
- Identify and evaluate the consequence(s) of a component fault mode
- Degree of severity, probabilities of occurrence and their detectability
- Prioritize and reduce risk
- Evaluate
- Perform: identify team, agree on scale, agree on examples

## RISK MANAGEMENT

- Prioritize/rank
- Eliminate the cause
- Label and instructions for minor stuff only; assume that the user will make mistake(s)
- Reevaluate after mitigation
- Review and update risk analysis
- Put the update on a schedule
- Require update when change(s) are made
- **MAKE THE EFFORT PAY FOR ITSELF**