

Safety Risk Management for Medical Devices

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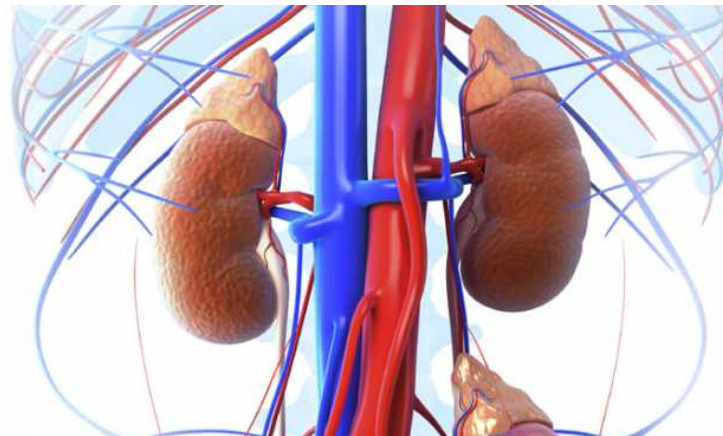
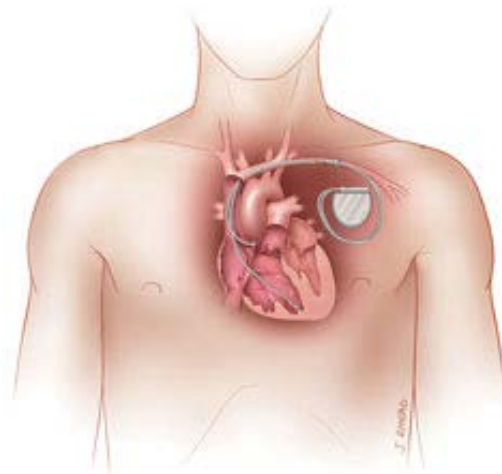
Founder: MedTech Safety, Inc.



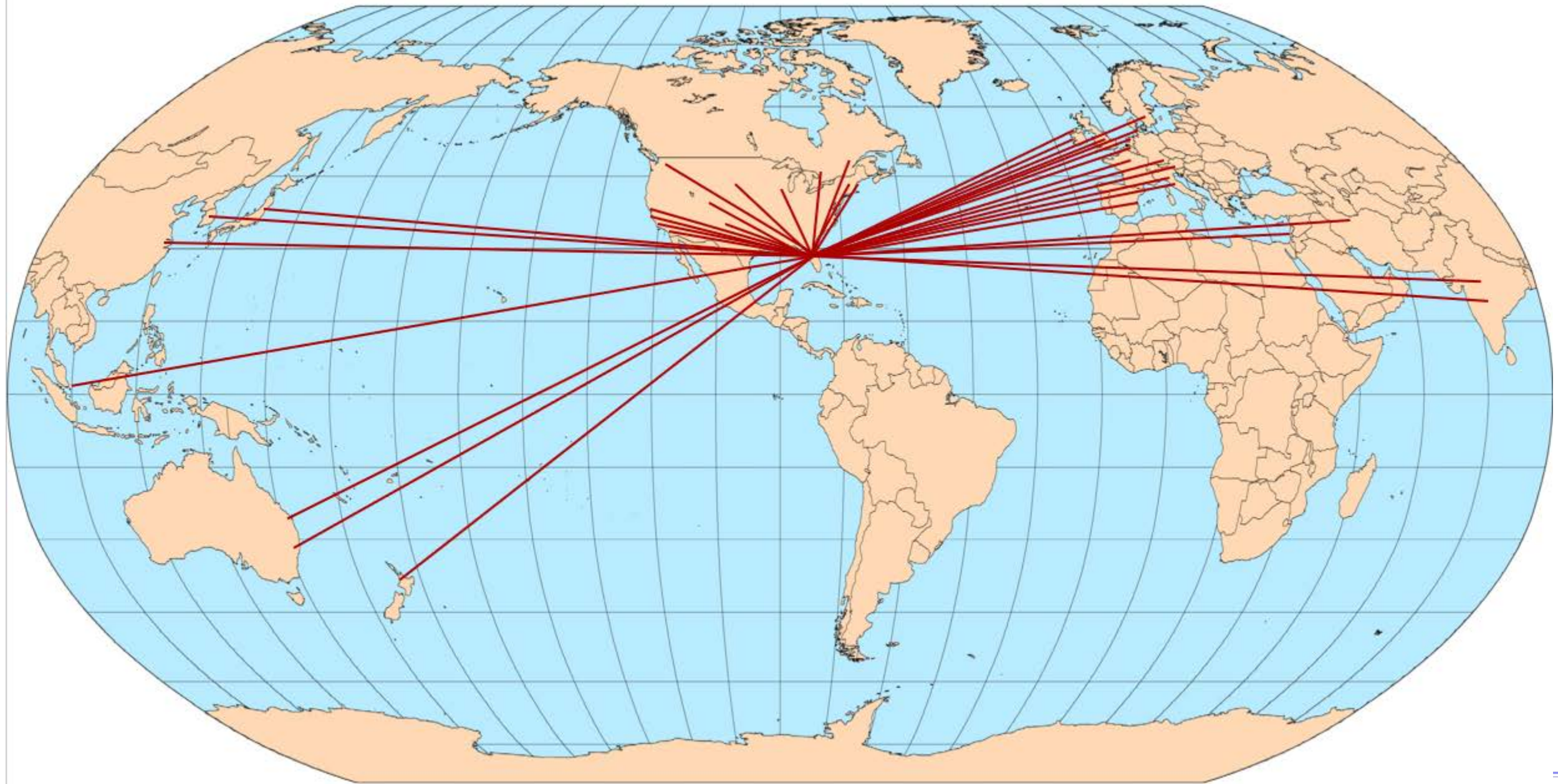
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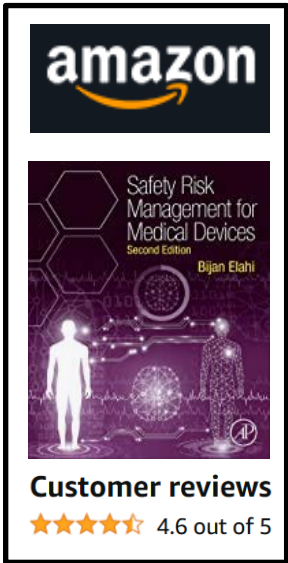
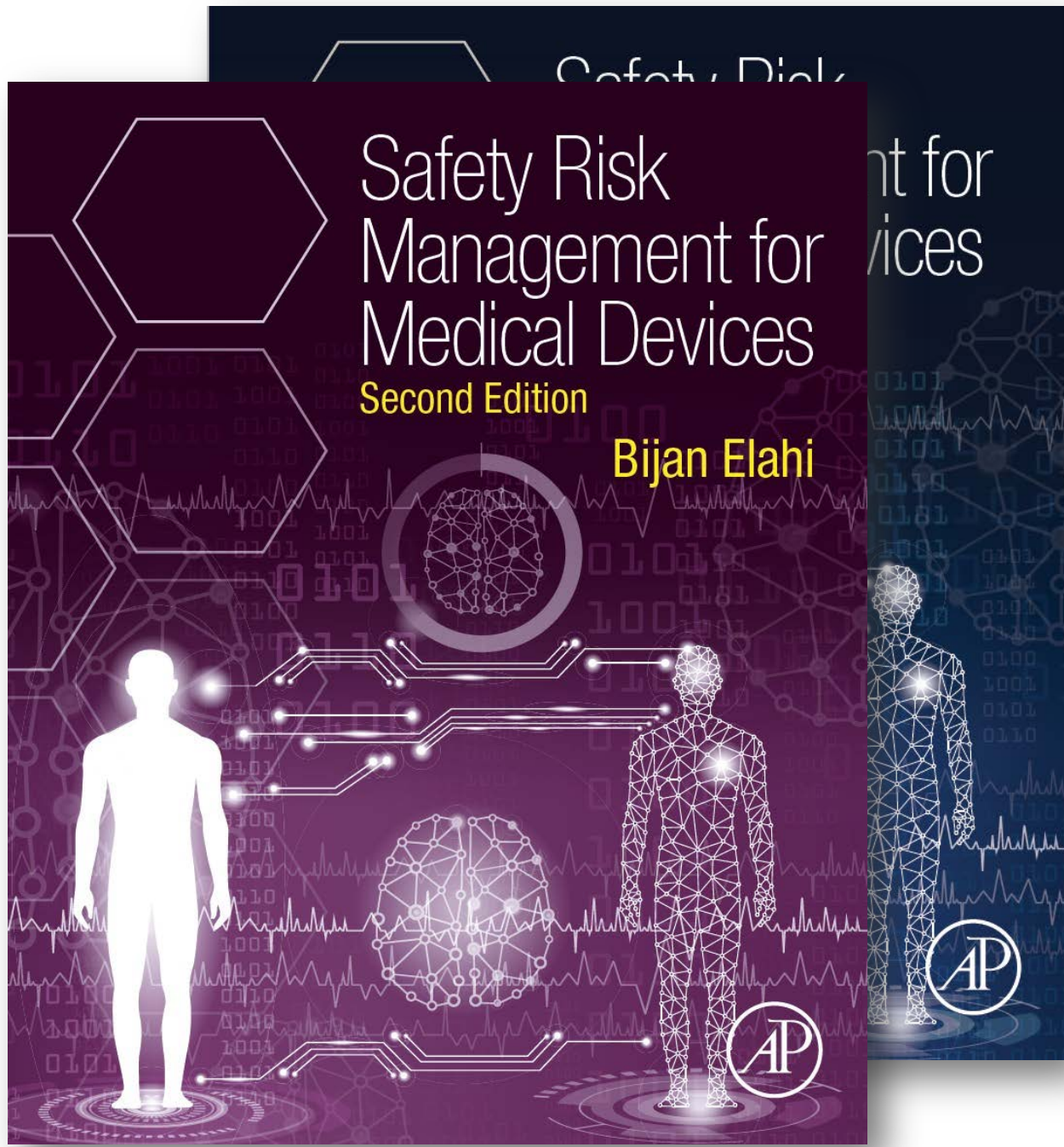
Risk Management Curriculum

- 101 - Introduction to Risk Management
- 102 - Clinical Hazards & Harms
- 103 - Fault Tree Analysis
- 104 - Failure Modes & Effects Analysis
- 105 - Risk Estimation, Control, and Evaluation
- 201 - Advanced Topics in Risk Management
- 301 - Risk Management for Clinical Investigations
- Medical Device Risk Management (3-Day Intensive Course)





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Safety Risk Management for Medical Devices

What is risk management?

Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk – ISO 14971

An interdisciplinary endeavor



Why is risk management important?



Ch 3



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Why is risk management important?

RESOURCE
OPTIMIZATION



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Why is risk management important?



Why is risk management important?



Cost of Poor Risk Management

24-Oct-2022



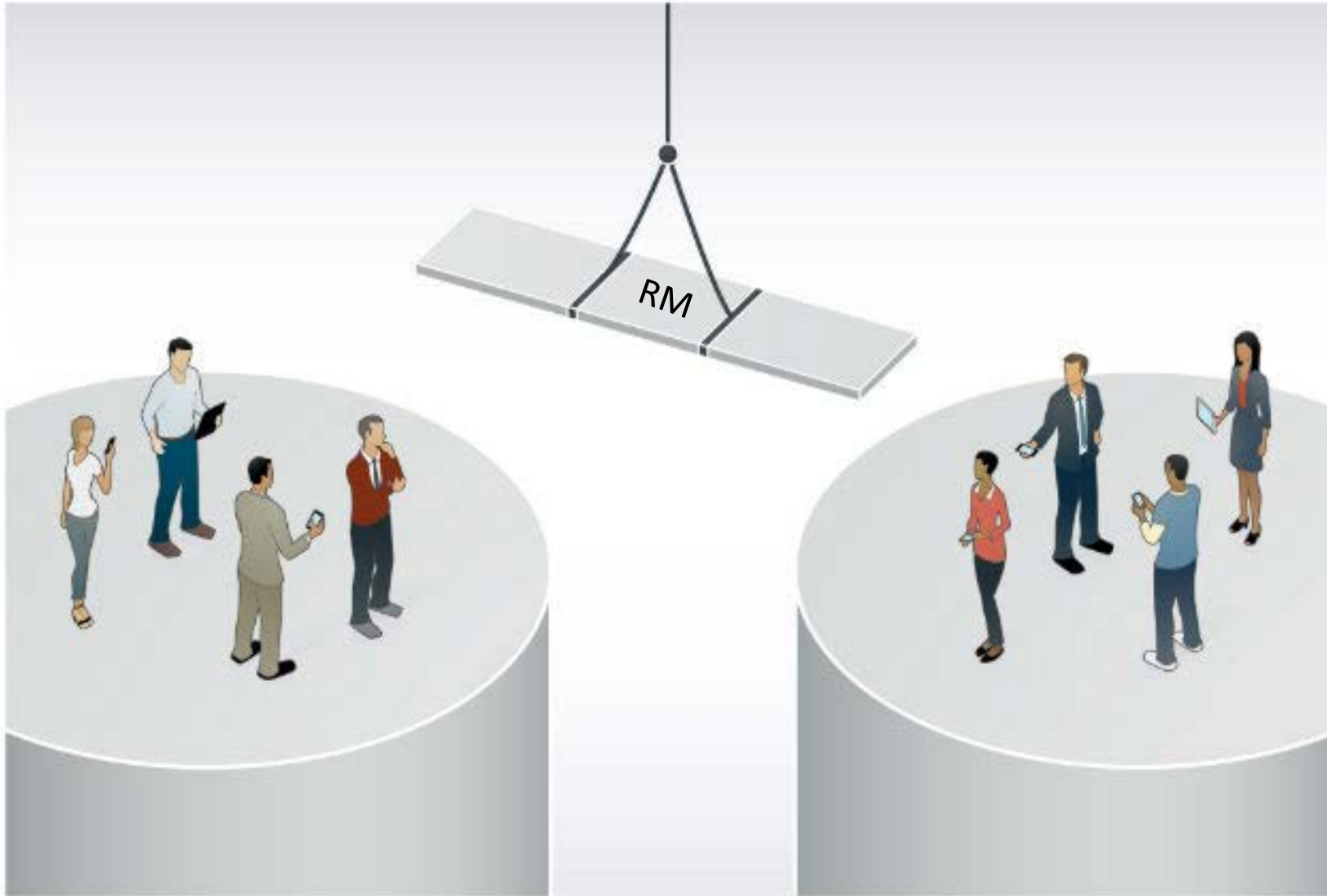
New Philips CEO Jakobs apologizes for handling of sleep apnea device recall

Philips to cut 4,000 jobs amid net loss related to recalls, declining sales

Philips has been reeling from the recall of 5.5 million CPAP, BiPAP and mechanical ventilator devices, which has spurred a 68 percent drop in its share price in the past year. The company is still discussing a proposed consent decree with the U.S. Dept. of Justice to resolve issues related to the recall and recorded a 1.3 billion-euro non-cash charge in the third quarter for “impairment of goodwill” of the Respironics unit.

Why is risk management important?





What is risk?

- Combination of the probability of occurrence of harm & the severity of that harm -- ISO14971
- “The objectified uncertainty regarding the occurrence of an undesirable event” -- Willett 1901
- The probability of occurrence of something undesirable
- Probability of sustaining harm in a hazardous situation
- Risk Types:
 - Technical risk
 - Project risk
 - Business risk
 - IP risk
 - Regulatory risk
 - Product performance risk
 - Security risk
 - Safety Risk
 - Patient/user
 - Not EHS

Risk perception

- Risk Perception and Tolerance

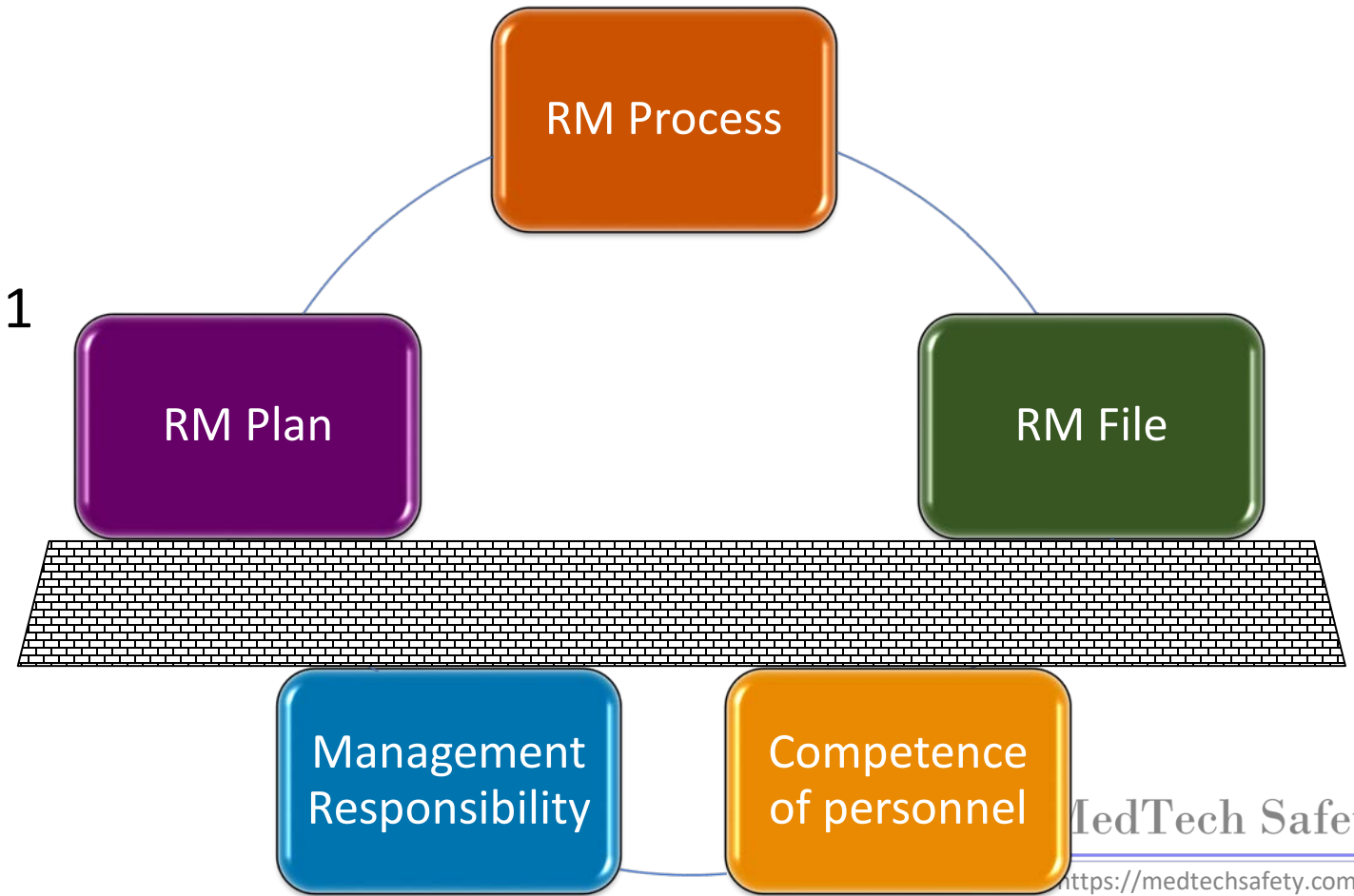
- When an accident happens the public perception of the risk goes to 100%.

- Risk management vs. Risk elimination

It is well established that the perception of risk often differs from empirically determined risk estimates. Therefore, the perception of risk from a wide cross section of stakeholders should be taken into account when deciding what risk is acceptable. To meet the expectations of public opinion, it might be necessary to give additional weighting to some risks. – 14971 D.4

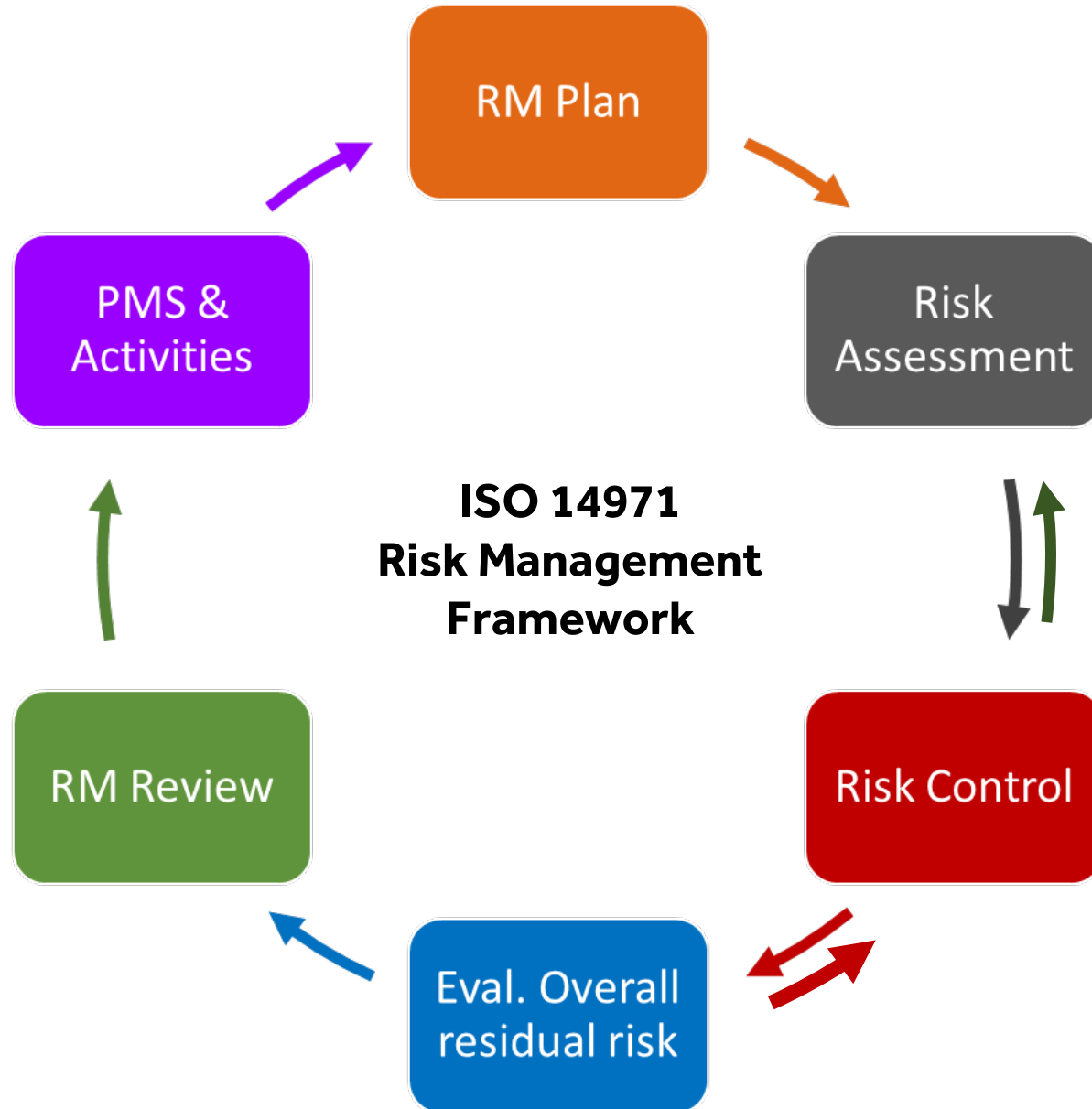
ISO 14971

- Role of ISO 14971
- History of ISO 14971
 - ISO 14971:2019
 - EN ISO 14971:2019+A11:2021
- Risk Management System



ISO 14971

- Role of ISO 14971
- History of ISO 14971
- Risk Management System
- Risk management framework
- Requirements of 14971



Requirements of ISO 14971

- Have a process
- Have a plan
- Use competent personnel
- Ensure completeness of risk control
- Evaluate overall residual risk
- Benefits outweigh risks
- Production & Post-production activities
- Risk management review
- Risk management file
- Traceability

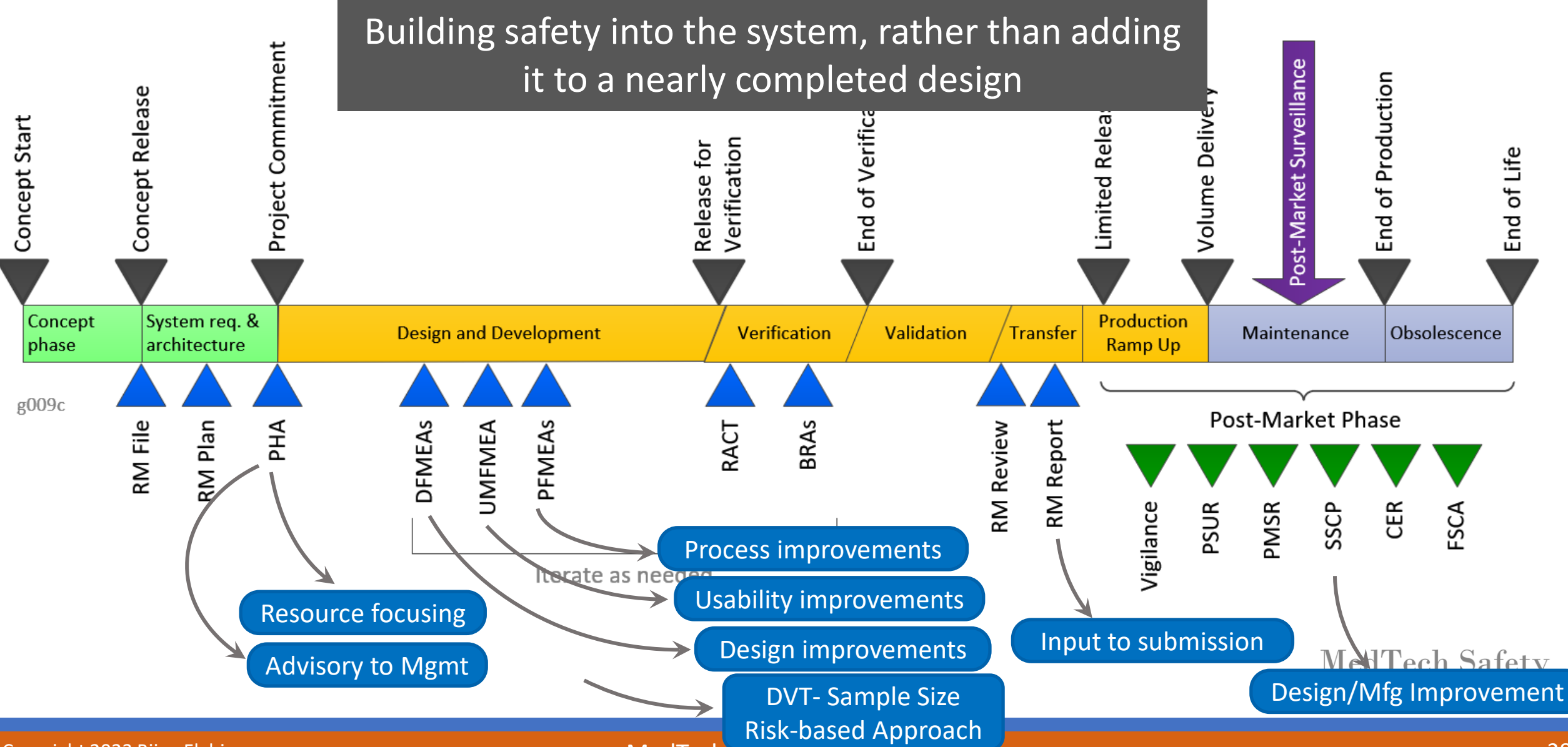
Challenges with Risk Management

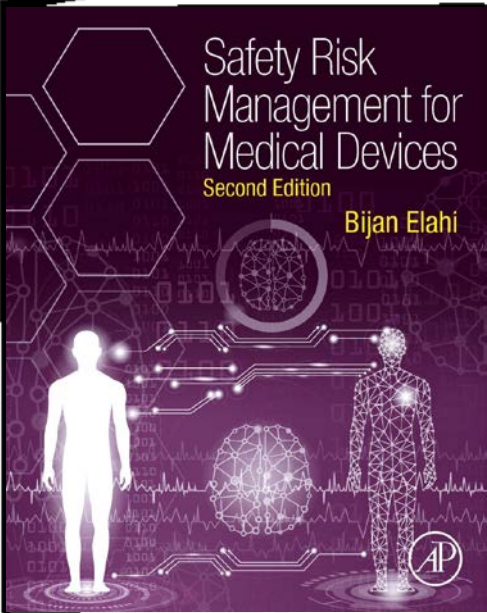
- All hazards and harms
- Risk estimation
- Risk evaluation
- Benefit-risk analysis
- Complaint handling and monitoring
- Complexity



Risk Management Process – Delivering Value

Building safety into the system, rather than adding it to a nearly completed design





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