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SHARE: From Theory to Practice: Teaching Risk Management in Medical Device Design through Case Studies

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SHARE: From Theory to Practice—Teaching Risk Management in Medical Device Design through Case Studies

Motivation: Engineering students entering the biomedical field face the dual challenge of designing innovative devices while navigating the complex legal and regulatory landscape that governs patient safety. To address this challenge, this SHARE activity adapts instructional strategies originally developed in a semester-long risk management course taught to a combined upper-level undergraduate and graduate level biomedical engineering class. The exercise suggested here draws upon the instructor's extensive medical-device experience to blend theory, regulatory frameworks, and analysis of real-world failures in a focused, transferable learning activity. Students often struggle to translate theory into practice when confronted with ambiguity, organizational pressure, and incomplete information. This activity responds to these challenges through structured, guided case-based instruction that emphasizes experiential learning for complex, multidisciplinary decision-making [1-4]. The activity blends high-level conceptual frameworks with analysis of real-world failures and culminates in students teaching core concepts to others through original case development.

Learning Objectives: Upon completion of this activity, students will be able to:

1. Understand how risk management integrates into the real-world medical device design and commercialization process, including regulatory and ethical considerations.

2. Apply high-level frameworks for risk, regulation, and ethics to ambiguous, real-world case scenarios.

3. Demonstrate communication and professional judgment skills by teaching selected concepts through original case development.

Implementation: The core SHARE activity uses structured case analysis and student-driven inquiry to engage students in applying theory to practice. Two instructor-curated exemplar cases serve as scaffolding. Information on these cases and related materials (including an introductory video) are given in the Appendices. Educators may, in the interest of available time, choose to truncate the activity to a single week by introducing the Challenger and Theranos material only. Student presentation of either case may then be evaluated using the Student Presentation Grading Rubric found in Appendix 7.

Case 1 - Challenger Disaster – involves ethical decision-making under uncertainty, communication breakdowns, and suppressed risk signals. Case 2 - Theranos – involves regulatory misalignment, misuse of regulatory pathways, and organizational ethics. These cases function as reference standards, modeling how conceptual frameworks apply imperfectly in practice. Students explicitly connect case features to assessment rubrics before completing their own deliverables.

Class Outline: Two-Week (Four-Class) Application and Teaching Module

Purpose: Exposure to the application of risk management, regulation, and ethics using exemplar cases, followed by exposure to deeper engagement by positioning students as teachers of risk, regulatory, and ethical concepts. Class periods should be a minimum of one hour to allow time for lecture, discussion and student presentations (in Class 3 & 4).

Week 1 – Modeling and Deconstruction

Class 1: Frameworks and Challenger discussion. Short lecture introducing high-level concepts in risk management and ethics, emphasizing risk and uncertainty rather than tools. Instructor-led discussion of Challenger focusing on ethical tension, organizational decision-making, and communication failures. Explicit mapping of discussion elements to the case presentation rubric. Appendix 2 provides a short introductory video that consolidates the risk and ethical topics, as well as providing an overview of the two cases. Appendix 3 is a summation of the key risk-related lecture topics, while Appendix 4 provides an overview of the Challenger case topics and suggested discussion questions.

Class 2: Theranos discussion with explicit attention to how cases are used in teaching, including preservation of ambiguity and the role of instructor notes. Appendix 5 provides an overview of the Theranos case topics and suggested discussion questions. For week 2, students will select a case topic drawn from historical or contemporary biomedical or engineering failures (list of potential topics given in the Appendix 6) and present these in Class 3 and (optionally) Class 4.

Week 2 – Student-as-Teacher

Class 3: Student presentations of developed cases emphasizing principles of risk and crisis management. Class 4: Meta-discussion on teaching effectiveness and submission of written case studies. If additional time is needed for student presentations, these may continue in the final class.

Assessment: Oral presentations lasting 10 minutes are evaluated using a case presentation rubric (Appendix 7). Written case studies are evaluated using a rubric assessing background research, key points relevant to risk and crisis management, discussion questions, instructor notes, and supporting materials, reinforcing peer-to-peer learning and curricular sustainability (Appendix 8). In a full semester class the student-created case is viewed as a "capstone" activity and represents 25 percent of total grade (6.25% presentation grade, 18.75% written case and materials). A lower percentage would be expected for this short exercise.

Situational Factors Affecting Implementation - This SHARE activity can be implemented in upper-level undergraduate or graduate engineering, business, or bioethics courses where understanding the intersection of design, regulation, and ethics is essential. Key situational factors include instructional time, class size, and student background. Required resources are minimal and include publicly available case materials, short lecture slides introducing high-level frameworks, and provided grading rubrics. Learning-management systems may be used to support preparation and engagement but are not required.

APPENDIX 1: Instructional Resources for Challenger, Theranos and Core Risk Management Text

This Appendix summarizes instructional resources used to support two scaffolded, case-based learning modules (Challenger and Theranos) and a core risk management text. Resources are organized consistently by case and resource type (case materials, supplemental readings, videos/multimedia, and books). Web links are presented in the References section to maintain formal manuscript formatting. Full bibliographic details for the cited resources are consolidated in the final References section.

A.1 Challenger Case

Case Materials

- Hastings, D. (2003). The Challenger Disaster (MIT OpenCourseWare case study).[5]
- Edmondson, A. (n.d.). The Challenger Launch Decision B (Harvard Business School 9-603-070): Engineer/Manager teleconference role-play (in-class).[6]

Supplemental Readings

- Online Ethics Center. (n.d.). Representation and misrepresentation: Tufte and Morton Thiokol engineers (Challenger).[7]
- Online Ethics Center. (n.d.). Engineers and scientists behaving well: Roger Boisjoly and the Challenger disaster.[8]
- NPR. (2012). Remembering Roger Boisjoly: He tried to stop shuttle Challenger launch.[9]

Videos / Multimedia

- The Challenger Disaster (2019). Feature film (teleconference scene ~49:00; trailer may be sufficient for class discussion).[10]

Books

- Higginbotham, A. (2024). Challenger: A True Story of Heroism and Disaster at the Edge of Space. Avid Reader Press.[11]
- McDonald, A. J., & Harrison, J. R. (2009). Truth, Lies and O-Rings. University Press of Florida.[12]

A.2 Theranos Case

Case Materials

- Fanning Center for Business Communication, University of Notre Dame. (n.d.). Theranos Inc.: Managing risk in a high-flying biotech startup (SAGE Business Cases).[13]
- Berkeley Haas Case Series. (n.d.). How did a $9 billion health tech startup end up DOA? (SAGE Business Cases).[14]

Supplemental Readings

- Design World Online. (n.d.). Schadenfreude for Theranos and satisfaction in how engineering doesn't lie.[15]
- USA TODAY. (2015). Safeway retreating from Theranos deal, report says.[16]

Videos / Multimedia

- The Verge. (n.d.). Theranos's invention never would have worked. Here's why. (YouTube video).[17]
- Cheung, E. (n.d.). TEDx talk (YouTube video).[18]
- Schultz, T. (n.d.). Interview (YouTube video).[19]

Book

- Carreyrou, J. (2023). Bad Blood: Secrets and Lies in a Silicon Valley Startup (Updated ed.). Vintage.[20]

A.3 Core Risk Management Text

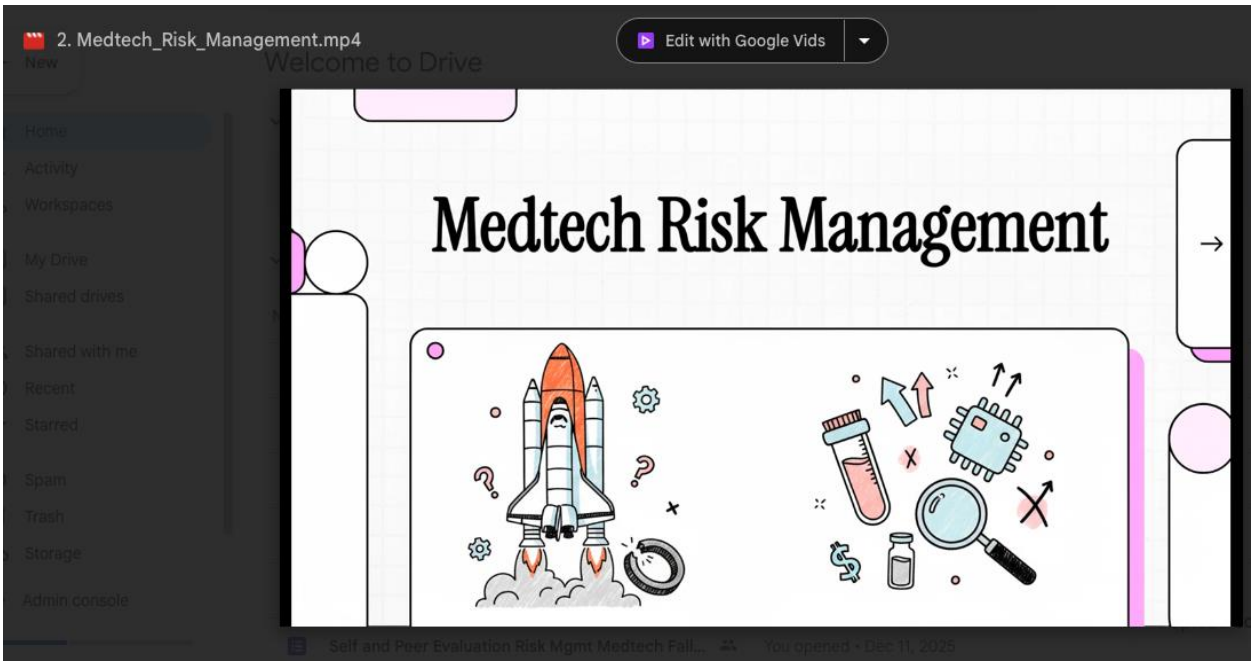
- Meyer, T., & Reniers, G. (2016). Engineering Risk Management. Wiley. (Unlimited online access to the 2016 edition via EBSCO; limited downloading available).[21]
  - Recommended chapters: Chapter 3 (Risk Management Principles) and Chapter 4 (Risk Diagnostic & Analysis).

APPENDIX 2: Introductory Video Resource

Video

An introductory short video was created using class slides and class syllabus as source materials in Google Notebook LM and is available at the following location. This 7-minute video provides an interesting overview of risk management and the two cases (Challenger and Theranos) that instructors may use to introduce the subject material. This video resource is available at the link below.

Video Available Here



APPENDIX 3: Risk Management Frameworks Used in Instruction

Overview

This appendix summarizes the core risk management concepts and frameworks introduced prior to case-based instruction. The goal is to provide students with a systems-level foundation that integrates ethics, regulation, and engineering design. The content described here may be utilized depending upon instructor objectives and class student background.

Key Conceptual Takeaways for Students

- Risk as systemic and multidimensional.
- Integration of ethics, regulation, and engineering design.
- Role of organizational culture and communication.
- Importance of early hazard identification.
- Continuous monitoring and lifecycle thinking.
- Difference between proactive risk management and reactive crisis response.

3.1 Conceptual Foundations of Engineering Risk Management

Instruction introduces risk management from an engineering systems perspective rather than a purely financial or actuarial view. Students are grounded in the working definition:

Risk = Probability × Consequence

Risk is framed as inherent to innovation, particularly in medical device development where uncertainty, incomplete information, and regulatory constraints coexist.

A key distinction emphasized early is between:

- Analytic approaches (studying parts first).
- Systemic approaches (studying the whole system first).

Engineering risk management emphasizes the systemic perspective because failures often arise from complex interactions rather than isolated component defects.

3.2 The Risk Management Process (ERM and ISO 31000 Alignment)

Enterprise Risk Management (ERM) principles are introduced with alignment to ISO 31000.[22]

The risk management cycle includes:

1. Establishing context.
2. Identifying risks.
3. Analyzing risks.
4. Evaluating risks.

5. Treating risks.
6. Monitoring and reviewing.

This is presented as a PDCA (Plan–Do–Check–Act) cycle emphasizing continuous improvement rather than one-time analysis.

Students are encouraged to view risk management as:

- Proactive rather than reactive (a "firefighting" mindset is discouraged).
- Iterative and embedded in design.
- A core part of decision-making and governance.

3.3 Models of Risk and Failure

Foundational conceptual models are introduced to support later student-developed case analysis:

- Swiss Cheese Model (barrier thinking): accidents occur when weaknesses align across multiple layers of defense.[23]
- P2T Model (People–Procedures–Technology): mitigation measures categorized as people, procedures, and technology.
- Normal Accident Theory (NAT): complex, tightly coupled systems may produce failures as a "normal" outcome of complexity.[24]

3.4 Types of Risk Analysis Techniques

Students may be introduced to high-level distinctions among risk analysis techniques:

- Inductive vs. deductive approaches (e.g., FMEA vs. FTA).
- Qualitative vs. quantitative methods (including semi-quantitative hybrids).
- Deterministic vs. probabilistic analyses.

3.5 Core Risk Analysis Methods Introduced

The following tools are summarized conceptually (not exhaustively applied in this SHARE module):

- Failure Modes and Effects Analysis (FMEA / FMECA): bottom-up, component-level analysis; ranks risk by severity, occurrence, and detection.
- Fault Tree Analysis (FTA): top-down, event-focused; models logical pathways to failure using gates.
- Static vs. dynamic risk modeling: differentiates risk as a potential state versus an evolving sequence of events (useful for cascading failures).

Students are not required to perform full formal analyses in the SHARE activity; rather, they use these frameworks as interpretive lenses during case discussions.

APPENDIX 4: Challenger Discussion Guide

Overview

This appendix provides a structured set of instructional topics and discussion questions that may be utilized for the Challenger case dependent upon instructor objectives and class student background. Topics are organized to support systems-level analysis across technical design, risk management tools, data communication, leadership ethics, and broader policy/economic pressures.

4.1. Technical Design and Proximate Cause (Understanding the "what" before the "why")

- O-ring failure: role of rubber O-rings in sealing segmented SRB joints and how low temperature reduced resiliency, increasing leak risk.[5]
- Segmented vs. unitary design: transportation-driven design decisions increased joint/seal risk relative to a unitary concept.
- Safety factors: misinterpretation of prior O-ring erosion as evidence of margin rather than a precursor signal.

Discussion Questions

- From an engineering standpoint, what made the O-rings a "single point of failure"?
- How did transportation and manufacturing constraints influence fundamental design risk?
- Why is interpreting damage as "acceptable" one of the most dangerous engineering behaviors?

4.2. Risk Management Frameworks

- Product-based tools: FMEA (identifying criticality) and FTA (causal logic via gates).
- Process-based tools: Swiss Cheese Model and Layer of Protection Analysis (LOPA) to evaluate safety barriers such as testing and communication.[23]
- Analytic vs. systemic thinking: why systemic thinking is essential in complex systems.

Discussion Questions

- How did FMEA fail to translate into meaningful risk mitigation?
- Using the Swiss Cheese Model, what were the major "holes" that aligned?
- Why is systemic thinking essential in complex engineering systems?

4.3. Data Representation and Communication

- Visual explanations: critique of pre-launch charts and the need for clear causal ordering (e.g., temperature vs. O-ring damage); see the Online Ethics Center resource listed in the consolidated references. [7,8]

- Communication gaps: breakdowns between contractor engineering teams and NASA decision-makers.

Discussion Questions

- How did data presentation influence management's perception of risk?
- What responsibility do engineers have to ensure their data is understood?
- How does framing ("prove it's unsafe" vs. "prove it's safe") change outcomes?

4.4. Leadership, Ethics, and Group Dynamics

- Groupthink and seniority bias: pressures for unanimity and suppression of dissenting technical views.
- "Management hat" dilemma: conflict between engineering judgment and organizational pressure.
- Whistleblowing and moral responsibility: ethical duty to prioritize public safety and the risks faced by whistleblowers.

Discussion Questions

- What ethical obligations did engineers have once their concerns were dismissed?
- How did organizational hierarchy suppress technical truth?
- Compare advocacy vs. inquiry models of group decision-making—how might inquiry have changed the outcome?

4.5. Policy, Economics, and System Complexity

- Space policy framing: transition to an "operational" mindset and the risks of normalizing deviance.
- Normal Accident Theory (NAT): tight coupling and complex interactions as drivers of catastrophic failure.[24]
- Dynamic complexity: how earlier policy/budget decisions created feedback loops influencing later risk.

Discussion Questions

- How did external pressures (schedule, politics, media) distort technical decision-making?
- Why are tightly coupled systems especially vulnerable to catastrophic failure?
- In what ways did early policy decisions shape later engineering risk?

APPENDIX 5: Theranos Discussion Guide

Overview

This appendix provides a structured set of instructional topics and discussion questions for the Theranos case. Topics are organized to support systems-level analysis across technical performance, risk management practices, data integrity, organizational culture, and regulation. The content described here may be utilized for the Theranos case dependent upon instructor objectives and class student background.

5.1. Technical Claims and Proximate Failure (Understanding "what failed" before analyzing "why")

- Core technical promise: Theranos claimed its Edison system could perform hundreds of assays from a single finger-stick sample; in practice, limited FDA clearance was achieved and much testing relied on conventional third-party analyzers.[13, 14, 20]
- Sample integrity and analytical validity: finger-stick capillary blood introduces variability (e.g., hemolysis, dilution, clotting) and many standard assays require venous samples.
- Hidden workarounds: sample dilution and routing to commercial machines undermined analytical validation and quality control.

Discussion Questions

- From a biomedical engineering perspective, what fundamental technical barriers exist to running comprehensive lab panels from microliter-scale finger-stick samples?
- How does sample integrity become a "single point of failure" in diagnostic systems?
- Compare this to Challenger's O-rings: what is the equivalent "critical component" in Theranos?

5.2. Risk Management Frameworks (or Their Absence)

- Lack of visible design controls: limited evidence of structured verification/validation or documented FMEA processes at Theranos.
- Quality system breakdown: later findings emphasized failures in quality control and lab operations.
- Swiss Cheese Model framing: failures aligned across device development, laboratory operations, regulatory oversight, corporate governance, and retail partnerships.[23]
- Analytic vs. systemic thinking: emphasis on isolated successes rather than system-wide performance.

Discussion Questions

- Where would FMEA have identified high-risk failure modes in Theranos?

- How did (apparent) lack of design controls enable technical problems to persist unchecked?
- Map Theranos onto the Swiss Cheese Model: what were the major “holes”?

5.3. Data Representation and Communication

- Narrative over evidence: reliance on endorsements and publicity rather than transparent validation.
- Suppression of negative data: concerns regarding deletion of outliers and concealment of failed QC runs; avoidance of external comparison studies.
- Misleading regulatory signals: CLIA certification represented as equivalent to FDA medical device approval/clearance.

Discussion Questions

- What responsibility do engineers have when management suppresses unfavorable data?
- How does this compare to the Challenger chart failures that obscured temperature risk?
- What constitutes ethical data presentation in safety-critical systems?

5.4. Leadership, Ethics, and Organizational Culture

- Culture of fear and secrecy: compartmentalization, aggressive NDAs, surveillance, and legal intimidation discouraged dissent.
- Whistleblowers: employees raised concerns despite personal and professional risk.
- Board failure: governance lacking technical diagnostics expertise provided legitimacy without oversight.

Discussion Questions

- Compare Roger Boisjoly (Thiokol engineer - Challenger) with Theranos whistleblowers: what barriers did each face?
- How did Theranos’ culture actively increase technical risk?
- What is the ethical obligation of engineers when leadership rejects technical reality?

5.5. Regulation, Economics, and System Complexity

- FDA vs. CLIA gap: exploitation of regulatory pathways (including LDT-related oversight dynamics) to avoid scrutiny while scaling.
- Regulatory arbitrage: ambiguity between device regulation and lab oversight accelerated deployment without proper validation.
- Retail pressure and FOMO: partners pursued adoption despite red flags, driven by competitive pressure.
- Normal Accident Theory: complexity, tight coupling, and rapid scaling increased the likelihood of failure.[24]

Discussion Questions

- Why is “move fast and break things” which has been said in Silicon Valley ventures fundamentally incompatible with healthcare?
- How did regulatory fragmentation enable Theranos to operate for years?
- What parallels exist between NASA’s institutional pressures and Silicon Valley venture culture?

APPENDIX 6: Candidate Student Case Study Topics

6.0 Topic List and Guidance (With Topic-Linked References)

This appendix lists suggested case study topics for a student case development exercise aligned with the SHARE module "From Theory to Practice – Teaching Risk Management in Medical Device Design through Case Studies."

For each topic below, students should define the system boundary, identify key stakeholders, summarize the proximate cause(s) and contributing systemic factors, and apply at least one risk framework (e.g., Swiss Cheese Model, FMEA/FTA, Normal Accident Theory, or People–Procedures–Technology).

6.1. Dalkon Shield and other contraception devices (including Essure)

- Explore ethical and design issues, adverse event reporting, and post-market surveillance.
- Discuss reputation persistence and how historical failures shape modern risk perception.
- Optional angle: compare IUD risk communication then vs. now; examine Essure post-market actions.

Suggested References

Mintz, M. (1985). At Any Cost: Corporate Greed, Women, and the Dalkon Shield. Pantheon Books.

U.S. Food and Drug Administration. (n.d.). FDA activities related to Essure. Retrieved February 21, 2026, from https://www.fda.gov/medical-devices/essure-permanent-birth-control/fda-activities-related-essure

Hysteroscopic tubal sterilization: A systematic review of the Essure system. (2009). Fertility and Sterility. Retrieved February 21, 2026, from https://www.sciencedirect.com/science/article/pii/S001502820900507X

The Cut. (2014). Why the IUD can't beat its bad reputation. Retrieved February 21, 2026, from https://www.thecut.com/2014/06/why-the-iud-cant-beat-its-bad-reputation.html

More recent discussion (Netflix series) related to a product called ESSURE. Hysteroscopic tubal sterilization: a systematic review of the Essure system from https://www.sciencedirect.com/science/article/pii/S001502820900507X

6.2. Reconstructive implants (total hip/knee arthroplasty; metal-on-metal bearings)

- Trace early biomaterials failures and how today's regulatory and quality system expectations would respond to these early product failures.
- Examine bearing-surface failures with hip and knee arthroplasty (design vs. processing vs. clinical use) and recall dynamics.

- Consider resurgence of hip metal-on-metal resurfacing designs and new interfaces (e.g., ceramic-on-ceramic).

Suggested References

The New York Times. (2013). The hip replacement case shows why doctors often remain silent. Retrieved February 21, 2026, from https://www.nytimes.com/2013/02/17/sunday-review/the-hip-replacement-case-shows-why-doctors-often-remain-silent.html

CBS News. (n.d.). Profemur artificial hips recalled; patients' fractures. Retrieved February 21, 2026, from https://www.cbsnews.com/news/profemur-artificial-hips-recalled-patients-fractures/

International Consortium of Investigative Journalists. (n.d.). Implant Files: Patient hopes rise and fall as an industry balances progress and profit. Retrieved February 21, 2026, from https://www.icij.org/investigations/implant-files/patient-hopes-rise-and-fall-as-an-industry-balances-progress-and-profit/

6.3. Temporomandibular joint (TMJ) arthroplasty and Proplast/Vitek litigation

- The Vitek Proplast-Teflon implant was designed as a cushion for the jaw joint, but it deteriorated inside the body, leading to massive foreign body reactions, bone destruction (resorption), and chronic pain.
- Discuss supplier/vendor liability and upstream quality responsibilities.
- Explore how litigation influenced innovation and market behavior.

Suggested References

Drug and Device Law Blog. (2009). Going after anyone in the neighborhood. Retrieved February 21, 2026, from https://www.druganddevicelawblog.com/2009/06/going-after-anyone-in-neighborhood.html

- FDA and TMJ implants. Available: https://tmj.org/living-with-tmj/tmj-implants/tmj-device-and-regulatory-history/

International Consortium of Investigative Journalists. (n.d.). Implant Files. Retrieved February 21, 2026, from https://www.icij.org/investigations/implant-files/patient-hopes-rise-and-fall-as-an-industry-balances-progress-and-profit/

6.4. Spinal pedicle screw litigation

- Analyze media coverage, plaintiff attorney dynamics, and manufacturer–surgeon relationships.
- Discuss how pedicle screw related litigation and settlements affected patient perceptions and market persistence.

- Connect to modern design controls, labeling, and clinical evidence expectations.

Suggested References

International Consortium of Investigative Journalists. (n.d.). Implant Files. Retrieved February 21, 2026, from https://www.icij.org/investigations/implant-files/patient-hopes-rise-and-fall-as-an-industry-balances-progress-and-profit/

6.5. Fracture fixation, including bioabsorbable fixation

- Evaluate safety factors, biomaterial testing, and early vs. late failure modes.
- Discuss market adoption barriers: perception of "disappearing implants" of resorbable materials, clinical evidence, and risk tradeoffs.
- Assess why certain bioabsorbable approaches remain niche relative to metal fixation.

6.6. Pacemaker recalls (e.g., Guidant, Medtronic)

- Examine recall decision-making, field actions, patient notification, and public trust.
- Discuss ethical issues in risk disclosure, and the balance between innovation and safety.
- Compare device malfunction risk communication with case-based engineering ethics frameworks.

Suggested References

Felder, J. (2006). Moral blindness and the Guidant recall. IEEE Engineering in Medicine and Biology, 25(1), 98–99.

Myerburg, R. J., et al. (2006). Life-threatening malfunctioning of implantable cardiac devices. New England Journal of Medicine, 354(22), 2309–2311.

6.7. Pharmaceutical litigation and safety crises (e.g., Vioxx; historical perspective such as thalidomide)

- Explore clinical study design, reporting, labeling changes, and crisis management.
- Discuss how regulatory burdens may trade off against delayed access to beneficial therapies.
- Analyze risk–benefit decision-making under uncertainty.

6.8. Drug-eluting stents (technology adoption and risk communication)

- Compare adoption risks vs. benefits relative to bare-metal stents.
- Explore appropriate-use decision-making, economics, and patient selection.
- Assess how evidence and marketing influence diffusion of innovation.

Suggested References

Stanford Graduate School of Business. (2006). Drug eluting stents: A paradigm shift in the medical device industry (Case OIT-50).

6.9. Pelvic mesh and public-facing documentaries (e.g., The Bleeding Edge)

- Analyze what went wrong: material selection, indications, training/learning curve, and post-market signals.
- Discuss how media narratives influence risk perception and policy response.
- Evaluate contemporary scientific reassessments and future directions.

Suggested References

Seifalian, A., Basma, Z., Digesu, A., & Khullar, V. (2023). Polypropylene pelvic mesh: What went wrong and what will be of the future? Biomedicines, 11(3), 741. https://doi.org/10.3390/biomedicines11030741

International Consortium of Investigative Journalists. (n.d.). Implant Files. Retrieved February 21, 2026, from https://www.icij.org/investigations/implant-files/patient-hopes-rise-and-fall-as-an-industry-balances-progress-and-profit/

6.10. Total hip arthroplasty: new materials/techniques (e.g., squeaking ceramic-on-ceramic hips)

- Explore public relations response to performance issues and how companies manage reputational risk.
- Discuss physician–industry relationships and transparency in reporting.
- Evaluate design issues and clinical performance monitoring.

Suggested References

The New York Times. (2013). The hip replacement case shows why doctors often remain silent. Retrieved February 21, 2026, from https://www.nytimes.com/2013/02/17/sunday-review/the-hip-replacement-case-shows-why-doctors-often-remain-silent.html

6.11. Automotive safety crises as analogs (e.g., Audi 5000 accelerator; Ford/GM defects; EV battery safety)

- Use an engineering risk lens to analyze crisis management, defect investigation, and media impact.
- Compare safety-critical decision-making in automotive vs. medical devices.
- Discuss how organizational incentives shape technical truth-telling.

Suggested References

The New York Times. (2014). A Florida engineer unlocked the mystery of GM's ignition flaw. Retrieved February 21, 2026, from https://www.nytimes.com/2014/03/29/business/a-florida-engineer-unlocked-the-mystery-of-gms-ignition-flaw.html

The New York Times. (2014). The Fault in the Cobalt Ignition Switch. Retrieved February 21, 2026, from https://www.nytimes.com/interactive/2014/06/05/business/The-Fault-in-the-Cobalt-Ignition-Switch.html

KBK Legal. (n.d.). The Ford Focus/Fiesta PowerShift transmission. Retrieved February 21, 2026, from https://www.kbklegal.com/resources/news-insights/the-ford-focus-fiesta-powershift-transmission-the-worst-of-both-worlds/

The Washington Post. (2019). Federal safety officials probe alleged Tesla battery defects. Retrieved February 21, 2026, from https://www.washingtonpost.com/technology/2019/11/01/federal-safety-officials-probe-alleged-tesla-battery-defects/

The New York Times. (2021). Tesla battery safety. Retrieved February 21, 2026, from https://www.nytimes.com/2021/10/04/business/tesla-battery-safety.html

6.12. Corporate ethics and crisis management: HP corporate spying scandal (pretexting)

- Focus on leadership ethics, decision-making, and reputational risk.
- Analyze governance, oversight failures, and use of outside investigators.
- Use of outside investigators to find source of information leaks from board members (used a legal, but probably unethical) technique called pretexting
- Connect to professional responsibility frameworks for engineers and leaders.

6.13. Mann Gulch fire disaster (Young Men and Fire) as a safety systems case

- Synthesize existing case studies and propose how the case can be taught for modern risk education.
- Analyze human factors, command structure, and decision-making under uncertainty.
- Connect to Swiss Cheese and Normal Accident Theory perspectives.

Suggested References

Maclean, N. (1992). Young Men and Fire. University of Chicago Press.

6.14. Medical device companies and surgeon relationships (e.g., Medtronic)

- Evaluate legal/regulatory scrutiny, public perception, and why surgeon involvement matters.
- Discuss conflicts of interest, disclosure, and implications for design and clinical evidence generation.

- Propose best practices for managing relationships while supporting safe innovation.

Suggested References

International Consortium of Investigative Journalists. (n.d.). Implant Files. Retrieved February 21, 2026, from https://www.icij.org/investigations/implant-files/patient-hopes-rise-and-fall-as-an-industry-balances-progress-and-profit/

6.15. Heart transplantation history under modern regulatory and ethical expectations

- Examine early risk-taking, clinical study design, and how failures/successes were covered in the press.
- Contrast pioneering eras with today's IRB/regulatory environment.
- Discuss lessons for innovation governance and patient safety.

6.16. Heart/Organ transplantation systems and failures (e.g., donor mismatch events)

- Analyze system design, workflow errors, and public relations considerations.
- Discuss quality systems and redundancy in high-risk care pathways.
- Include an international perspective on system-level risk.
- Study the history of heart transplantation in light of the current legal and regulatory environment, starting with initial work by pioneering cardiovascular surgeons such as Norman Shumway, Christiaan Barnard and Adrian Kantrowitz.
- Analyze risk management, risk taking, scientific background and clinical study prior to human use, failures and successes and how the work was covered in the press, lessons learned, etc

6.17. Hospital-acquired infections and safety culture

- Explore preventability, hygiene protocols, and the role of systems engineering in care delivery.
- Discuss litigation pressure, measurement, and continuous improvement.
- Connect to barrier models and human factors.

6.18. Opioid crisis (Purdue Pharma; Insys; mass litigation; public health ethics)

- Analyze corporate strategy, marketing ethics, regulation, and societal harm.
- Discuss systems-level failure across prescribers, payers, regulators, and manufacturers.
- Evaluate lessons for risk governance and accountability.

Suggested References

Keefe, P. R. (2021). Empire of Pain. Doubleday.

Meier, B. (2018). Pain Killer. Random House.

Macy, B. (2018). Dopesick. Little, Brown.

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6.19. Infant formula litigation/recalls and risk communication

- Examine allegations of awareness and failure-to-warn dynamics.
- Discuss post-market surveillance, supply chain risk, and public trust.
- Consider how risk communication influences caregiver decision-making.

6.20. Robotic surgery complications and adverse event reporting

- Explore learning curves, adoption incentives, and underreporting of complications.
- Analyze how companies promote expensive technologies and communicate risk.
- Discuss use of FDA adverse event databases for retrospective safety analyses.

Suggested References

Underreporting of robotic surgery complications. (2013). PubMed. Retrieved February 21, 2026, from https://pubmed.ncbi.nlm.nih.gov/23980819/

Johns Hopkins Gazette. (2013). News roundup: Robot surgery complications. Retrieved February 21, 2026, from https://hub.jhu.edu/gazette/2013/october/news-roundup-robot-surgery-complications/

Adverse Events in Robotic Surgery: A retrospective study of 14 years of FDA data. (2016). PubMed Central. Retrieved February 21, 2026, from https://pmc.ncbi.nlm.nih.gov/articles/PMC4838256/

6.21. Medical tourism (risk–benefit tradeoffs and system-level safety)

- Analyze quality variability, pricing incentives, and patient decision-making.
- Discuss how standards and oversight differ internationally and what risks emerge.
- Propose decision frameworks for patients and payers.

6.22. Safety in healthcare operations (OR safety and checklists; broader ‘bad design’ cases)

- Explore how operational safety differs from product safety but shares common risk frameworks.
- Use checklists, human factors, and systems engineering to discuss preventable harm.
- Optionally draw from curated case repositories to identify additional case ideas.

Suggested References

The writings of surgeon-author Atul Gawande such as Complications: A Surgeon's Notes on an Imperfect Science; Better: A Surgeon's Notes on Performance and The Checklist Manifesto;

Additional case ideas: Bad Designs. Retrieved February 21, 2026, from http://www.baddesigns.com

Additional case ideas: Device Events. Retrieved February 21, 2026, from https://deviceevents.com/

Student Deliverable Guidance (Optional)

If used as an assignment prompt, instructors may ask students to submit a 1–2 page proposal at the end of Week 1 that includes:

7. Topic selection and justification (why it is a risk management case).
8. Stakeholders and system boundary (who/what is included).
9. Proximate failure vs. systemic contributing factors (at least three).
10. Two risk frameworks to be applied (e.g., Swiss Cheese + FMEA).
11. Topic-linked preliminary reference list (≥5 credible sources).

APPENDIX 7: Student Presentation Grading Rubric

Rating Scale and Scoring Instructions

Each presentation is 10 minutes, with 2-3 minutes of that for discussion.

To support consistent scoring across reviewers, mark one rating box (DW, S, NI, or NA) for each criterion and provide brief comments. Suggested interpretation:

- DW (Does Well): Clear, accurate, and exceeds expectations for this assignment.
- S (Satisfactory): Meets expectations; minor gaps do not materially affect clarity or accuracy.
- NI (Needs Improvement): Partially meets expectations; gaps affect clarity, logic, or accuracy.
- NA (Not Addressed): Criterion not addressed or missing from the presentation.

Oral presentation (10 pts)

	DW	S	NI	NA	General Comments:
Talk as a whole: (volume/speed/ clarity)					
Smooth transitions:					
Answers questions clearly:					

Visual presentation (10 pts)

	DW	S	NI	NA	General Comments:
Clarity:					
Content:					
Visually appealing:					

Technical content (80 pts)

	DW	S	NI	NA	General Comments:
Introduction & overview					
Background					
Key points for course - risk and crisis management					
Stakeholders and consequences					

Key discussion questions and alternatives					
Conclusions and key points					

Comments/suggestions for case discussion and write up by student:

APPENDIX 8: Written Case Development Rubric

For students, remember what a case study does:
The case study method conveys real-world situations involving the design process and product failure, including the ambiguity, confusion, and complexity of such settings.

Case studies are grounded in course material; students apply relevant theories, frameworks, processes, practices, and tools to understand both the application (and limitations) of background readings and in-class lectures.

Grading Rubric Overview

Total points: 100. Score each section according to completeness, clarity, evidence, and alignment with course frameworks.

I. Background and history (objective - completeness and breadth of coverage of the topic):
(20 points)

II. Key points relevant to the course (objectives include: principles of risk and crisis management, including the identification, analysis, prioritization, resolution and monitoring of risk. Risk management techniques can be discussed such as failure modes and effects analysis and fault tree analysis. Crisis management may include contingency planning, crisis recognition and containment.)
(25 points)

III. Discussion questions (for this section write-up remember that the students using this case for a future class will define the problem, examining the response of technical and management professionals to the emerging crises and making recommendations for alternative approaches using the conceptual framework developed in the class, ask questions that relate to the course topics)
(25 points)

IV. Instructor notes (this section includes ideas for instructor for in-class discussion, primary purpose and key points of the case, supplemental readings suggested, outline key questions raised by the case and relation to class materials and other cases covered in class)
(20 points)

V. Appendix, background materials (objectives - completeness of materials, sources for students to review and separate materials that only the instructor will have, wide array of sources not only from websites and of varying detail. Remember the purpose of a case – the case imitates or simulates real situation and will include verbal representations of reality that put reader in the role of a participant. The background materials ideally will convey all the cross-currents and rough edges of real-life – including irrelevancies, sideshows, misconceptions, and variable amounts of information)
(10 points)

Scoring Notes (Optional for Instructors)

- Use the section descriptions as anchors for grading. Prioritize evidence-based analysis and clear linkage to course frameworks.
- For Section II, reward explicit use of risk management terminology (hazard, severity, probability/occurrence, controls/mitigations, monitoring) and appropriate frameworks (e.g., Swiss Cheese, FMEA, FTA).
- For Section V, reward diversity and credibility of sources (peer-reviewed, regulatory/standards, investigative journalism, official reports) and clear separation of student vs. instructor-only materials when used.

References:

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[10] The Challenger Disaster, motion picture, 2019. Available: https://www.imdb.com/title/tt7783966/

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