Systems Engineering: The Bridge between the Aerospace and Medical Industries

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System Engineering Definition

- Systems Engineering is an interdisciplinary approach and means to enable the realization of successful systems. It focuses on **defining customer needs** and required functionality early in the development cycle, documenting requirements, then proceeding with design synthesis and **system validation** while considering the complete problem Systems Engineering integrates all the disciplines and specialty groups into a team effort forming a **structured development process** that proceeds from concept to production to operation. Systems Engineering considers both the business and the technical needs of all customers with the goal of providing a **quality product** that meets the user needs.

System Engineering Challenges

- Reduced resources for schedule and cost
- Increasing regulatory requirements
- Constant changes to requirements
- Increasing interoperability and complexity demands

FDA Mission

FDA is responsible for ensuring the safety and high quality of more than a trillion dollars worth of products that are critical for the survival and well-being of all Americans -- products that include some 80 percent of the United States food supply, all human health care products, electronic products that emit radiation, animal drugs and feed, and cosmetics.

CDRH: Assure patient safety and device efficacy

FDA CDRH 2011 Strategic Priorities

- Priority 1: Fully implement a **Total Product Lifecycle Approach**
- Priority 2: Enhance communications and transparency
- Priority 3: Strengthen our Workforce and Workplace
- Priority 4: Proactively **Facilitate Innovation** and Address Unmet public Need

FDA Approach

- Justify design decisions based on assessment of **safety risk**
- *Design* **validation** *shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions* (820.30(g))
- Applying FDA Guidance 6/22/2011: Human Factors and **Usability Engineering** to Optimize Medical Device Design

FDA References to MIL-STD Documents

- Safety – MIL-STD 882
- Validation – MIL STD 2167A/498
- Human Factors – MIL STD 1472
- FMEA – MIL-STD 1629

FDA and Aerospace Differences

- FDA provides has only an oversight role:
  - inspects to published regulations and
  - clears/approves new devices
- International regulatory bodies and requirements are growing (ISO, CE Mark…)
- Companies have discretion on how to satisfy regulatory requirements

Regulatory Risk Challenges

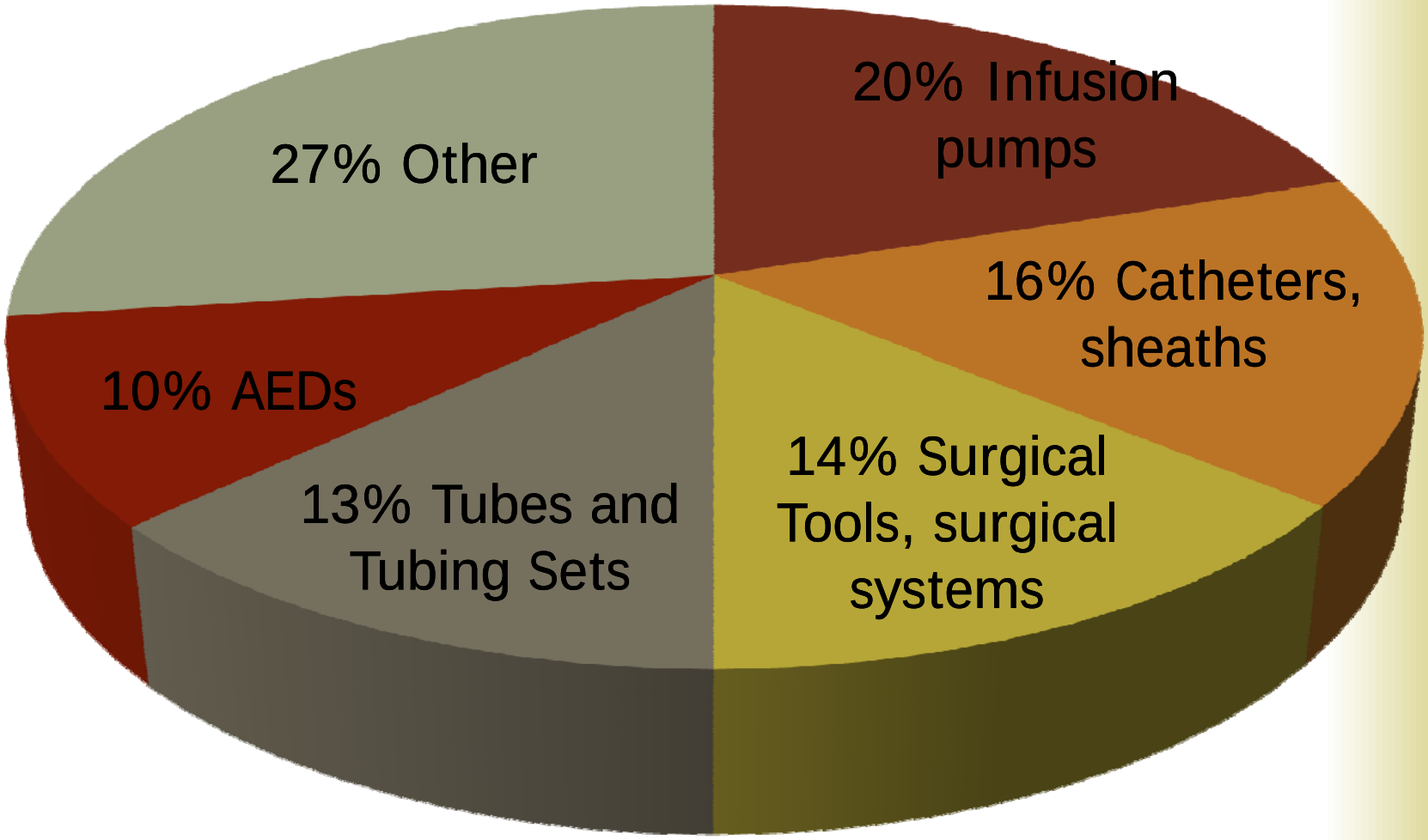
- Balancing regulatory procedural requirements and time to market?
- Achieving safety without impacting reliability and usability?
- How can legacy and off-the-shelf products (SOUP) be leveraged for new systems?

Case Study: FDA Medical Device Class I Recalls

- Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

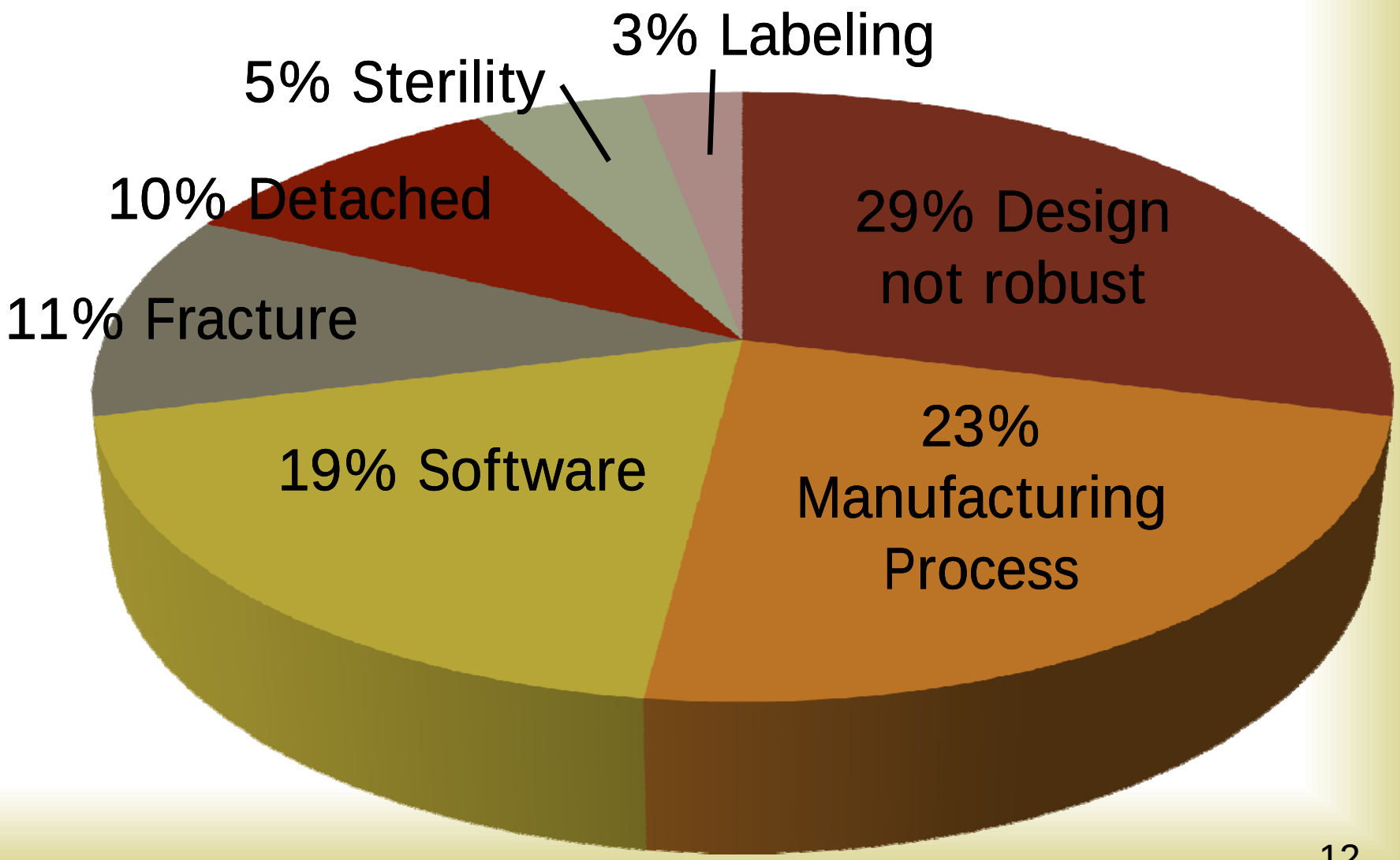
- Results of review of 100 Class 1 recalls between 2005 and 2011

Recalls by Product



Other: Apnea monitor, diagnostic tests, drug preparation, glucose meters, heat therapy, introducers, oxygen tank, teether, tubes, tubing sets, VAD, wheelchair

Recalls by Cause



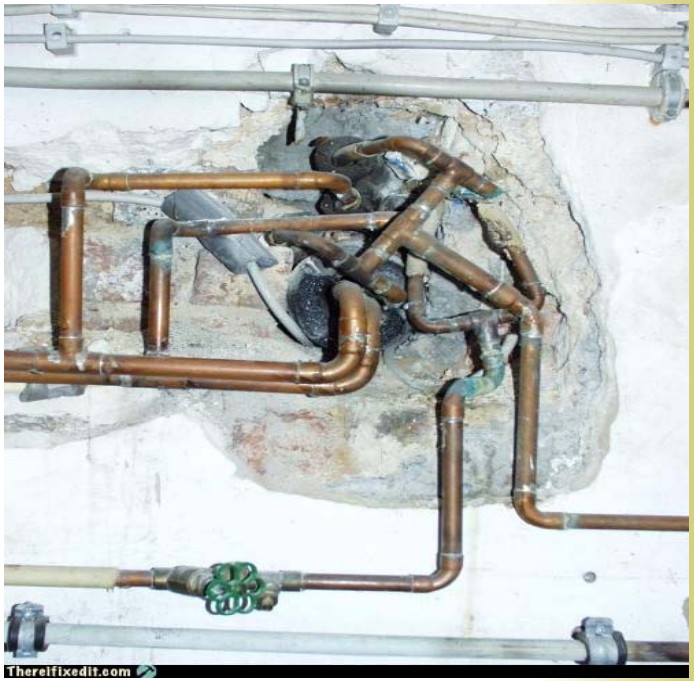
Process Problems

- Design: EMC, environmental conditions, component failures, power failures, rupture, fragments, wear, kinking
- Manufacturing process: Contamination, leaks, PCB failures, improper wiring, plastic deformation, wrong dimensions, packaging integrity, misassembled, inadequate bonding, improper formulation

Process Problems (cont.)

- Software: Algorithm failures, lock-ups, alarm handling, memory leaks, communication failures, control system failures, rapid data entry

Design Problems



- Requirements not understood
- Process not defined
- Ineffective testing
- Unrealistic schedules
- Lack of technical expertise
- Poor root cause and failure investigations for problems found
- Lack of accountability for defective designs

Required Solutions

- More sophisticated processes to address more complex designs
- More automated tools to facilitate implementation of new processes
- More effective techniques to leverage and apply historical lessons learned
- More proven methods to leverage unproven components

Summary

- The FDA has always leveraged Aerospace System Engineering (SE) standards
- Evolving technology will be increasingly reliant on SE for success
- SE processes must continue to evolve to address the increasing complexity of future systems