MEDICAL DEVICES RELIABILITY AND DURABILITY

3.1 Design for Reliability (DFR) is a process that spans the entire product development cycle from concept to release. It increases the probability of delivering a reliable product with the appropriate life-cycle cost to the market in a timely manner

3.1.1 Need for Design for Reliability (DFR) Program

- The challenges faced by medical device manufacturers in bringing safe, reliable, products to market in a timely manner, to maximize profits and increase market share is increasing rapidly
- With the global recession and increasing safety recalls, a good design for reliability (DFR) program is becoming imperative
- However, theoretical knowledge of DFR is not enough. Paradigms based on practical, "lessons learned" experience is necessary to ensure a successful DFR program in the medical device industry

3.2 5 successful paradigms with high ROI (return on investment)

3.2.1 Paradigm 1: Spend significant effort on requirement analysis

At start of project, ensure you have well defined requirements in the following areas.

Customer requirements	Functional performance
Reliability	FDA standards and compliance requirements
Durability	Manufacturing line yield
Environment	Serviceability/Maintainability
User Interface	Input /Output Interface
Installation	Shipping / Handling

Use / Misuse Model

- After requirements analysis, build a use/misuse model to drive design & testing
- The use/misuse model captures
- Who
- When
- Where
- How

The product may be used / misused, over its intended life; potentially resulting in failures.

Use / Misuse Model

Use/misuse model considers

- Environment of use - temperature, altitude, humidity, cleanliness, home/hospital, height from floor, portable/stationary, country of use etc.
- User demographics - seniors/adults/pediatric users, non-responsive or responsive patients etc.
- Frequency of use - continuous 24X7 operation or 8 hours a day operation, several million cycles or just a few cycles etc.

3.2.2 Paradigm 2: Critical failure is not an option for medical devices

- Use FMEA or FTA to identify all failure modes
- Design failure modes out of product
- Develop comprehensive test plan to test all failure modes
- Implement robust backup system like alarms, to mitigate risk in case of failures
- Build redundancy in detection & annunciation system
- Perform shock and vibe test, environmental test, drop test, ESD test and fault insertion testing on the alarm system
- Source critical components in alarm system from different suppliers

3.2.3 Paradigm 3: Measure reliability in terms of total lifecycle cost

- Do not discuss reliability in statistical terms such as probability percentage, confidence levels, distribution methods etc.
- It is hard for non-statistical people to understand the true impact of (un)reliability
- Measure reliability in terms of lifecycle cost (i.e. warranty cost, cost of repair and maintenance, cost of losing unsatisfied customers and litigation costs) and talk in terms of dollars and cents while making decisions that impact reliability

Impact of Reliability on Lifecycle Cost

- Most critical care products have a preventive maintenance program to inspect and service products at regular intervals
- The impact of reliability on the frequency, and cost of a maintenance check is an important consideration while making reliability related decisions
- Preventive maintenance program is tied together with the warranty program
- Warranty cost is inversely proportional to the reliability of a medical device

Example of using lifecycle cost to evaluate reliability

- 2 piece shaft and gear assembly. Lower reliability, lower upfront cost
- 1 piece assembly. Higher reliability, higher upfront cost
- Life of product is 5 years
- LCC = Parts Cost + Inspection/test Costs + Scrap/rework Costs + Warranty Costs + Safety Costs
- LCC (2 piece design) = 6.5M + 2.5M + 3M + 20M + 5M = 36.5M
- LCC (Single piece design) = 8.5M + 0 +0 +0 +0 = 8.5M
- Parts cost for the single piece design is higher by 2M since it includes the initial higher investment in the casting process

- However, potential life cycle savings for this project are 36.5M - 8.5M =28M. The return on investment of preventing the failure from occurring, is 28M/2M = 1400%

3.2.4 Paradigm 4: Don't just design for reliability, design for durability

- Use durability analysis to analyze what happens when a part operates over and over, cycling, day after day
- Durability analysis includes defect characterization, crack initiation and propagation mechanism, and long-term performance prediction at different stress levels
- Safety margin analysis, mold flow analysis, stress-strain analysis, stack-up analysis, fault tolerance analysis and derating analysis are tools that can be used while designing for durability

Durability Test Plan – Life Testing

- Base durability test plan on use/misuse model
- Test to several lives. Definition of lives:
- 1Life – Reliability requirement. Represents nominal usage patterns of a typical user
- 2Life – Goal, to ensure very high reliability
- 3Life/4Life - Margin testing with misuse scenarios and information gathering for warranty return evaluation

Pass/Fail criteria for life cycles

- 1Life – Device is fully functional as stated in user manual. No wear out or cracks or binding of any components. No cosmetic damage that would cause a product return.
- 2Life - Device is functional. May exhibit minor nuisance behavior. Some wear out of components is acceptable.

- 3Life – Most key functionality is still available. Wear out and hairline cracks acceptable.
- 4 Life - For information gathering purpose only

3.2.5 Paradigm 5: Design for prognostics to minimize surprise failures

- Purpose of prognostics is to detect the symptoms of malfunctions and failures, and warn the user well in advance before a product actually fails.
- Prognostics in medical devices analyze the data collected from various types of sensors in real-time to diagnose performance problems, discern impending faults, and schedule maintenance procedures.

Example of Prognostics

- Output of a pressure feedback sensor of a ventilator is fed into a microprocessor
- Data is used to adjust the motor speed to control the pressure delivered to the patient
- Sensor output signal has to be in a certain range
- If it starts drifting towards the edges of the limit, the prognostic circuit should display a “schedule service call” message.
- Preventive action can be taken before a failure actually occurs, shutting down therapy and putting patient safety at risk.

Application of Prognostics

- To frequently verify if the alarm system is working
- To check whether the backup power source i.e. battery is in good working condition
- In a dFMEA, as a detection mechanism and as a mitigation mechanism
- BIST (built in self tests) and POST (power on startup tests) can be used to implement prognostic capabilities

- Prognostic implementation strategies should be part of device requirements that should be specified at the beginning of the project.

3.3 Summary

- Define requirements fully at the beginning of the project
- Try to design failures out of your product
- Always evaluate the impact of reliability in terms of lifecycle cost
- Design for durability and prognostics
- Apply the five paradigms mentioned in this paper to ensure a successful DFR (design for reliability), program in the medical device industry