

# “Meet the Experts”

Medical Product Design and Validation Forum

## SMP Tech

September 22, 2010

**Speaker: Mike Silverman, Ops A La Carte**

**Title: Reliability Challenges in the Medical Industry – Case Studies of Two Medical Products**





Mike Silverman is founder and managing partner at [Ops A La Carte](http://www.opsalacarte.com/), a Professional Consulting Company that has in intense focus on helping customers with end-to-end reliability, especially in the medical industry.

We have our own Reliability Lab called HALT and HASS Labs where we have successfully helped customers improve the reliability on over 500 different products.

Mike has a book coming out this fall entitled “*How Reliable Is Your Product? 50 Ways to Improve Your Product Reliability*”

<http://www.opsalacarte.com/>



# **CASE STUDY 1: FDA Class III Medical Device Pacemaker**

**The following case study  
illustrates how to use  
regulatory and reliability  
together in a program.**

# Case Study: FDA Class III Medical Device Pacemaker interrogating device Pre Market Approval

Submitted and approved documents:

- 1) Corporate Quality System Handbook
- 2) Product Development Handbook
- 3) Product Development Management Plan and Report
- 4) Product development, review and approval record
- 5) Risk Analysis for both software and hardware
- 6) Failure Rate Prediction, parts count
- 7) Failure Mode Effects Analysis / Fault Tree Analysis
- 8) Product Validation test reports both hardware and software
- 9) Document change procedure
- 10) Document release procedure
- 11) Purchase procedure
- 12) Product serial number system
- 13) Material Review Board Procedure
- 14) Finish Goods Procedure
- 15) Internal Audit Procedure
- 16) Training Procedure
- 17) Standard Operations Procedure

# Risk Analysis

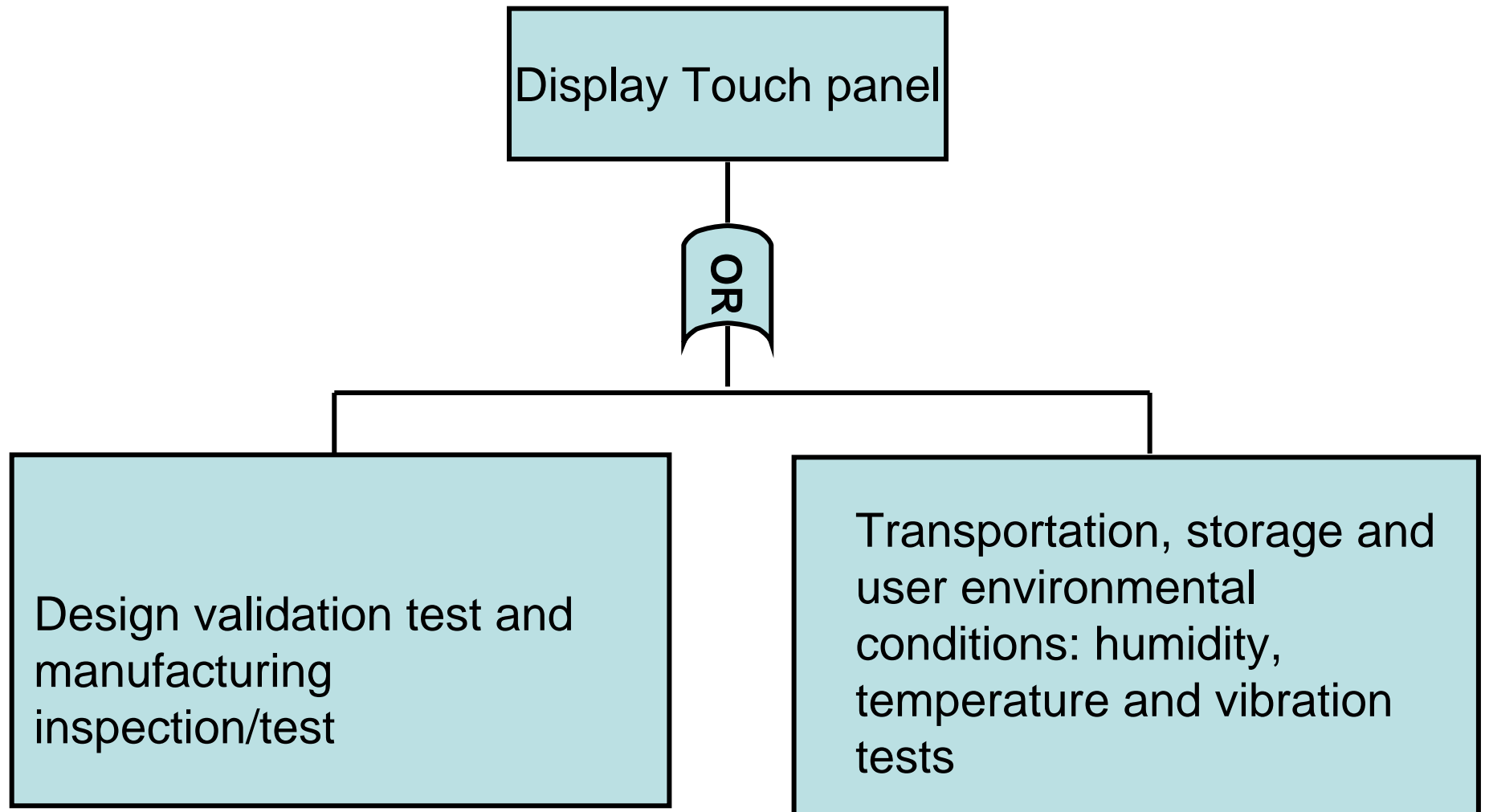
Risk	Analysis	Mitigation
01 Leakage current From AC mains to implemented and non-implemented devices	Patients & users safety	Design, test & manufacture compiling with IEC60601-1 and collateral standards  Validation plans, tests and reports
02 Rough & cutting surface	Patients & users safety	
03 High temperature	Patients & users safety	
04 Electromagnetic Compatibility	Susceptible or causing malfunction with other electronic devices through RF interference	
05 Hardware Malfunction	Components, accessories, modules & systems	- Validation test - Field returns analysis and corrective action implementation

# Failure Mode Effects Analysis (FMEA)

## Sorted by Severity x Occurrence

Failure Mode ID #	Failure Modes application analysis	Descriptions
01	Display Touch panel	No or wrong response
02	Printer	Missing or no printing
03	System function	Fail system self test
04	ElectroMagnetic Compatibility	ESD, ElectroMagnetic field and AC mains immunity & emission
05	Leakage current	AC mains or other connected equipments

# Fault Tree Analysis



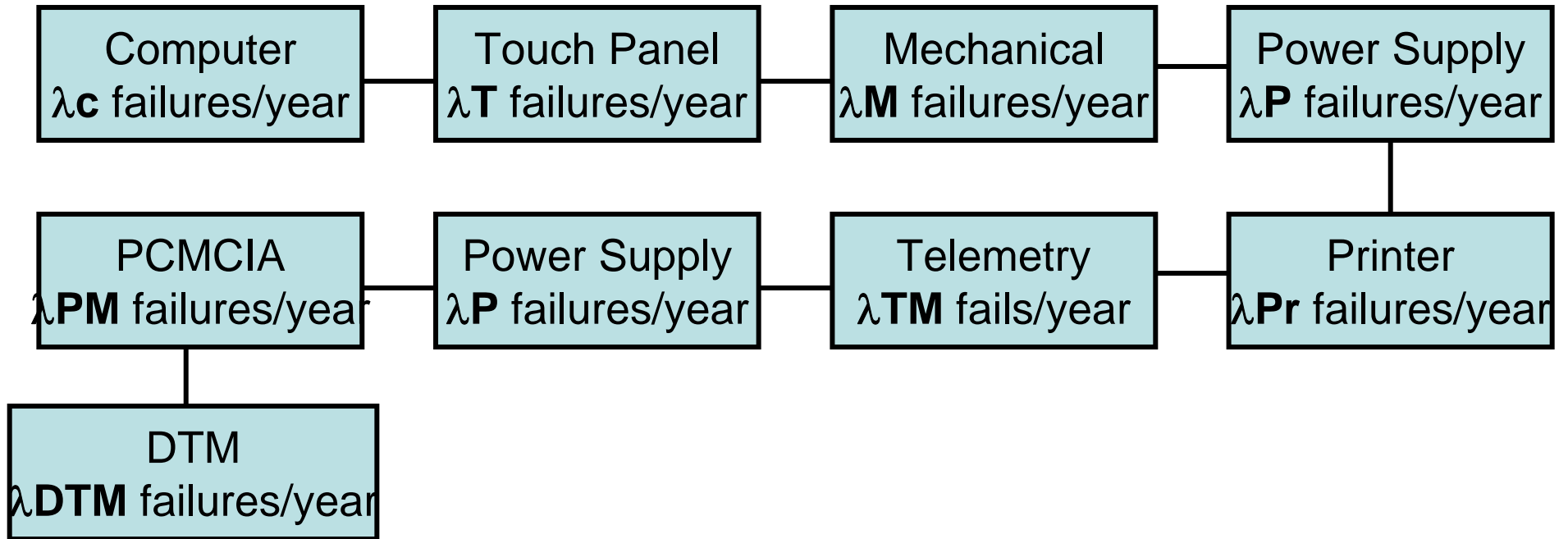
# Failure Mode Effects Analysis (FMEA)

FMEA
ID 01: Display Touch panel (1.5% per year)
Test software: Calibration errors due to operators or software design
Detection: No response, wrong response or out of range of buttons
Root Cause: Poor training or software quality
Effects: Can not correctly program or monitor pacemakers

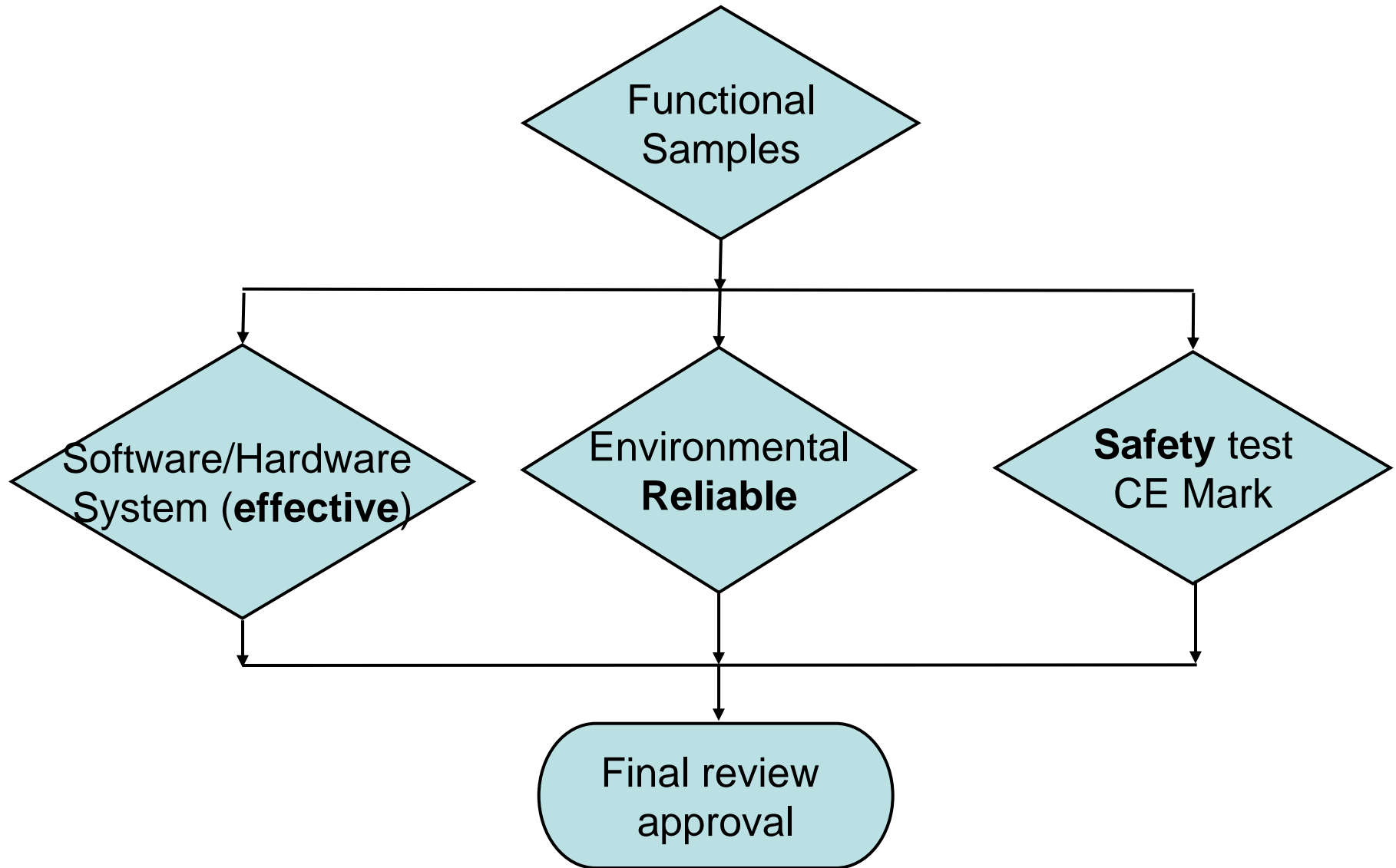
# Failure Mode Effects Analysis (FMEA)

FMEA
ID 01: Display Touch panel
Probability: 1 $\leq$ 2% per year (1 to 5 of occurrence) Severity: 2 Low (1 to 5)
Criticality: 1 x 2 = 2 1 to 5 - None, Low, Significant, High & Catastrophic
Risk reduction: Implement touch panel calibration software, hardware & system validation test & review.
Notes: 1) Manufacturer inspect and test touch panel. 2) Receiving, production and shipping inspection/test

# MTBF PREDICTION



# VALIDATION TEST FLOW CHART



The previous case study illustrated how to use regulatory and reliability together in a program.

But what about reliability issues not related to regulatory concerns?

The FDA does not give much guidance in how to develop a reliable product. Their principle concern is safety! If the product fails, it must fail safe.

***Therefore, we must come up with appropriate methods to ensure reliability.***

# **CASE STUDY 2: Infusion Pump**

**The next example illustrates how we worked with a company and took them through an entire reliability program to make sure we addressed all major risks to reliability.**

# CASE STUDY II: MEDICAL INFUSION PUMP



# MEDICAL INFUSION PUMP

- The infusion pump was an n+1 design
- We started with a reliability goal statement
- Then we wrote a comprehensive reliability program plan

# MEDICAL INFUSION PUMP

## RELIABILITY PROGRAM PLAN

- Which areas were the same
- Which areas were new
- Reliability allocations
- Gap analysis
- Reliability Tools Deployed, General for all assys
- Reliability Tools Deployed, Specific to certain assys
- How will tools be used
- Metrics to be used during program
- Reliability Reporting and Issues Management
- Roles and Responsibilities
- Reliability Deliverables
- Contingency Planning
- Ongoing Reliability Assurance

# MEDICAL INFUSION PUMP

## NEW ASSEMBLIES

- Two new motors - one for the cassette insertion and removal, and one for the air sensor to pinch the tubing in order to detect air bubbles in the line.
- A new power supply that was larger and also had a battery charging circuit for the new rechargeable battery.
- A touch screen
- An 802.11 wireless interface
- A new rechargeable battery design
- New software to handle all of these new features

# MEDICAL INFUSION PUMP

## IDENTIFY RELIABILITY RISKS

- Using the Risk Analysis process, we identified as many new risks as possible
- Then we set out to figure ways of mitigating these risks
  - Design analysis techniques such as FEA, DOE, and Thermal Analysis
  - Accelerated Testing techniques such as HALT, ALT, and RDT
- The important element here is that we always had an eye on our goal.

# MEDICAL INFUSION PUMP

## RELIABILITY TECHNIQUES USED

- Motors – FEA, ALT
- Power Supply – HALT then RDT
- Touch Screen – ALT, Abuse Testing
- Wireless Interface - HALT
- Battery – Application Specific ALT
- Software – Software FMEA, Software Use Case Testing

# MEDICAL INFUSION PUMP

## RESULTS

- Using this process we saved time and money.
- We found out issues during the design analysis that would have required a redesign had we found them later in the design, or worse, out in the field
- We found out issues during the testing that would have set our program back months.
- End result: We developed and delivered a very reliable product and got it to market faster.

# SUMMARY

- **Comply** with FDA GMP, IEC60601-1 Safety, ISO14971(EN1441) & IEC60601-1-4
- **Perform** Risk Analysis, Failure Mode Effects Analysis, MTBF prediction, HALT, Accelerated Life Tests, Environmental tests, Validation tests & Safety compliance test
- **Provide Confidence** for Safe, Effective and Reliable products and services in product life cycle: Development, Approval, Production, Field services and End of usage
- Manufacturers should develop the **Appropriate** and **Practical** solutions

# THE CHALLENGES

- Need both reliability and regulatory expertise
- Need management of cost, samples and test facility

# THE REWARD

Having these will provide you with

- reliable product
- timely approval by FDA and other agencies