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Winter 2009

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MEDICAL RELIABILITY



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SPECIAL OFFERS - \$1000 for leads, Free Job Listings

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MESSAGE FROM THE CEO

Welcome to our 20th quarterly newsletter. This was perhaps our busiest quarter yet in terms of trade shows and new customers. We exhibited and presented at ASTR in New Jersey, ASQ in Santa Clara, TCA in San Jose, and MEPTec Solar in San Jose. And we still have the Biomed show left this year, and then next year starts out busy with RAMS, followed by MD&M and then CMSE. We will be exhibiting at all of these shows as well.

And we were just as busy with new customers in new territories. We just closed our largest deal ever in China and our first deal ever in Turkey.

We are experiencing a bit of a slowdown to our military/space vertical market, but the activity in solar and medical is more than making up for it. We've worked with more solar companies in 2009 than the past 9 years of our company combined.

And to help capitalize on the momentum in the medical market, we are teaming up with [Voler Systems Design Services](#) and [SigmaQuest Quality Systems](#) at the Biomed Show coming up Dec 9-10 in San Jose (if you come to the show, stop by and visit us in booth 1100) followed up by our annual open house on Dec 11th. In keeping with the medical theme, we have decided that the theme of the Open House will be Medical Devices and we will only be inviting medical device companies and consultants with a strong medical device practice to help increase the value and cross-flow of ideas at the event.

I just finished writing my first reliability book entitled "How Reliable Is Your Product? 50 Ways to Improve Your Product Reliability". We will be giving away FREE e-copies of the book at booth at the Biomed Show and at our open house. The book will be out in print in Q1 '10.

We are also seeing quite a bit of new activity in Canada, and for that reason, we have just added a new consultant in Toronto. Please help us welcome Peter Arrowsmith. You can read all about Peter in our [about team](#) page.

Our HALT and HASS Lab continued to see a high demand this past quarter and based on the current schedule, it appears we will remain busy through the end of the year and on into Q1 '10.

We hope you enjoy the following newsletter. Thank you for your continued support and interest.

- Mike Silverman, Managing Partner/CEO

COURSES

Course: Design for Reliability (DfR) Seminar in Taiwan and China

Dates: Dec 2 in Taiwan, Dec 7 in Shenzhen China

Time: 8:30am to 4:30pm

Instructor: :Mike Silverman, Ops A La Carte

Cost: \$30 USD / NTD 1000 / 250 RMB

▶ Course: Certified Reliability Engineer (CRE) Preparation Course

Dates: Jan 12 - Feb 23, 2010

Time: 6pm-10pm one night a week, 7 weeks

Instructor: :John Cooper and Doug Farel, Ops A La Carte

Length: 7 weeks

Cost: \$1295. We offer 25% discount for the following a) webinar attendees, b) unemployed, and c) those not get re-imbursed by their company. We offer a 50% discount to full time students.

Location: San Jose, CA

Offered via webinar for out of town students.

Description: Becoming certified as a Reliability Engineer (CRE) can be valuable to your employer and your career. We are offering this Exam Preparation Course. Students have found it very valuable in preparing for the exam. Even if you are not planning on taking the exam but need a good, in-depth course in Reliability Engineering, this can benefit you substantially.

Course Webpage: [CRE Course by Ops A La Carte](#)

▶ For information on other course offerings go to: [Ops A La Carte Schedule](#)

▶ All our courses are offered as **in-house tailored** seminars. To view a list of all our seminars, go to [Ops A La Carte Course List](#)

SEMINARS

▶ Product Realization Group (PRG) Lunch and Learn Series (all are FREE)

Dec. 15, 2009 [Quality from the Start](#)

Feb. 11, 2010 [Positioning Your Business to Ramp out of the Recession](#)

Mar. 11, 2010 [New Paradigms for Designing Green Products](#)

Apr. 15, 2010 [Medical Product Development and Validation](#)

May 13, 2010 [Driving Product Realization with Global Collaboration](#)

▶ Note that we have started offering these lunch and learns via webinar as well. If you cannot attend in person and would like to attend via webinar, please note that on your registration form. To register for any of these lunch and learn sessions, please go to [L&L registration form](#)

EVENTS

▶ Biomed Device Show - Dec 9-10, San Jose , CA

We will be exhibiting together with [Voler Systems](#) (a design firm) and [SigmaQuest](#) (a quality tools firm). We will be showing our new collaborative services for the medical industry.



Download: [Ops, Voler, & SigmaQuest: Leaders in Reliability & Quality Solutions for Medical Products](#)



For more info, please

▶ Biomed Open House - Dec 11, Santa Clara , CA

Following the Biomed Show, Ops A La Carte will be having a special Open House event targeted to the Biomed/Medical Device community. We will be highlighting our over 70 products we have worked on as well highlighting our collaborative relationship with our partners [Voler Systems](#) (a design firm) and [SigmaQuest](#) (a quality tools firm) as well as our many other partners in this space. We will also have guest presentations from some of the top medical companies in the valley. We will be sending out a special RSVP to all our medical customers and partners.



For more info or if you know you would like to attend, please

▶ [Reliability, Maintainability, and Availability Symposium \(RAMS\)](#)

Date: **January 25-28**

Location: Doubletree Hotel, San Jose, CA

About Event: We will be exhibiting and presenting the follow papers at this event.

"*How to Design a Better Test Program*", by Mike Silverman

"*Using Electronic Design Automation (EDA) throughout Product Life Cycle*", by Bryan Stallard and Mike Silverman

"*Estimating Field Failure Rate from the Results of HALT*", by Harry McLean and Mike Silverman

For more info, please



▶ [Medical Device and Manufacturing \(MD&M\) West](#)

Date: **Feb 9-11**

Location: Anaheim Convention Center, Anaheim, CA

About Event: We will be presenting the follow papers at this event.

"*HALT and ALT for Medical Products*", by Mike Silverman

For more info, please



▶ [Components for Military and Space Electronics](#)

Date: **Feb 8-11**

Location: LAX Radisson Hotel, Los Angeles, CA

About Event: We will be presenting the follow papers at this event.

"*HALT and ALT for Medical Products*", by Mike Silverman

For more info, please



SPECIAL OFFERS

\$1000 off your next service or seminar or one free pass to any of our upcoming events or seminars *to any individual who introduces us to a new customer with whom we engage.*

Email us via our [Special Offers Contact Form](#)

NEWS



BELOW ARE NEWS HIGHLIGHTS FOR THE PAST QUARTER. MORE DETAILS FOR EACH ITEM CAN BE FOUND AT [NEWS](#).

All presentations that we gave can be found on the technical download section of our website at [Technical Papers](#).

- November 19, 2009: **MEPTEC "Semiconductor to Solar" Symposium, San Jose**

We exhibited and presented the paper: "**Reliability Challenges for Solar Photovoltaics and Opportunities for Semiconductors**"

Also, congratulations to the winner of our Solar-Powered RC Car, Jim Huang of Hong Kong Science Park. See pictures of the [Solar Symposium](#). This is quite appropriate because Managing Partner Mike Silverman will be in Hong Kong next month on his way to Shenzhen China. As a result of the two meeting at the Solar Symposium, Mike will be visiting the HKSP on his trip to discuss business relations between the two companies.

- November 15, 2009: **Ops adds a new consultant to our team**

Peter Arrowhart (*Eastern Canada - Toronto*) has over 20 years industry experience in magnetic disk drive manufacturing, electronics and optoelectronics packaging and assembly, in the areas of materials analysis, process development, technical problem solving, reliability and quality improvement. See the [Ops Team](#) for more details.

- **November 13, 2009: Ops celebrates writing its 2000th proposal.** Even though we officially became a company in January 2001, we started numbering our proposals in May, 2004 and since that time, we have written 2000 proposals. That is an average of one proposal every day for 5 1/2 years (including weekends). And our success rate in receiving orders for written proposals remains one of the highest in the consulting industry - over 50.

See the attached pictures of our [2000 Proposals Party](#).

- **November 7, 2009: "HALT to AFR Calculator" Webinar**

Thank you for those who joined us for our webinar on November 6th introducing our revolutionary "HALT to AFR Calculator". We have developed a model in which we can calculate the actual field failure rate of a product solely based on the results of HALT (and very accurately I should add). Over 300 people signed up for this webinar and we have had lots of follow on interest and inquiries. If you missed it or want to show to a friend or colleague, go to [Tech Papers](#) for the video download or the pdf slide download (all the rest of our tech papers are there for download as well, including the Solar Reliability presentation we gave at last week's Semiconductor to Solar Symposium in San Jose).

- **October 28, 2009: Advanced TCA Show, San Jose**

We exhibited at the event and presented the paper: **"New Fast Method for Determining Product MTBF"**

- **October 24, 2009: ASQ Quality Conference "Road to Excellence: Best Practice Trails", San Jose**

We exhibited and presented the paper: **"Estimating Field Failure Rate From the Results of HALT"**

Also, congratulations to the winner of our RC Helicopter, Lily Tso of JDSU. See pictures of the [ASQ Conference](#)

- **October 8, 2009: Ops Named One of Fastest Growing Companies in Silicon Valley**

SJ Business Journal announces Ops A La Carte as one of the 70 fastest growing private company in the Bay Area. Each year, the Silicon Valley/San Jose Business Journal comes out with a list of the fastest growing private companies in Silicon Valley, and this year, Ops A La Carte has made the list. On October 8th, they held a banquet and announced that we placed 60th on the list. For more details, go to [SJ Business Journal's Fast 70 List](#).



- **October 7-9, 2009: Accelerated Stress Testing and Reliability Workshop, New Jersey**

We exhibited at the event and presented the following papers and tutorials

"How to Design a Better Test Program"

"Green Reliability"

"Estimating Field Failure Rate From the Results of HALT"

Also, congratulations to the drawing winner, Ablel Fessehaye of SoHaR. See pictures of the [ASTR Conf.](#)

- **October 2, 2009: Hunter Technology OktoberTechFest**

Ops gave a presentation on **"Design for Reliability - an Overview"**

- **September 30, 2009: "Green Reliability" talk at the IEEE Reliability Society, Cupertino, CA**

We presented a paper on **"Green Reliability - Where Do We Start?"**

► **For more information** on news, please visit our [News Page](#) or call (408) 654-0499.

FEATURED SERVICE



MEDICAL RELIABILITY

Authors: Mike Silverman and David Tu

The Food and Drug Administration (FDA) <http://www.fda.gov/> develops and enforces compliance for safety, effectiveness and reliability. FDA does not develop engineering specifications and standards for Medical Devices. FDA regulations are free for reference.

International Electrotechnical Commission <http://www.iec.ch/> Develop regulatory and engineering safety specifications and standards for medical device safety.

Medical devices at European market requires CE marking. It is a self declaration process with the compliance of all applicable standards. IEC standards are available for purchase online.

21 CFR Parts 808, 812, and 820 Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Page 2

SUPPLEMENTARY INFORMATION: I. Background (Design Controls)

“Specifically, in January 1990, FDA published the results of an evaluation of device recalls that occurred from October 1983 through September 1989, in a report entitled “Device Recalls: A Study of Quality Problems”. FDA found that approximately 44 percent of the quality problems that led to voluntary recall actions during this 6-year period were attributed to errors or deficiencies that were designed into particular devices and may have been prevented by adequate design controls.”

21 CFR Parts 808, 812, and 820 Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule A. General Provisions, page 55, § 820.3 Definitions

B. Complaint means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

C. Design Controls, page 18, 72.

FDA emphasizes, however, that the section requires the manufacturer to ensure that the design input requirements are appropriate so the device will perform to meet its intended use and the needs of the user. In doing this, the manufacturer must define the performance characteristics, safety and reliability requirements, environmental requirements and limitations, physical characteristics, applicable standards and regulatory requirements, and labeling and packaging requirements, among other things, and refine the design requirements as verification and validation results are established. For example, when designing a device, the manufacturer should conduct appropriate human factors studies, analyses, and tests from the early stages of the design process until that point in development at which the interfaces with the medical professional and the patient are fixed.”

The purpose of conducting design reviews during the design phase is to ensure that the design satisfies the design input requirements for the intended use of the device and the needs of the user. Design review includes the review of design verification data to determine whether the design outputs meet functional and operational requirements, the design is compatible with components and other accessories, the safety requirements are achieved, the reliability and maintenance requirements are met, the labeling and other regulatory requirements are met, and the manufacturing, installation, and servicing requirements are compatible with the design specifications. Design reviews should be conducted at major decision points during the design phase.

APPLICATION OF DESIGN CONTROLS

Design controls may be applied to any product development process. The simple example shown in Figure 1 illustrates the influence of design controls on a design process.

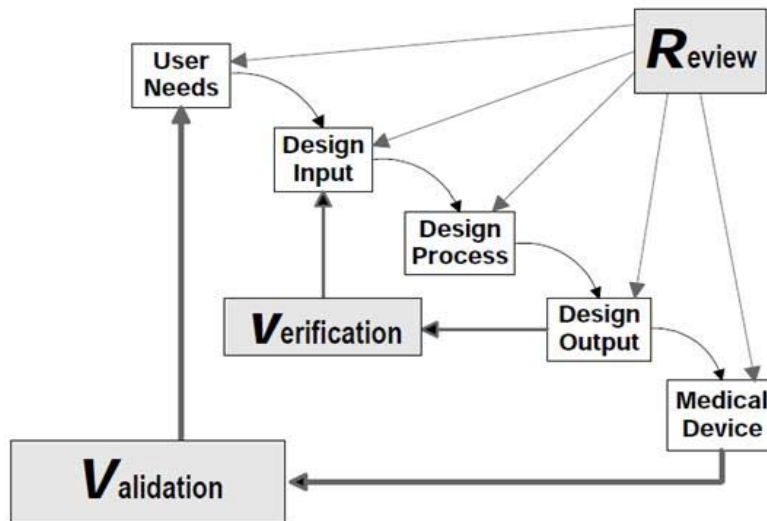


Figure 1 – Application of Design Controls to Waterfall Design Process (figure used with permission of Medical Devices Bureau, Health Canada)

THE QUALITY SYSTEM AND DESIGN CONTROLS. In addition to procedures and work instructions necessary for the implementation of design controls, policies and procedures may also be needed for other determinants of device quality that should be considered during the design process. The need for policies and procedures for these factors is dependent upon the types of devices manufactured by a company and the risks associated with their use. Management with executive responsibility has the responsibility for determining what is needed.

Example of topics for which policies and procedures may be appropriate are:

- risk management
- device reliability
- device durability
- device maintainability
- device serviceability
- human factors engineering
- software engineering
- use of standards
- configuration management
- compliance with regulatory requirements
- device evaluation
- clinical evaluations
- document controls
- use of consultants
- use of subcontractors
- use of company historical data

SCOPE AND LEVEL OF DETAIL

Design input requirements must be comprehensive. This may be quite difficult for manufacturers who are implementing a system of design controls for the first time. Fortunately, the process gets easier with practice. It may be helpful to realize that design input requirements fall into three categories. Virtually every product will have requirements of all three types.

- Functional requirements specify what the device does, focusing on the operational capabilities of the device and processing of inputs and the resultant outputs.
- Performance requirements specify how much or how well the device must perform, addressing issues such as speed, strength, response times, accuracy, limits of operation, etc. This includes a quantitative characterization of the use environment, including, for example, temperature, humidity, shock, vibration, and electromagnetic compatibility. Requirements concerning device reliability and safety also fit into this category.
- Interface requirements specify characteristics of the device which are critical to compatibility with external systems; specifically, those characteristics which are mandated by external systems and outside the control of the developers. One interface which is important in every case is the user and/or patient interface.

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 and Criticality Analysis Report
- 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

See the web version of this newsletter to go through a case study on how we 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.

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



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

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

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.

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 Good Manufacturing Practice , IEC60601-1 Safety, Risk Analysis ISO14971(EN1441) & IEC60601-1-4
- Perform Risk Analysis, Failure Mode Effects and Criticality Analysis, MTBF prediction, HALT, Accelerated Life Tests, Environmental tests, Validation tests & Safety compliance test.
- Provide adequate 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

Mention this article and receive \$1K off your next service in Medical Reliability.

RELIABILITY BLOG



Below is a summary of the Best of our Blog for last quarter - highlights of the best blog topics we had. If you would like to contribute to our blog, please either



or go to



- ▶ [LED diodes – Life test](#)
- ▶ [HALT Vibration Table in Slow Motion](#)
- ▶ [Green Reliability discussion](#)
- ▶ [Setting Reliability Goals using Benchmarking](#)

PROBLEM SOLVER

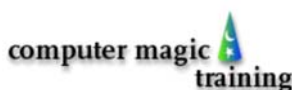


MEDICAL RELIABILITY: REGULATORY vs. RELIABILITY

Name In medical devices, we must abide by the rules set out in 21 CFR. What does CFR mean and what is the title for Code 21?

The best response within the next 5 days will receive one free pass to our next Certified Reliability Engineer (CRE) or Certified Quality Engineer (CQE) course.

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JOB OPENINGS

Given the current economic climate, we know of many talented individuals that are currently looking for work. Therefore, if you are an employer and have a need for any position within reliability, engineering, or operations, we are offering to advertise in our newsletter at no cost. Just doing our part to help stimulate the economy! Below are a few positions that we do know about.



Senior Reliability Consultant

Ops A La Carte is looking for Senior Reliability Consultants *around the world* to join our team of consultants and work on some of the most exciting and challenging projects in the industry. Whether you have an existing consulting practice or are interested in developing one, please contact us.

If interested, email us via our [OPS Job Search Contact Form](#) or call (408) 654-0499.

Ops A La Carte's newsletter goes out to over 18,000 subscribers. If you would like to put a job opening in next quarter's "Reliability News", email us via our [Job Openings Contact Form](#) or call at (408) 654-0499.

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