

# MEDICAL RELIABILITY SOLUTIONS

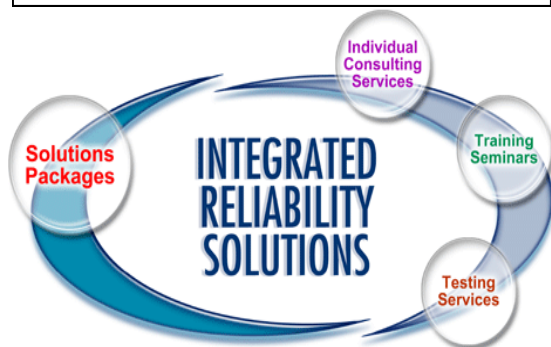
We are the leader in **reliability and quality solutions** for the **medical** industry.

We offer a flexible method of engagement:  
 End-to-end reliability solutions solving specific issues, or providing individual reliability services.

We consult in every life cycle phase, train in every aspect of reliability, and test in our state-of-the-art HALT and HASS Labs™

We provide **Confidence in Reliability**.

## INTEGRATED RELIABILITY SOLUTIONS TO THE MEDICAL INDUSTRY



**Solutions** - end-to-end solutions that target the corporate product reliability objectives.

**Individual Consulting Services** - providing the missing key elements needed for a fully integrated reliability program.

**Training Seminars** - highly specialized experts in the industry train others in both standard and customized training seminars.

**Testing Services** - a comprehensive list of state-of-the-art reliability testing services.



## MISSION CRITICAL VALUES

- We are committed to Highly Reliable Systems that save human lives
- We successfully analyze and test critical medical products with confidence
- We deliver accuracy and precision to extend product and human life for each application
- We deliver customized solutions & consultancy to address all program risks

## OUR SERVICES

### PROGRAM MANAGEMENT SERVICES

- End-to-end Regulatory, Safety & Reliability management programs
- Reliability Assessment/Set Goals/Write RAM Plans

### RELIABILITY ANALYSIS SERVICES

- Risk Management
- Requirements Analysis/Review of FDA Regulations
- Reliability Modeling/Reliability Predictions
- Reliability and Availability
- Failure Modes Effects Analysis (FMEA) / Fault Tree Analysis
- CE and UL safety standards analysis/(EMI/EMC)
- Thermal/Derating Analysis
- Materials/Components Selection
- Preventive Maintenance
- Corrective and Preventive Action (CAPA)/Root Cause Analysis
- Software Reliability

### RELIABILITY TESTING SERVICES

- Verification and Validation (V&V) Testing
- Environmental Testing/Qualification Testing
- Highly Accelerated Life Testing (HALT)
- Highly Accelerated Stress Screening (HASS)
- Accelerated Life Testing (ALT)
- On-Going Reliability Testing (ORT)
- Reliability Demonstration Test (RDT)
- Packaging Design and Testing

### RELIABILITY IN MANUFACTURING SERVICES

- Process FMEA (PFMEA)
- Corrective and Preventive Action (CAPA) System

### RELIABILITY SEMINARS

- Applied Data Analysis (ADA)
- Best Accelerated Reliability Tests - HALT, HASS, ALT, RDT
- Certification - CRE, CQE
- Design for Reliability
- Design for X / Design for 6 Sigma
- Elegant Problem Solving Techniques
- Risk Management/FMEA/FMECA
- Software Reliability
- Supplier Selection/Certification

# OPS DELIVERS RELIABILITY IN THE MEDICAL INDUSTRY

**Over 70 customers in various medical applications**

**3M Health Care** - Reliability Plan and data analysis for drug delivery systems and devices

**Abbott** - ALT for glucose monitoring system

**Accuray** - Reliability Assessment and program plan for stereotactic radiosurgery device for tumors

**Applied Biosystems** - HALT and RoHS services for DNA sequencing products.

**Boston Scientific** - HALT, V&V, and CRE/CQE Training for minimally invasive medical devices

**Cardiac Assist** - HALT for cardiac surgery device

**Cardinal Health** - ALT for neonatal CPAP device, root cause analysis for nebulizer

**Carestream** - DfR Training for mammography solutions company

**Cochlear** - ALT Training for implantable hearing aids

**Covidien** - Reliability plan and predictions for drug delivery systems

**Fisher and Paykel Healthcare** - ALT for sleep apnea device

**Flextronics Medical** - Software reliability for medical systems

**Hospira** - Complete reliability program for infusion pumps

**Inogen** - HALT for oxygen therapy device

**Intrapace** - HALT and RDT for appetite suppression systems for obesity

**Intuitive Surgical** - HALT, V&V, Reliability Improvement Plan, & Vendor Quality for medical robotics

**Iridex** - HALT for ophthalmology systems

**Lifescan/Johnson+Johnson** - HALT for glucose monitoring system

**Lumenis** - Package testing and HALT for laser lithotripsy system

**Luminetx** - ALT for vein finding system

**Mako Surgical** - Reliability plan for robotic knee surgery system



**Next Safety** - Reliability prediction for pulmonary drug delivery devices

**OmniCell** - HALT and ALT for medical dispensing systems

**Ortho-Clinical/Johnson+Johnson** - HALT for transfusion medicine

**Perfint Healthcare Devices** - Reliability test plan for image guided procedure system

**Perkin-Elmer** - HALT and HASS for medical illumination system

**Philips Medical** - Cable qualification testing for sonogram system

**Proteus Biomedical Inc.** - HALT and environmental testing for in-body computing

**Pulmonetic** - HALT for ventilator system

**Philips Medical (formerly Respironics)** - Reliability plan, HALT, ALT, and teardown analysis for sleep apnea device

**Siemens Medical (formerly Acuson)** - Reliability prediction for nuclear medicine system

**Solta Medical (formerly Thermage)** - HALT for radiofrequency cosmetic procedure systems

**Stryker** - HALT for medical illumination system

**Suni Medical** - Quality system review for dental medical imaging systems

**Tecan Systems** - HALT and root cause analysis for laboratory instrument

**Terumo Medical (formerly Mission Medical)** - Reliability plan, FMEA, HALT, and ALT for blood collection system

**Thoratec** - HALT and ALT for heart pump devices

**Ventana Medical** - HALT and environmental testing for automated immunohistochemistry (IHC) system

**World Heart** - HALT for pulsatile ventricular device



**WE PROVIDE CONFIDENCE IN RELIABILITY !**