

# LUMINA

## ENGINEERING

### A Leader In Software Testing

*It has been known for some time that, in a typical programming project, approximately 50% of the elapsed time and over 50% of the total cost are expended in testing the program... Given this knowledge, one would expect that program testing would have by now been refined into an exact science, but this is far from the actual case. In fact, less seems to be known about software testing than about any other aspect of software development. Glenford J. Myers; The Art Of Software Testing; New York; John Wiley & Sons, 1979*

Software is arguably the most significant technical achievement of the last 100 years. For companies in the medical device and pharmaceutical industries, software represents one of the largest areas of investment, and also one of the greatest risks to business operations and business practices.

At Lumina Engineering, we have decades of experience in Software Verification and Validation and aggressively work to extend best practices. Traditional software testing works through manual processes to define requirements, develop methods for testing identified requirements and tracking testing progress.

Lumina Engineering has significant experience in testing medical device software under GMP and 510K regulations. Our experience with sophisticated embedded systems such as implantable and infusion Class One/Two/Three devices involves the use and application of state of the art technology.

Lumina engineers have extended industry best practices by developing tools that automate the testing process. These tools have a significant impact on the testing process by reducing regression testing levels of effort, streamlining the translation of requirements to software tests, and automating the management of test status tracking. The impact of this on testing activities is greater schedule accuracy, reduced levels of effort, and increased quality and consistency of software tests.

Whether your system is a Client Server information system or a life critical board level embedded system, we have the technical expertise to test it. Lumina Engineering skills and technologies will improve your testing efforts.

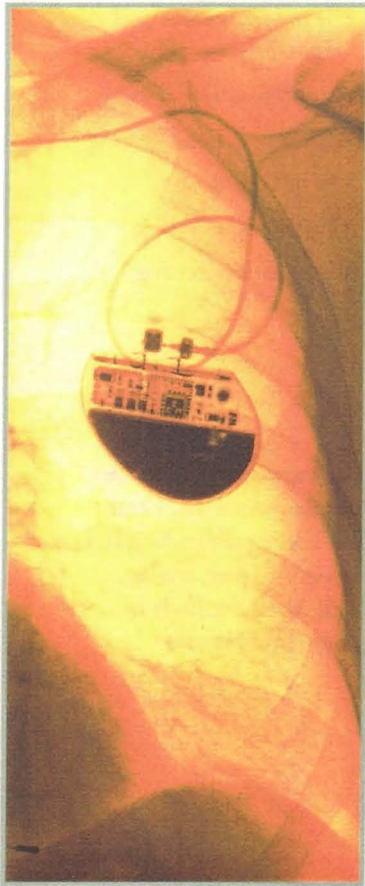
#### Methodology

It's not enough to know test techniques or test automation. The most important aspect of developing a cost-effective set of tests is how to optimize the required testing for safety, quality, and business objectives. At Lumina Engineering we have developed proven analytical methods to identify what needs to be tested and the best way to test it.

The heart of selecting an external testing staff is, do they know how to test? We do.

#### Risk Analysis

Understanding the intended use of software is key to defining successful test programs. All software is not the same, and methods to test software needs to consider the whole software development life cycle. There is an infinite difference between a child's paint program and a computerized medical x-ray and Lumina Engineering's expertise in FDA 21CFR regulations allows for optimized application of testing methodologies that maximizes safety while optimizing regulatory compliance traceability.



*Testing practices for the majority ... Haven't changed in twenty years. Testing is still dominated by end-point feature testing of an integrated package. ...*

*I'd be happy if most software developers were where the art [Testing] was 15 years ago.*

**Boris Beizer; Testing Technology - The Growing Gap; American Programmer, April, 1994**

*Testing is the art of selecting an economically viable subset of tests from an infinite set. Steven Gitelis; Software Quality; Proceedings of the Medical Device Manufacturers Conference, February, 1994*

## Segmenting The System

At Lumina Engineering, we have the software engineering expertise and industry subject matter knowledge to analyze and segment the software plans so that each module or component is tested to an appropriate depth. This approach requires a multidisciplinary skill set that is not available to many software testing organizations.

## Failure Analysis

Another sophisticated methodology we use at Lumina Engineering is Failure Analysis. With this method we analyze the parts of the system that could fail, and then test to ensure that the modes of control work. Depending on system requirements, this analysis may consist of Failure Mode Effects Analysis (FMEA) and/or Fault Tree Analysis (FTA). By understanding where potential failures may occur, we can optimize testing activities to ensure appropriate diligence for critical software modules while avoiding the tendency to over bake the testing process due to a lack of understanding of the application.

## Test Management

Test Management is critical to the success of any significant testing program. We have spent decades learning how to do this.

## Tracking

Lumina Engineering's Automated Testing Systems enables us to Track and Report:

- Tests as they are executed
- Pass/Fail status
- Execution schedule
- Status of corrective builds including corrections and new features
- Problems/issues reporting and resolution to ensure closure
- Schedule and status of regression testing

## Types of Testing

Lumina applies multiple and different testing methods depending on the project specific needs. These include:

- Black Box Testing (system & feature testing)
- Blue Box Testing (active interpretation and stimulus of the tested environment)
- White Box Testing (unit/module testing)
- Micro-Performance Testing
- Macro-Performance Testing
- Acceptance Testing
- Regression Testing
- Test Automation and Test Drivers
- Configuration Testing
- Stress and Load Testing
- Beta Testing
- Installation Testing
- Integration Testing

## Test Case Design

To design black box tests our primary strategy includes Equivalence Partitioning, Boundary Analysis, Error Guessing, and State Transition Testing. For white box testing we primarily rely on predicate path testing. These remain the most field validated methods of testing. However, special system requirements might require:

- Transaction Flow Testing
- Data-Flow Testing
- Domain Testing
- Path Products
- Syntax Testing
- Logic Based Testing

## Out-Sourced Testing

Lumina Engineering specializes in assuming the complete Verification and Validation responsibility for your products. Our Twin Cities facility is equipped with resources which enable you to out-source your testing. We can also supplement your staff with the key individuals needed to meet your technical requirements and schedules.

