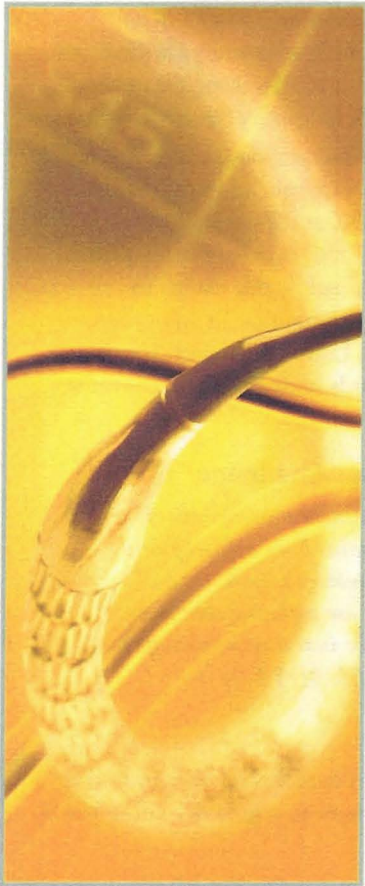


LUMINA

ENGINEERING



Software Validation

Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part. 21 CFR Sec. 820.5 Quality system.

Our Mission

Lumina Engineering provides services solutions to organizations seeking to:

Comply with and benefit from regulatory/quality standards including FDA regulations 21 CFR 820 Parts 11, 30, and 70 and ISO standard 13485 as pertaining to the creation and maintenance of electronic records and quality systems records for the manufacturing of medical devices.

Improve quality and lower operational costs by instituting a disciplined process focus

Our Background

Lumina Engineering was formed by a group of seasoned industry professionals dedicated to applying software quality principals. Our management experience ensures that you work with professionals who understand your requirements and point-of-view. Our experience with major corporate clients provides us with the knowledge and skills to design and implement software quality systems. Our real world experience in software quality system standards such as ISO 9000 2000, GAMP 4, GMP (21 CFR 820), ISO 13485, .DO178-B, and MIL-Q 9858 & MIL-2167A/2168 gives us the expertise to implement processes that meet corporate objectives and comply with stringent regulatory requirements.

Software Design and Development

After the project planning for the medical device is complete, Lumina Engineering assists customers with software development, testing, change control, and software risk management. These services are offered with two different structures depending on client preferences and project demands, either as an on-site (insourced) service or off-site (outsourced) at our facility. In both scenarios, we can furnish necessary equipment or work with customer furnished equipment. All work is performed using IEEE and FDA compliant software development methodologies.

Regulatory Compliance Planning and Support

Based on our involvement in industry standards based activities, we guide our clients on architecture and implementation practices to integrate quality practices from the project inception. This approach lowers the cost of compliance by allowing the development engineers to understand compliance requirements from an early stage in the project lifecycle, thus increasing productivity and eliminating conjecture that often occurs from inconsistent specification of compliance criteria. Additionally, when necessary, Lumina Engineering assists with planning and structuring the software development activities required by the project.

Verification and Validation

Testing necessary to verify and validate software is a significant part of Lumina's business. Lumina has developed extensive verification and validation expertise working with medical devices and systems ranging from FDA Class 1 through 3. Depending on the organizational structure required by the client, we have performed these services as part of the client project team leading and in some cases supporting validation activities. Alternatively, we also have the ability to handle Software Verification and Validation as an outsourced project activity that is performed at our facility. We have a dedicated project team that brings extensive experience to managing and delivering validation and verification solutions. This experience delivers customer value through more efficient, timely and cost effective validation of the software environment, as well as increased management insight into the verification and validation processes and remediation activities. Our team leaders are integrally involved with FDA validation requirements. This allows us to uniformly apply knowledge of compliance requirements to all testing activities and ensure that software development standards are being applied uniformly across a corporation.

We are committed to making software quality standards compliance cost-effective and profitable.

Our Consulting Services

Software Quality Assurance consulting services are provided to help firms meet the requirements of national and global standards and regulations. Our specific expertise in software and equipment validation ensures your quality system will be fully implemented. Our background in Software Development result in processes and systems that are accurate, efficient and economically supported.

Industry Standards

Lumina Engineering works with the FDA and participates in standards initiatives from ISO and AAMI to stay abreast and lead when possible in the advancement of software quality including:

IEC/ISO 62304 This international standard will govern software development and testing requirements for medical device software. We are currently balloting on this standard as a permanent member of the AAMI Software Committee. Ultimately this standard will supersede AAMI SW68.

AAMI Software Risk TIR This guidance document is currently being submitted for secondary balloting. As a permanent member of the AAMI Software Committee, we will be made suggested changes earlier this year. This TIR will give guidance on the application of 14971 to medical device software, and is anticipated to have a significant industry impact. Lumina is a primary reviewer of this document.

AAMI Quality System Validation (QSV) TIR Lumina's CEO, Steven Gitelis is currently Co-Chairing this committee. This TIR is standardizing the medical device industry's approach to Quality System Validation.

These standards guide the medical device industry in complying with FDA software validation regulations including 820.70(i), 820.30, and Part 11. Because standards impact clients' interests in very consequential ways, Lumina is often retained by our clients to represent them in standards activities. In addition to client paid representation, Lumina also participates directly in relevant standards bodies and will continue to do so into the future.

Software Engineering: Challenge

After two decades of unfulfilled promises about productivity and quality gains from applying new software methods and technologies, industry and government organizations are realizing that their fundamental problem is the inability to manage the software process CMM/SEI- 91-TR-24-1.

Our Solution

Lumina Engineering has the technical background to help you meet the challenges to regulatory compliance, including:

- Program and Project Based Services
- Staff Augmentation and Staff Supplementation Services
- Equipment Move and Equipment Revalidation Services
- Software and System Validation Planning and Management Services
- Database Implementation and Validation Services
- Part 11 Remediation and Implementation Services
- COTS and Third Party Software Validation
- Customer Software Validation



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