

Regulatory Compliance

When it comes to complying with FDA Laws, Regulations, Guidances and Standards (LRGS), the nation's top medical device and pharmaceutical companies turn to Lumina Engineering. Lumina understands the parameters of the FDA's LRGS and is able to apply our knowledge and experience to deliver total compliance.

Our nationally recognized engineering team can lead your SQA, Audit and Compliance groups in attaining your goals. We have intricate knowledge of FDA General Principles of S/W Validation Final Guidance (GPSV), 21 CFR Part 11 Electronic Records; Electronic Signatures Rule, AAMI/ANSI Medical Device Software Standard (SW68) and Quality System Regulation (QSR).

Lumina's expertise include:

- *Interpreting FDA Laws, Regulations and Guidance Standards*
- *Systems Inventory*
- *Gap Analysis*
- *Remediation*
- *Validation: Preparation and Execution of S/W Installation, Operational and Performance Qualifications*
- *SOP and Protocol Development and Review*
- *Internal and Supplier Audits*
- *Design Controls and Design Review*
- *Change Control and Configuration Management*
- *Develop Formal Life-Cycle Model Procedures*
- *Maintenance: Maintain Systems in a Validated State Using Appropriate Procedures and Policies*

Experience speaks for itself. Lumina Engineering's consultants have extensive experience in FDA Software Regulatory Affairs. Let our experience work for you.

We welcome inquiries.

We cover compliance in:

- *21 CFR Part 11*
- *HIPAA*
- *GLP*
- *QSR/cGMP*