Systems and Regulatory Solutions

Eolus provide compliance and management **consulting, auditing, systems and regulatory solutions** to premiere pharmaceutical, medical device, and biotechnology companies worldwide.

We focus on improving the quality of our customers systems and processes while enabling technical and procedural compliance to applicable regulations and ISO standards. Our fast response, project management expertise and global problem solving capability is important to our clients success.

We evaluate and access your current operation and provide solutions to reduce waste, minimize variability, reduce cycle and lead times, achieve targeted milestones, and **mitigate regulatory exposure**.

We provide best practice knowledge and expertise in HIPAA, ICH, EU and FDA Quality Systems Regulations (QSR), GCP/GLP/GMP, IS09001:2000, IS012207 ISO17799, ISO13485, Risk Assessments, Process Improvement, Electronic Recordkeeping, Systems Security, Business Continuity Planning, Archiving, Change Management, Project Management, Software Validation, Systems Life Cycle and Validation Methodologies.

Consulting Engagements:
Eolus provides services based both on reAudits, Assessments and Gap Analysis:
Eolus conducts quality system audits and provides analyses of your systems to determine how well they meet technical and procedural compliance with GxP, Quality Systems Regulations (QSR), ISO12207, ISO9001, HIPAA, and 21 CFR Part 11. Using proven methods and techniques; we evaluate systems, procedures, process, and technologies and provide action plans and impact analyses.

Compliance Support:
Eolus provides extensive experience with project planning, requirements analysis, system design, product capability assessments, and vendor evaluations. Our services include regulatory compliance plans, policies, procedures, and training. Eolus provides detailed guidance and assistance towards assuring compliant and secure electronic records and electronic signature systems.

Product Capability:
Eolus offers various assessment methods to determine whether or not a particular software product has the capability to meet technical and regulatory requirements. These methods may involve an audit focusing on supplier quality and software engineering practices and procedures to provide a reasonable degree of assurance in selecting software vendors.

Systems and Regulatory Consulting:
Eolus has experienced systems consultants trained in FDA and related industry regulations and guidelines. Our consultants have experience providing technology, systems software solutions, consulting and training to clients who strive to achieve quality and compliance with their systems. Our services include:

- Strategic planning and evaluation for software solutions
- Customized systems and solutions to meet your needs
- In depth systems analysis, design and process engineering
- Feasibility and risk analysis
- Functional requirements study, analysis, and documentation
- Project and team consultation and facilitation
- System and vendor evaluations; product capability assessments
- Security and infrastructure reviews
- Design and review of policies and procedures for regulatory compliance
- Assistance with FDA 483 and warning letter solutions
- Customized project management and system life cycle methodologies
- Review of project life cycle documents and deliverables for compliance
- Training programs for software validation and project management
- Training and audits
- 21 CFR Part 11, HIPAA, SOX
- ISO9001:2000, 12207, 13485,
- GCP, ICH, QSR, GAMP, GLP

Eolus Philosophy:
Eolus principals have been providing custom consulting services and solutions to the pharmaceutical industry since 1995 and creativity is key to our approach. Our task is to provide creative answers to problems, and to adaptively and correctly size the solution effort to the size of the problem to meet the customers needs.

For more information on our custom services call us at 919-673-4001

Located in North Carolina, we provide consulting services worldwide. Eolus provides compliance consulting which includes best practice examples for applying the regulations to improve the quality of your software and systems.

- ***Project Management***
- ***Audits and Training***
- ***Systems Compliance***
- ***Clinical Trials***
- ***Process Improvement***
- ***Software Lifecycle***
- ***Validation Methodology***
- ***Policies and Procedures***
- ***Systems Documentation***

Systems Compliance Solutions For Medical Devices, IVD, Pharma, Biologics, eClinical, ePRO, IVRS, Clinical Trials, Biotech, and Genomics

Eolus®

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We Measure our Success by Our Customers

Eolus Provides Regulatory and Compliance Solutions Worldwide

In mythology ***Eolus*** *was the "****Keeper of the Winds****". Today with over 20 years of experience in pharmaceuticals, biotech and medical device software,* ***We measure our success by our customers success in*** *navigating the increasingly complex* ***regulatory*** *environment for systems, electronic records, security,* ***and software****.*

- **Develop a Quality System**
- **Training in FDA Regulations**
- **Preparation for Inspections**
- **Compliance Counseling**
- **Software Evaluations**
- **Validation Support**
- **Gap Analysis**
- **Remediation Planning**
- **GCP, GLP, GMP, QSR**
- **ISO9001:2000,**
- **IS0 13485, 12207, 17799**
- **21 CFR Part 11**
- **HIPAA**
- **Mock FDA Inspections**
- **IT Security Audits, SOX**
- **Vendor Evaluations**
- **Process Assessments**
- **Requirements Facilitation**
- **Systems Analysis and Design**
- **Test Case Development**