



maxiom  
GROUP



Maxiom Group helps clients reduce risk by significantly improving the quality and compliance levels of their IT operations

## Information Technology Governance & Compliance

In the life sciences industry, an information technology (IT) system is not properly implemented until adequate controls to maintain the system in a quality and compliant state have been established. Maxiom Group's Quality and Compliance Services practice helps clients design and implement IT solutions that operate as intended, to maximize return on investment and minimize risk.

Maxiom Group has significant life science experience implementing IT systems, IT Governance programs and Good Automated Manufacturing Practices (GAMP 4). Our consultants are proficient in industry best practices for:

- ◆ IT Governance
- ◆ Risk Assessment
- ◆ Master Validation Planning
- ◆ Qualification and Validation
- ◆ System Development Lifecycle

### IT Governance

Information technology is an integral part of every life science company. IT supports mission-critical business operations and is a significant driver for increasing productivity and competitive advantage. Therefore, it is imperative that the oversight and governance of IT reflect its integral role within the company.

*Maxiom Group helps clients establish and focus their IT Governance activities on implementing value-added capabilities designed to ensure effective planning, management and control of information systems and data.*

### Risk Assessment

U.S. Food and Drug Administration (FDA) guidance suggests that the life sciences industry adopt and employ a risk-based approach to quality and regulatory compliance. Maxiom Group provides a proven systematic and risk-based approach that supports the FDA's direction. Through our methodology, clients receive well-documented risk assessments and mitigation action plans that serve as a guide for enhancing compliance and performance of the IT environment.

*Our thorough and pragmatic philosophy ensures that gaps are clearly identified, prioritized and systematically addressed.*



# Information Technology Governance & Compliance

## Master Validation Planning

A Master Validation Plan is a key component of IT Governance in life sciences but it is more than just a policy document; it is the foundation for establishing the critical capabilities necessary for implementing systems that operate with high performance and in a compliant state.

*Maxiom Group assists clients in developing a Master Validation Plan that serves as a strategic tool for ensuring quality and compliance of the crucial IT environment.*

## Qualification and Validation

Qualification and validation of systems is a very important step in assuring that only quality and compliant systems enter production. Maxiom Group supports clients in developing effective and efficient protocols and executing those protocols to ensure proper Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ).

*Maxiom Group helps clients assure that their systems will not only perform as intended, but also be maintainable in a quality and compliant state.*

## System Development Lifecycle

Quality and validation are integral parts of an effective System Development Lifecycle methodology (SDLC). Our integrated approach to implementing and maintaining information systems ensures that they not only operate with a high degree of operational performance, but also in a compliant state. Maxiom Group's SDLC framework contains the processes, activities, and tasks involved in the development, operation, maintenance and eventual decommissioning of a system and integrates system validation and compliance activities throughout the process.

*Through this approach, our clients are assured that their systems support the business, perform as intended and are compliant.*

## Complete Support

Maxiom Group's Quality and Compliance Services practice supports the complete life cycle of activities necessary to ensure a compliant IT environment. We provide support for IT Governance, master validation planning, implementation of IT validated solutions and validation execution.

*Through our pragmatic and risk-based approach, quality and compliance are not an "event" but an integral part of establishing and operating an effective IT environment that support a life science company's business objectives.*

## About Maxiom Group

Maxiom Group is a leading strategic business and IT consulting firm exclusively serving the life sciences industry. We help transform emerging, established and mature biotechnology, pharmaceutical and medical device companies at each stage of their life cycle by solving mission critical business issues. From drug discovery and development, to clinical trials, to commercial launch and sustained market leadership, Maxiom Group clients rely on our unique focus, insight and approach.



Maxiom Consulting Group, Inc.  
CityPoint | 230 Third Avenue  
Waltham, MA 02451  
[www.maxiomgroup.com](http://www.maxiomgroup.com)

Contact:  
Todd Martin  
Vice President, Business Development  
TEL 781.250.4890 [tmartin@maxiomgroup.com](mailto:tmartin@maxiomgroup.com)