



maxiom
GROUP

TRANSFORMING
LIFE SCIENCES

Medical Device Industry Services

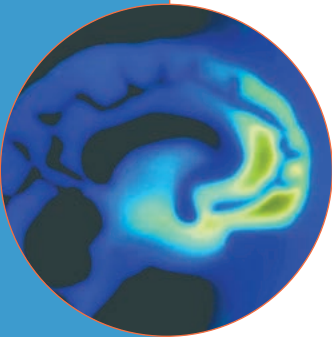


Our Value



FOCUS

- Exclusive commitment to the medical device and biopharma industries
- Keen understanding of the entire life cycle, from R&D to product launch to sustained market leadership
- Services, methodologies and tools specifically tailored and aligned to meet our clients' needs at every stage of their development
- Commitment to industry best practices and technology solutions



INSIGHT

- Deep industry knowledge, experience, and demonstrated success
- Fresh perspectives on solving mission critical business issues
- Capability to transform companies by addressing strategic, organizational, business process, and information technology needs
- Cross-industry experience to bring new insights to our clients



APPROACH

- Proven methodologies that are pragmatic and flexible
- Collaborative, hands-on team approach to ensure project success
- Partnership philosophy that assures ongoing advice and support
- Located near our clients for superior responsiveness and value

About Us

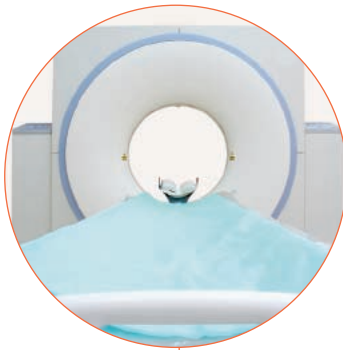
Maxiom Group is the leading strategy, operations, and information technology consulting firm exclusively serving the medical device and biopharma industries. Our objective is to help our clients achieve profitable growth that translates into sustainable market leadership.

We assist our clients in transforming their businesses to achieve success at each stage of their life cycle – taking them from emerging to established to mature market leadership. We apply our subject matter expertise to a variety of issues that drive the medical device industry, from device development to commercial launch to supply chain and enterprise software.

Our clients are engaged in important work: developing products that will improve people’s lives. Maxiom Group becomes part of this process by supplying the capabilities needed to successfully transform our clients from technology-driven innovation to business-driven execution.

To do so, we provide a pragmatic, hands-on process led by senior practitioners with years of industry experience.

With offices in the Boston and Newtown, PA areas, Maxiom Group is located in key medical technology industry centers. The proximity of our people to our clients assures that we provide a high level of focus and service.



Case Study	Emerging Medical Device Company
Client	<ul style="list-style-type: none">• Pre-revenue, development stage• Revolutionary renal therapy
Issues	<ul style="list-style-type: none">• Managing materials for clinical trials• Driving market acceptance of new therapy
Our Role	<ul style="list-style-type: none">• Developed clinical materials management processes and tools• Created commercial launch road map• Coordinated functional activities

Our Services

STRATEGY/OPERATIONS SERVICES

- Strategic Decision Support
- Commercial Launch
- Supply Chain Management
- Business Process Design
- Operational Excellence
- Brand Integrity

IT SOLUTIONS SERVICES

- Project Management Office
- IT Strategic Roadmap
- IT Utilization/Value Assessment
- Software Package Selection
- Software Package Implementation
- System Integration
- Validation & Compliance

Maxiom Group has developed services that help our clients think strategically about their business direction and goals. We work with them to develop and align their strategies, operations, and information technology capabilities to help execute their vision. Maxiom Group focuses on:

- **Product Development:** We help clients design and implement a compliant infrastructure that supports design controls as required by 21CFR820. Whether it is streamlining processes like Engineering Change Control or assisting in the selection of an Engineering Document Control System, Maxiom Group helps our clients balance the pressures of time-to-market with the demands of regulatory agencies.
- **Product Supply:** Whether virtually or vertically integrated, Maxiom Group helps clients establish capabilities to manage the production and distribution of products to clinical or commercial sites. We assist in selecting supply chain partners, designing processes, and implementing the necessary transactional and information systems needed to establish a compliant and efficient supply chain.
- **Commercial Operations:** Maxiom Group assists companies in establishing the commercial infrastructure necessary to launch, market, sell, and distribute products throughout their life cycle by planning and executing commercial launches, analyzing markets, establishing sales operations, and selecting distribution partners.

Through the delivery of these services, we help companies improve their business in meaningful ways, including:

- Building business strategies and supporting critical decisions
- Bringing new products to market faster and more effectively
- Establishing effective, scalable and compliant infrastructure
- Improving the productivity and work environment of their people
- Achieving better financial performance to maximize return on investment
- Continuously improving their business and achieving operational excellence

Case Study Established Medical Device Company

Client • Global leader in Class II patient monitoring devices

Issues • Inefficient engineering change control
• Lack of effective engineering document control in compliance with QSR

Our Role • Streamlined engineering change control process
• Defined and selected document control system in compliance with 21CFR 820

Who We Serve

Client Life Cycle Stage	Key Challenges	Our Solutions
 <p>Emerging Companies Proceeding through product development and planning for commercialization</p>	<ul style="list-style-type: none"> • Lack of resources and business infrastructure • Significant financial constraints • Balancing investments with business uncertainty • Need to plan, design and build business infrastructure 	<ul style="list-style-type: none"> • Strategic Decision Support • Supply Chain Management • Commercial Launch • IT Strategic Roadmap • Software Package Selection • Quality & Compliance
 <p>Established Companies With one or more initial commercial products and a growing development pipeline</p>	<ul style="list-style-type: none"> • Growing complexity of business • Changing product requirements • Incomplete or inefficient business processes • Not leveraging information systems to maximum extent • Protect product supply chain 	<ul style="list-style-type: none"> • Strategic Decision Support • Supply Chain Management • Business Process Design • IT Utilization/Value Assessment • Software Package Selection • Software Package Implementation • Project Management Office • Quality & Compliance • Brand Integrity
 <p>Mature Companies With multiple commercial products and a deep technology base</p>	<ul style="list-style-type: none"> • Optimize performance of overall (often global) supply chain • Implement specific systems • Increase integration with key supply chain partners • Implement advanced distribution strategies • Seek continuous process improvement • Protect product supply chain 	<ul style="list-style-type: none"> • Strategic Decision Support • Supply Chain Management • Operational Excellence • Software Package Selection • Software Package Implementation • System Integration • Project Management Office • Quality & Compliance • Brand Integrity

Case Study Mature Medical Device Company

Client	<ul style="list-style-type: none"> • Division of Fortune 500 innovator in orthopaedics
Issues	<ul style="list-style-type: none"> • Ramping up manufacturing process and supply chain capacity to meet demand anticipated from U.S. market entry
Our Role	<ul style="list-style-type: none"> • Led efforts to identify and prevent manufacturing process weaknesses • Rapidly developed client organization, processes, know-how and technology to support expanded production volumes




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Transforming Life Sciences™

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