

OUR PRODUCTS AND SERVICES

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Combining our decades of regulatory experience with insightful customer feedback, we have developed a series of services targeted specifically at those business areas where medical device and tissue organizations struggle to achieve a combination of compliance and process efficiency. Each of our products has been designed specifically to ensure regulatory compliance and to accelerate product-to-market timeframes.

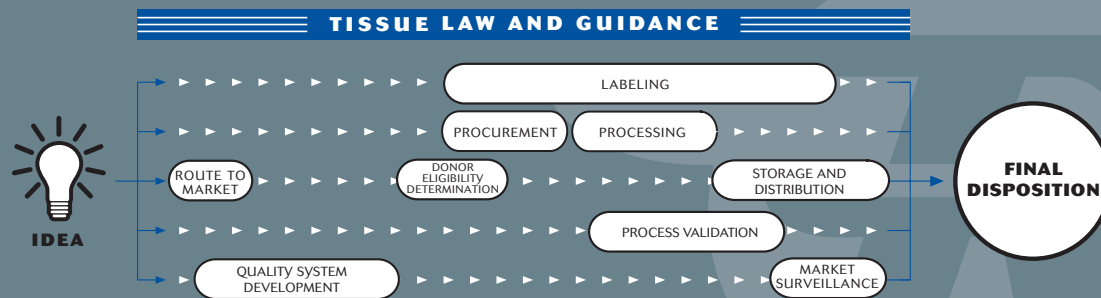
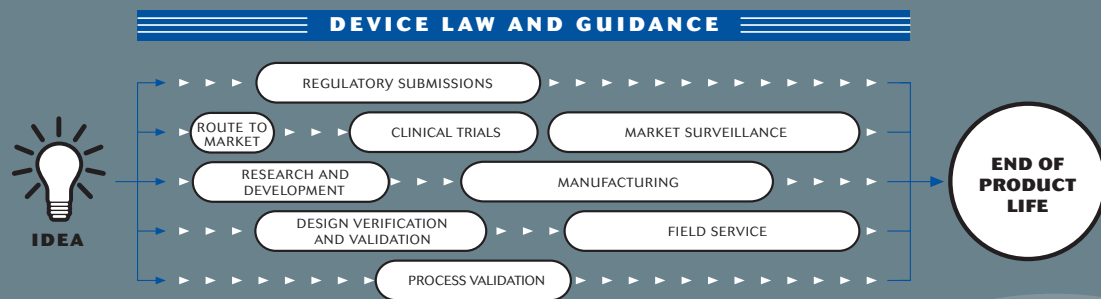
Some of our offerings include the following:

CONSULTING

- Quality System Development
- Compliance Remediation
- Validation Projects
- Corrective and Preventive Action
- Warning Letter Remediation
- Clean Rooms
- Environmental Controls
- Gap Assessments
- Design Controls
- FDA Strategy Development
- Route to Market
- Regulatory/Quality Training
- Audit Preparation
- Donor Records Management
- Aseptic Practices
- Market Surveillance

OUTSOURCING

- Document and Change Control
- Training Records Management
- Electronic Donor Eligibility
- Complaint Handling
- Adverse Event and MDR Filing
- Supplier and Internal Audits
- Validation Programs
- Regulatory Submissions



REGLERA

Simplifying Regulatory Law and Guidance

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WHO WE ARE

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Navigating the regulatory maze that surrounds the biomedical industry is difficult at best. It is complicated, continuously in flux, and has the potential to prevent your vital products from getting to the customer. Since 1994, the people at Reglera have been ensuring the viability of our customers' products by simplifying regulatory law and guidance.

Whether you are developing a new product, improving an existing product, or simply trying to comply with the myriad of regulations and standards, Reglera's products and services will accelerate your success and profitability. We accomplish this through a combination of core competencies including:

- Regulatory strategy and quality system development
- Design control and structured development
- Strategic operations

Reglera is one of the largest and fastest growing regulatory consulting and service outsourcing companies in the world. With more than 100 employees nationwide, and an unmatched group of strategic partners, Reglera is uniquely positioned to provide companies with products and services covering a wide variety of technical and support areas.

Reglera operates both nationally and internationally to service our client base of the medical device and human tissue industries.

A DIFFERENT APPROACH

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Our approach to your project is unique in our industry. Most consulting services and service products are delivered solely on a time and material (T&M) basis. Reglera, however, performs a detailed analysis of your needs in the beginning to establish clear deliverables and schedules and then quotes your projects on a fixed bid or blended (fixed and T&M) basis. This allows you to firmly establish your budget and plan accurately for the completion of the project. With Reglera, you know up-front what to expect at the end of the project, ensuring you receive desired results without surprises.

Our service products are designed and guaranteed to deliver reliable, repeatable results including:

- Decreased time to market with compliant, approved products developed with the latest design control systems
- Significantly lower compliance costs through systems that meet both business and regulatory requirements
- Decreased overhead costs and increased productivity, flexibility and availability of resources
- Lower operational and product costs through efficiency improvements and outsourcing of non-core processes
- Retention of core intellectual property and competencies

Through a unique combination of regulatory expertise and operations knowledge, our consulting teams deliver results that combine regulatory compliance and process efficiency. We do not solve your regulatory problems by installing the quality system over the top of your business system. At Reglera, we know that the most effective way to sustain business success is to combine business and quality requirements into a single, efficient system.

THE TEAM

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Reglera's team of industry professionals has decades of medical device and tissue bank experience. From regulatory and quality to engineering and operations, we only choose people who have a true desire to bring the latest medical technology to the market and keep it there. Each and every Reglera associate has a proven track record of delivering results on time and on budget.

The Reglera management team was also chosen directly from the Medical Device and Tissue industries. Each member possesses a combination of business skills and technical know-how that provides the vision and direction for our field workforce. When you call Reglera, you can be confident that you will talk to an experienced professional who not only has the industry knowledge you need, but also the experience to put it to work to accomplish your organizational goals. We pride ourselves on delivering outcomes, not advice without action.