EVERSANA™

LET EVERSANA HELP YOU WITH YOUR TISSUE COMPLIANCE NEEDS

Whether it's short-term assistance or a long-term relationship, our consulting experts and outsourced services team members can help you with your compliance needs. As your trusted regulatory partner, we not only advise, but also specialize in implementation and results.

REGULATORY EXPERTISE AND OPERATIONAL KNOWLEDGE

Staffed with seasoned quality and regulatory staff, including former FDA investigators, our combination of regulatory expertise and operational knowledge helps to ensure your compliance and operational efficiency. So, whether you have a one-time question or need ongoing support, EVERSANA's industry experts will provide you with the advice you need, when you need it.

HIGH LEVEL OF REGULATORY COMPLIANCE

Our Outsourcing Compliance Services have been designed to help tissue, medical device and pharma establishments comply with the various regulatory requirements that impact business operations. These services are developed and implemented to provide a high level of regulatory compliance while allowing your business to operate more compliantly and efficiently.

SERVICES INCLUDE:

- Document Control (electronic system)
- Training Management (electronic system)
- Donor Eligibility System (facilitates electronic donor eligibility determination)
- Standard Operating Procedures
- Internal Audits
- Supplier Quality Audits
- Executive Management Support
- FDA and ISO Remediation Assistance
- Adverse Event and Deviation Reporting
- Complaint Handling
- Recall Management
- Contract Manufacturing Services
- IND/BLA/510(k) Submissions
- Validation and Test Planning
- Strategic Route-to-Market Planning
- Regulatory Product Assessment
- Pre-licensure Inspections

To learn more about EVERSANA's Outsourced Compliance Solutions, call 303.832.8200 or email des@eversana.com

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REGULATORY EXPERIENCE MATTERS

Imagine This:

A small group of research scientists developed a novel HCT/P using cancellous bone. They sought outside Quality Management System (QMS) and Regulatory expertise to bring this product to market while managing costs. Their challenges included:

- Objective to keep direct headcount and infrastructure to a minimum while having access to best practice systems, processes and people on an "as needed" basis
- Regulatory pathway for tissue product lacked a clear path to approval
- Time and investment was over the provided budget
- Inexperience in regulated industry; preferring to focus their time on the science
- Lack of experience with a QMS and writing SOPs

The Solution

- Developed and executed a regulatory strategy
- Deployed a full suite of outsourcing products to provide QA processes and infrastructure ensuring compliance with minimum financial investment
- Prepared the entire QMS
- Provided training and support for client's FDA inspections

Resulting In:

- Simplified FDA regulatory pathway for the tissue product
- Minimized cost, infrastructure, headcount, and time to market
- Increased confidence in QMS, since it was developed by experienced regulatory professionals

Our experts have helped many HCT/P establishments navigate unusual situations, diverse demographics and unique circumstances to maintain compliance and determine eligibility appropriately.

About EVERSANA™

EVERSANA is the leading independent provider of global services to the life science industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product lifecycle to deliver long-term, sustainable value for patients, prescribers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies to advance life science solutions for a healthier world. To learn more about EVERSANA, visit EVERSANA.COM or connect through LinkedIn and Twitter.