

# EVERSANA'S OUTSOURCING COMPLIANCE SOLUTIONS

In a highly regulated industry, lack of quality systems and inexperienced staff can result in gaps related to processes, procedures and training – which can lead to inadequate preparation for inspections by regulatory bodies, orders to cease manufacturing, substantial fines and, in the most severe cases, possible prison sentences.

EVERSANA's outsourcing compliance solutions are designed to help tissue, medical device and pharma establishments comply with the various regulatory requirements that impact business operations.

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.





See how EVERSANA helped one client navigate FDA regulatory pathways while minimizing cost and reducing time to market.



[eversana.com/outsourcing-compliance-solution](https://eversana.com/outsourcing-compliance-solution)

## KEY FEATURES & BENEFITS:

- ✓ Whether it's short-term assistance or a long-term relationship, EVERSANA's 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.

## SOLUTIONS 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
- Remediation Assistance (FDA, ISO, etc.)
- Adverse Event and Deviation Reporting
- Complaint Handling, Recall Management
- IND/BLA/510(k) Submissions
- Validation and Test Planning
- Strategic Route-to-Market Planning
- Regulatory Product Assessment
- Pre-licensure Inspections