EVERSANA™

EVERSANA has solved some of the most complex FDA compliance challenges for reproductive establishments. We are unique in our ability to deliver a comprehensive set of FDA service capabilities from preparation to onsite support, including remediation and management. We don't just advise you on what to do, we help you do it right!

Our expert staff has extensive experience in FDA-regulated industries. We provide peace of mind and ensure you will be ready for the FDA by implementing:

- Mock FDA inspection
- Managing FDA Inspection training
- FDA Inspection support – remote or onsite
- FDA 483, Warning Letter, Untitled Letter and Order to Cease Manufacturing response strategies and drafts
- Remediation planning and execution support

Our HCT/P clients rely on us for:

- FDA registration
- Gap assessments
- Internal audits
- Procedure development and review
- Training programs
- Quality Management System creation
- Validation for processing and equipment
- Supplier qualifications

EVERSANA also has the infrastructure and expertise to provide you with electronic outsourced:

- Document control
- Training documentation and management
- Donor eligibility

In 2018, one in six Tissue Establishments inspected by the FDA received 483s or other compliance actions. Before your next FDA inspection, contact EVERSANA.

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

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COMPLIANCE MATTERS

Imagine This:

A reproductive clinic received an Order to Cease Manufacturing following its last FDA inspection. Challenged with the below issues, they contacted EVERSANA asking for assistance in responding to FDA and developing updates for their procedures.

- Disorganized procedures caused steps in the eligibility determination to be missed
- Lack of document control organization resulted in the use of different revisions of the same procedure and forms
- Donor eligibility requirements were not fully understood

The Solution

- Created remediation response to FDA's Order to Cease Manufacturing
- Within three weeks, created and delivered procedures and forms to provide a fully-compliant Quality Management System
- Trained physicians and staff on 21 CFR 1271 to instill an understanding of regulatory requirements and the importance of compliance
- Provided client with a complete response to FDA, including a remediation plan
- Attended and supported the client during their meetings with FDA to discuss the response and remediation plan

Resulting In:

- Client resumed a portion of their activities with three months, while FDA reviewed the remainder of the response and remediation plan
- Implemented clear, organized Document Management System, which allowed for easy expansion of materials and training
- Greater clinic understanding of regulatory standards through training and its partnership with EVERSANA

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